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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0796; Project Identifier MCAI–2020–00902–T; Amendment 39–21367; AD 2020–26–12]

RIN 2120–AA64

Airworthiness Directives; Gulfstream Aerospace LP Airplanes

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

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Gulfstream Aerospace LP Model Gulfstream G280 airplanes. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a Civil Aviation Authority of Israel (CAAI) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 1, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 1, 2021.

ADDRESSES: For material incorporated by reference (IBR) in this AD, The Civil Aviation Authority of Israel (CAAI), P.O. Box 1101, Golan Street, Airport City, 70100, Israel; phone: 972–3–9774665; fax: 972–3–9774592; email: *aip@mot.gov.il.* You may find this IBR material on the CAAI website at *https://www.caa.gov.il.* You may view this IBR material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0796.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0796; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3226; email: *tom.rodriguez@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The CAAI, which is the aviation authority for Israel, has issued CAAI AD ISR–I–04–2020–06–02, dated June 28, 2020 (CAAI AD ISR–I–04–2020–06–02) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Gulfstream Aerospace LP Model Gulfstream G280 airplanes. Airplanes with an original airworthiness certificate or original export certificate of airworthiness issued after September 15, 2019, must comply with the airworthiness limitations specified as part of the approved type design and referenced on the type certificate data sheet; this AD therefore does not include those airplanes in the applicability.

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Gulfstream Aerospace LP Model Gulfstream G280 airplanes. The NPRM published in the **Federal Register** on September 16, 2020 (85 FR57799). The NPRM was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The NPRM proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in CAAI AD ISR–I–04–2020–06–02.

The FAA is issuing this AD to address solder cracking of the flight control electronic control units (FCECUs), which, combined with latent failure of the horizontal stabilizer trim actuator (HSTA) ''no-back'' mechanism, could result in uncontrolled HSTA operation. See the MCAI for additional background information.

Comments

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

Conclusion

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

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

Related Service Information Under 1 CFR Part 51

CAAI AD ISR–I–04–2020–06–02 describes new or more restrictive airworthiness limitations for airplane structures and safe life limits. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 160 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. In the past, the agency has estimated that this action

takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–26–12 Gulfstream Aerospace LP: Amendment 39–21367; Docket No. FAA–2020–0796; Project Identifier MCAI–2020–00902–T.

(a) Effective Date

This airworthiness directive (AD) is effective February 1, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Gulfstream Aerospace LP Model Gulfstream G280 airplanes, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before September 15, 2019.

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Reason

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address solder cracking of the flight control electronic control units (FCECUs), which, combined with latent failure of the horizontal stabilizer trim actuator (HSTA) ''no-back'' mechanism, could result in uncontrolled HSTA operation.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Civil Aviation Authority of Israel (CAAI) AD ISR–I–04–2020–06–02, dated June 28, 2020 (CAAI AD ISR–I–04–2020–06–02).

(h) Exceptions to CAAI AD ISR–I–04–2020–06–02

(1) Where CAAI AD ISR–I–04–2020–06–02 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where CAAI AD ISR–I–04–2020–06–02 refers to the date of its issuance, this AD requires using the effective date of this AD.

(i) Provisions for Alternative Actions, Intervals, and Critical Design Configuration Control Limitations (CDCCLs)

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections), intervals, and CDCCLs are allowed unless they are approved as specified in the provisions of CAAI AD ISR–I–04–2020–06–02.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(k) Related Information

For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, Large Aircraft Section, International Validation Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3226; email: *tom.rodriguez@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) The Civil Aviation Authority of Israel (CAAI) AD ISR–I–04–2020–06–02, dated June 28, 2020.

(ii) [Reserved]

(3) For CAAI AD ISR–I–04–2020–06–02, contact the CAAI, P.O. Box 1101, Golan Street, Airport City, 70100, Israel; phone: 972–3–9774665; fax: 972–3–9774592; email: *aip@mot.gov.il.* You may find this IBR material on the CAAI website at *https://www.caa.gov.il.*

(4) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0796.

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

Issued on December 10, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–28406 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0792; Project Identifier 2018–SW–049–AD; Amendment 39–21368; AD 2020–26–13]

RIN 2120–AA64

Airworthiness Directives; Sikorsky Aircraft Corporation Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for Sikorsky Aircraft Corporation (Sikorsky) Model S–92A helicopters. This AD was prompted by seven incidents of fatigue cracks in the horizontal stabilizer root fitting FWD (forward root fitting). This AD requires establishing the life limit of certain part-numbered forward root fittings, establishing the life limit of certain part-numbered stabilizer strut fittings, repetitively inspecting certain parts, and depending on the inspection results, removing parts from service. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective February 1, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of February 1, 2021.

ADDRESSES: For service information identified in this final rule, contact your local Sikorsky Field Representative or Sikorsky's Service Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–946–4337 (1–800–Winged–S); email *wcs_cust_service_eng.gr-sik@lmco.com.* Operators may also log on to the Sikorsky 360 website at *https://www.sikorsky360.com.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0792.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0792; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Dorie Resnik, Aerospace Engineer, Boston ACO Branch, 1200 District Avenue, Burlington, Massachusetts 01803; telephone 781–238–7693; email *dorie.resnik@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to Sikorsky Model S–92A helicopters with certain part-numbered horizontal stabilizer assemblies (stabilizer assembly), certain part-numbered forward root fittings, or certain part-numbered stabilizer strut fittings installed. The NPRM published in the **Federal Register** on September 17, 2020 (85 FR 58007). The NPRM was prompted by seven incidents of fatigue cracks in forward root fittings. Fatigue cracking in a forward root fitting degrades the load path and increases the load on other assembly parts, particularly at the aft horizontal stabilizer attachment points.

The NPRM proposed to require establishing the life limit of certain part-numbered forward root fittings and certain part-numbered stabilizer strut fittings. The NPRM also proposed to require repetitively inspecting each stabilizer assembly attachment bolt and barrel nut set, each forward root fitting, each attachment fitting including the bolt holes and fastener holes, condition of the fasteners, and each attachment fitting mating surface. Depending on the inspection results, the NPRM proposed to require removing parts from service. Finally, the NPRM proposed to prohibit installing certain stabilizer assemblies on any helicopter. The FAA is issuing this AD to address the unsafe condition on these products.

Comments

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

Conclusion

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

Related Service Information under 1 CFR Part 51

The FAA reviewed S–92 Maintenance Manual, SA S92A–AMM–000, Temporary Revision (TR) 55–33, dated March 24, 2020 (TR 55–33), which adds additional part numbers (P/Ns) to the Horizontal Stabilizer—Maintenance Practices and specifies procedures for inspecting each forward root fitting and aft root fitting bolt holes and fasteners, each forward and aft root fitting mating surface for wear of the abrasion-resistant Teflon coating, procedures for chemically striping the abrasion-resistant Teflon coating from the entire mounting pad, applying alodine, and applying an abrasion-resistant Teflon coating. This service information also describes procedures for removing and installing a stabilizer (Tasks 55–11–01–900–001 and 55–11–01–900–002), checking the torque stabilization (Task 55–11–01–280–001), and inspecting the stabilizer and attaching hardware (Task 55–11–01–210–004). This service information also provides assembly diagrams and lists interchangeable stabilizer P/Ns and compatible strut P/Ns.

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

Other Related Service Information

The FAA also reviewed S–92 Maintenance Manual SA S92A–AWL–000, TR No. 4–58, dated October 2, 2017 (TR 4–58), and S–92 Maintenance Manual SA S92A–AWL–000, TR No. 4–66 dated November 20, 2019 (TR 4–66). This service information revises Task 4–00–00–200–000, Table 1 Replacement Schedule, dated November 30, 2015. Both TR 4–58 and 4–66 revise the Airworthiness Limitations Schedule by removing certain part-numbered components, introducing new part-

numbered components, and establishing replacement intervals and recurring inspections for the forward root fitting and the horizontal stabilizer strut fitting. TR 4–58 also specifies inspecting the horizontal stabilizer and attaching hardware at a recurring interval of 250 hours time in service (TIS).

Differences Between This AD and the Service Information

The service information requires returning affected parts to a Sikorsky specialist; this AD does not.

Costs of Compliance

The FAA estimates that this AD affects 85 helicopters of U.S. registry. Labor costs are estimated at $85 per work-hour. Based on these numbers, the FAA estimates the following costs to comply with this AD.

Visually inspecting the stabilizer assembly and attached hardware will take about 3 work-hours for an estimated cost of $255 per helicopter and $21,675 for the U.S. fleet per inspection cycle.

If required, replacing a hat bushing and both upper fittings and lower fittings will take about 1 work-hour and parts will cost about $10,000 for an estimated cost of $10,085 per replacement.

If required, replacing the upper and lower support strut rod ends, including lug and conical fitting, will take about 1 work-hour and parts will cost about $10,000 for an estimated cost of $10,085 per replacement.

If required, performing a fluorescent penetrant inspection will take about 3 work-hours for an estimated cost of $255 per inspection.

If required, replacing a stabilizer assembly will take about 6 work-hours and parts will cost about $312,000 for an estimated cost of $312,510 per replacement.

If required, replacing a forward root fitting will take about 10 work-hours and parts will cost about $25,000 for an estimated cost of $25,850 per replacement.

If required, replacing a stabilizer strut fitting will take about 10 work-hours and parts will cost about $10,000 for an estimated cost of $10,850 per replacement.

If required, replacing a forward root fitting and an aft attachment fitting will take about 20 work-hours and parts will cost about $50,000 for an estimated cost of $51,700 per replacement.

If required, removing wear or corrosion and applying corrosion preventative compound will take about 0.5 work-hour and parts will cost a nominal amount for an estimated cost of $43 per action.

If required, replacing a stabilizer attachment bolt and barrel nut set will take about 1 work-hour and parts will cost about $500 for an estimated cost of $585 per replacement.

If required, replacing a fastener will take about 0.1 work-hour and parts will cost a nominal amount for an estimated cost of $9 per fastener.

If required, removing the abrasion-resistant Teflon coating to inspect each forward and aft attachment fitting mating surface will take about 5 work-hours for an estimated cost of $425 per inspection.

If required, applying alodine or equivalent and applying abrasion-resistant Teflon coating will take about 5 work hours with minimal parts cost for an estimated cost of $425 per application.

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–26–13 Sikorsky Aircraft Corporation: Amendment 39–21368; Docket No. FAA–2020–0792; Project Identifier 2018–SW–049–AD.

(a) Effective Date

This airworthiness directive (AD) is effective February 1, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Sikorsky Aircraft Corporation Model S–92A helicopters, certificated in any category, with the following installed: Horizontal stabilizer root fitting FWD (forward root fitting) part number (P/N) 92209–07111–101 or 92070–20125–101; or stabilizer strut fitting P/N 92209–07404–041, 92209–07403–041, or 92070–20117–041 installed on horizontal stabilizer assembly (stabilizer assembly) P/N 92070–20117–045, 92070–20117–046, 92070–20125–041, 92070–20125–042, 92070–20125–043, 92070–20125–044, 92205–07400–043, or 92205–07400–045.

(d) Subject

Joint Aircraft System Component (JASC) Code: 5510, Horizontal Stabilizer Structure.

(e) Unsafe Condition

This AD was prompted by incidents of fatigue cracks in a forward root fitting and life limit recalculations for forward root fitting P/N 92209–07111–101 and 92070–20125–101. The FAA is issuing this AD to prevent a forward root fitting from remaining in service beyond its life limit, detect fatigue cracking in a forward root fitting, and prevent

increased load and stress cracking in the stabilizer root fitting aft. The unsafe condition, if not addressed, could result in failure of a stabilizer root fitting, separation of the stabilizer assembly from the helicopter, and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 50 hours time-in-service (TIS):

(i) Determine the total hours TIS of the forward root fitting P/N 92209–07111–101 or 92070–20125–101. If the hours TIS of the forward root fitting is unknown, use the hours TIS of the stabilizer assembly instead.

(A) If the forward root fitting has accumulated 7,900 or more total hours TIS, before further flight, remove the forward root fitting from service.

(B) If the forward root fitting has accumulated less than 7,900 total hours TIS, before exceeding 7,900 hours TIS, remove the forward root fitting from service.

(ii) Thereafter following paragraph (g)(1)(i) of this AD, remove the forward root fitting from service before accumulating 7,900 total hours TIS.

(iii) For stabilizer assemblies with stabilizer strut fitting P/N 92070–20117–041 installed, perform the following actions:

(A) Determine the total hours TIS of stabilizer strut fitting P/N 92070–20117–041.

(B) If the stabilizer strut fitting has accumulated 19,100 or more total hours TIS, before further flight, remove the stabilizer strut fitting from service.

(C) If the stabilizer strut fitting has accumulated less than 19,100 total hours TIS, before exceeding 19,100 total hours TIS, remove the stabilizer strut fitting from service.

(iv) Thereafter following paragraph (g)(1)(iii) of this AD, remove the stabilizer strut fitting from service before accumulating 19,100 total hours TIS.

(2) For helicopters with stabilizer strut fitting P/N 92209–07404–041 or 92209–07403–041 installed, within 50 hours TIS and thereafter at intervals not to exceed 50 hours TIS:

(i) Remove the support strut and using a cheese cloth (or similar cloth) and isopropyl alcohol, clean the upper and lower support strut rod ends, horizontal stabilizer attachment fitting, and the tail rotor pylon attachment fitting.

(ii) Using a 10X or higher power magnifying glass, a flashlight, and a mirror, visually inspect the hat bushing and both upper fittings and lower fittings for a crack, corrosion, fretting, deformation, and wear. If there is a crack, corrosion, fretting, deformation, or wear, before further flight, remove the hat bushing and both upper fittings and lower fittings from service.

(iii) Using a 10X or higher power magnifying glass, a flashlight, and a mirror, visually inspect both upper and lower support strut rod ends, including lug and conical fitting, and both upper and lower attachment fittings on the stabilizer and pylon including the bushings for a crack, corrosion, fretting, deformation, and wear. If there is a crack, corrosion, fretting, deformation, or wear, before further flight, remove the upper and lower support strut rod ends, including lug and conical fitting, and both upper and lower attachment fittings on the stabilizer from service.

(3) Within 250 hours TIS or one year, whichever occurs first, and thereafter at intervals not to exceed 250 hours TIS or one year, whichever occurs first:

(i) Remove the stabilizer assembly and visually inspect each stabilizer attachment bolt and barrel nut set for corrosion, a crack, and damage to the threads. For the purposes of this inspection, damage may be indicated by uneven threads, missing threads, or cross-threading.

(A) If there is corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA-approved procedures.

(B) If there is corrosion that exceeds allowable limits, or a crack or damage to the threads, before further flight, remove the bolt and barrel nut set from service.

(ii) Inspect the forward root fitting and the aft attachment fitting by:

(A) Gaining access to the inside of the horizontal stabilizer.

(B) Using Brulin Cleaner SD 1291 (or equivalent) and a low-lint cloth, remove all traces of sealing compound, oil, and dirt from the stabilizer mounting surfaces.

(C) Using a 10X magnifying glass, inspect for any crack, wear, and corrosion.

(*1*) If there is a crack, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(*2*) If there is wear or corrosion that exceeds allowable limits, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(*3*) If there is wear or corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA-approved procedures.

(D) Visually inspect each attachment fitting bolt hole and fastener hole for a crack, wear, and corrosion.

(*1*) If there is a crack, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(*2*) If there is wear or corrosion that exceeds allowable limits, before further flight, remove the affected forward root fitting and the affected aft attachment fitting from service.

(*3*) If there is wear or corrosion within allowable limits, before further flight, treat for corrosion in accordance with FAA approved procedures.

(E) Inspect for loose or working fasteners. If there is a loose or working fastener, before further flight, remove the fastener from service.

(iii) As an alternative means to inspect for cracks in paragraphs (g)(3)(i) and (ii) of this AD, perform a florescent penetrate inspection (FPI).

(iv) Visually inspect each forward and aft attachment fitting mating surface for wear of the abrasion-resistant Teflon coating and degradation. For the purposes of this inspection, degradation may be indicated by fretting. Refer to Figure 204, of S–92 Maintenance Manual, SA S92A–AMM–000, Temporary Revision 55–33, Task 55–11–01–210–004, dated March 24, 2020 (TR 55–33), for a depiction of the area to be inspected. For the purposes of this inspection, wear may be indicated by less than 100% coverage of the abrasion-resistant Teflon coating. If there is wear to the abrasion-resistant Teflon coating or degradation, before further flight:

(A) Chemically strip the abrasion-resistant Teflon coating from the entire mounting pad in accordance with paragraph 7.A.(7)(a) of TR 55–33.

(B) FPI or eddy current inspect for a crack. If there is a crack, before further flight, remove the stabilizer assembly from service.

(C) If there is no crack, treat the affected area by applying alodine or equivalent. Apply abrasion-resistant Teflon coating in accordance with paragraphs 7.A.(7)(d) through (e) of TR 55–33.

(4) Installing stabilizer strut fitting P/N 92070–20117–041 is a terminating action for the 50 hour TIS repetitive requirements in paragraph (g)(2) of this AD.

(5) As of the effective date of this AD, do not install stabilizer assembly P/N 92205–07400–043, 92205–07400–045, or 92205–07400–047 on any helicopter.

(h) Alternative Methods of Compliance (AMOCs)

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

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

(i) Related Information

For more information about this AD, contact Dorie Resnik, Aerospace Engineer, Boston ACO Branch, 1200 District Avenue, Burlington, Massachusetts 01803; telephone 781–238–7693; email *dorie.resnik@faa.gov.*

(j) Material Incorporated by Reference

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

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

(i) S–92 Maintenance Manual, SA S92A–AMM–000, Temporary Revision (TR) 55–33, dated March 24, 2020.

(ii) [Reserved]

(3) For Sikorsky Aircraft Corporation service information identified in this AD, contact your local Sikorsky Field Representative or Sikorsky's Service

Engineering Group at Sikorsky Aircraft Corporation, 124 Quarry Road, Trumbull, CT 06611; telephone 1–800–946–4337 (1–800–Winged–S); email *wcs_cust_service_eng.gr-sik@lmco.com.* Operators may also log on to the Sikorsky 360 website at *https://www.sikorsky360.com.*

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

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

Issued on December 10, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–28385 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0468; Product Identifier 2018–SW–046–AD; Amendment 39–21365; AD 2020–26–10]

RIN 2120–AA64

Airworthiness Directives; Leonardo S.p.a. Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Leonardo S.p.a. (Leonardo) Model A119 and AW119 MKII helicopters. This AD requires revising the existing Rotorcraft Flight Manual (RFM) for your helicopter and installing a placard to prohibit intentional entry into autorotation. This AD would also allow replacement of an affected fuel control unit (FCU) as an optional terminating action for the RFM revision and placard installation. This AD was prompted by reports that certain FCUs may not have been calibrated to specification during overhaul. The actions of this AD are intended to address an unsafe condition on these products.

DATES: This AD is effective February 1, 2021.

The Director of the Federal Register approved the incorporation by reference of a certain document listed in this AD as of February 1, 2021.

ADDRESSES: For service information identified in this final rule, contact Leonardo S.p.A. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://www.leonardocompany.com/en/home.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0468.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0468 or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD, any service information that is incorporated by reference, any comments received, and other information. The street address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mitch Soth, Flight Test Engineer, Southwest Section, Flight Test Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *mitch.soth@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Leonardo Model A119 and AW119 MKII helicopters. The NPRM published in the **Federal Register** on June 11, 2020 (85 FR 35602). The NPRM proposed to require revising the Limitations Section of the existing RFM for your helicopter and installing a placard to prohibit intentional entry into autorotation. The NPRM also proposed to allow replacing affected FCUs with non-affected FCUs as an optional terminating action for the RFM revision and placard installation. The proposed requirements were intended to address certain FCUs that may not have been calibrated to specification during overhaul, which can lead to N1 fluctuations, hung engine starts, and the inability to recover power during autorotation training, and possibly result in reduced control of the helicopter.

The NPRM was prompted by EASA AD 2018–0124, dated June 5, 2018, issued by EASA, which is the Technical Agent for the Member States of the European Union, to correct an unsafe condition for all Leonardo Model A119 and AW119 MKII helicopters. EASA advises that certain FCUs may not have been calibrated to specification during overhaul, and that this condition, if not corrected, can lead to N1 fluctuations, hung engine starts, and the inability to recover power during autorotation training, possibly resulting in reduced control of the helicopter. To address this unsafe condition, the EASA AD requires amendment of the applicable RFM and installation of a placard to prohibit intentional entry into autorotation. The EASA AD also allows removal of the RFM limitation and placard after replacement of an affected FCU.

Comments

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

FAA's Determination

These helicopters have been approved by EASA and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the European Union, EASA has notified the FAA of the unsafe condition described in its AD. The FAA is issuing this AD after evaluating all of the information provided by EASA and determining the unsafe condition exists and is likely to exist or develop on other helicopters of the same type design and that air safety and the public interest require adopting the AD requirements as proposed.

Interim Action

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

Related Service Information Under 1 CFR Part 51

Leonardo has issued Leonardo Helicopters Emergency Alert Service Bulletin 119–089, Revision A, dated June 5, 2018. This service information describes procedures for revising the RFM and installing a placard in the cockpit.

This service information is reasonably available because the interested parties have access to it through their normal

course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 64 helicopters of U.S. Registry. Labor rates are estimated at $85 per work-hour. Based on these numbers, the FAA estimates that operators may incur the following costs in order to comply with this AD.

Revising the existing RFM for your helicopter and installing a placard takes about 2 work-hours and parts cost about $50, for an estimated cost of $220 per helicopter and $14,080 for the U.S. fleet.

The FAA has received no definitive data that would enable it to provide cost estimates for the optional terminating action specified in this AD.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2020–26–10 Leonardo S.p.a.: Amendment 39–21365; Docket No. FAA–2020–0468; Product Identifier 2018–SW–046–AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective February 1, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Leonardo S.p.a. Model A119 and AW119 MKII helicopters, certificated in any category.

(d) Subject

Joint Aircraft Service Component (JASC) Code 1100, Placards and markings.

(e) Reason

This AD was prompted by reports that certain fuel control units (FCU) may not have been calibrated to specification during overhaul. The FAA is issuing this AD to address certain FCUs that may not have been calibrated to specification during overhaul. This condition, if not corrected, can lead to N1 fluctuations, hung engine starts, and the inability to recover power during autorotation training, possibly resulting in reduced control of the helicopter.

(f) Compliance

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

(g) Definitions

For the purposes of this AD, the definitions in paragraphs (g)(1) through (3) of this AD apply.

(1) An affected FCU is one that is identified in section 1.A., ''Effectivity,'' of Leonardo Helicopters Emergency Alert Service Bulletin 119–089, Revision A, dated June 5, 2018.

(2) Group 1 helicopters are those that have an affected FCU installed.

(3) Group 2 helicopters are those that do not have an affected FCU installed.

(h) Required Rotorcraft Flight Manual (RFM) Amendment

For Group 1 helicopters: Before further flight involving intentional autorotation, or within 30 days after the effective date of this AD, whichever occurs first, revise the Limitations Section of the existing RFM for your helicopter in accordance with paragraph 4. of the Accomplishment Instructions of Leonardo Helicopters Emergency Alert Service Bulletin 119–089, Revision A, dated June 5, 2018.

(i) Required Placard Installation

For Group 1 helicopters: Concurrently with the RFM amendment required by paragraph (h) of this AD, install a placard in the cockpit in accordance with paragraph 3. of the Accomplishment Instructions of Leonardo Helicopters Emergency Alert Service Bulletin 119–089, Revision A, dated June 5, 2018.

(j) Optional Terminating Action

For Group 1 helicopters: Replacing the affected FCU with a non-affected FCU allows the amendment to be removed from the existing RFM for your helicopter and the placard to be removed from the helicopter.

(k) Parts Installation Prohibition

(1) For Group 1 helicopters: Do not install an affected FCU on any helicopter after replacement with a non-affected FCU.

(2) For Group 2 helicopters: Do not install an affected FCU on any helicopter after the effective date of this AD.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Mitch Soth, Flight Test Engineer, Southwest Section, Flight Test Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

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

(m) Related Information

The subject of this AD is addressed in European Aviation Safety Agency (now European Union Aviation Safety Agency) (EASA) AD 2018–0124, dated June 5, 2018. This EASA AD may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0468.

(n) Material Incorporated by Reference

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

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

(i) Leonardo Helicopters Emergency Alert Service Bulletin 119–089, Revision A, dated June 5, 2018.

(ii) [Reserved]

(3) For service information identified in this AD, contact Leonardo S.p.A. Helicopters, Emanuele Bufano, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–225074; fax +39–0331–229046; or at *https://www.leonardocompany.com/en/home.* You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177.

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

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

Issued on December 9, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–28383 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0924; Airspace Docket No. 20–ANE–1]

RIN 2120–AA66

Revocation of Class E Airspace; Newburyport, MA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action removes Class E airspace at Newburyport, MA, as Plum Island Airport no longer has instrument approaches and controlled airspace is no longer required. This action would enhance the safety and management of controlled airspace within the national airspace system.

DATES: Effective 0901 UTC, February 25, 2021. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it removes Class E airspace extending upward from 700 feet above the surface at Plum Island Airport, Newburyport, MA, due to the cancellation of all instrument flight rules approaches into the airport.

History

The FAA published a notice of prosed rulemaking in the **Federal Register** (85 FR 69279, November 2, 2020) for Docket No. FAA–2020–0924 to remove Class E airspace extending upward from 700 feet above the surface at Plum Island Airport, Newburyport, MA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020, and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic routes, and reporting points.

The Rule

This amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 removes Class E airspace extending upward from 700 feet above the surface at Plum Island Airport, Newburyport, MA, as the airport no longer has instrument approaches. Therefore, the airspace is no longer necessary. This action would enhance the safety and management of controlled airspace within the national airspace system.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 20, 2020, effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ANE MA E5 Newburyport, MA [Removed]

Issued in College Park, Georgia, on December 17, 2020.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2020–28552 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31346 Amdt. No. 3935]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

DATES: This rule is effective December 28, 2020. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 28, 2020.

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

For Examination

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

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

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

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

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

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29 Room 104, Oklahoma City, OK 73169. Telephone (405) 954–4164.

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

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

Availability and Summary of Material Incorporated by Reference

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

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

The Rule

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

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

effective date at least 30 days after publication is provided.

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

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

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on December 11, 2020.

Wade Terrell,

Aviation Safety, Manager, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of The Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

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

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

Effective 28 January 2021

Cullman, AL, KCMD, RNAV (GPS) RWY 20, Amdt 1B
Hope, AR, M18, VOR RWY 4, Orig-A
Killdeer, ND, 9Y1, RNAV (GPS) RWY 13, Orig
Killdeer, ND, 9Y1, RNAV (GPS) RWY 31, Orig
Killdeer, ND, 9Y1, Takeoff Minimums and Obstacle DP, Orig

Effective 25 February 2021

Toksook Bay, AK, PAOO, RNAV (GPS) RWY 34, Amdt 3B
Grand Canyon, AZ, 40G, RNAV (GPS) RWY 1, Orig-D
Grand Canyon, AZ, 40G, RNAV (GPS) RWY 19, Orig-C
Hollister, CA, KCVH, RNAV (GPS) RWY 31, Amdt 1A
Los Angeles, CA, KLAX, ILS OR LOC RWY 24R, ILS RWY 24R (CAT II), ILS RWY 24R (CAT III), Amdt 26A
Los Angeles, CA, KLAX, RNAV (GPS) Y RWY 24R, Amdt 3A
Los Angeles, CA, KLAX, RNAV (RNP) Z RWY 24R, Amdt 1B
San Luis Obispo, CA, San Luis County Rgnl, Takeoff Minimums and Obstacle DP, Amdt 8
Denver, CO, Centennial, Takeoff Minimums and Obstacle DP, Amdt 5A
Lamar, CO, Southeast Colorado Rgnl, RNAV (GPS) RWY 8, Amdt 1D
Lamar, CO, Southeast Colorado Rgnl, RNAV (GPS) RWY 18, Amdt 1E
Lamar, CO, Southeast Colorado Rgnl, RNAV (GPS) RWY 26, Orig-E
Lamar, CO, Southeast Colorado Rgnl, RNAV (GPS) RWY 36, Amdt 1D
Lamar, CO, Southeast Colorado Rgnl, VOR RWY 18, Amdt 10E
Lamar, CO, Southeast Colorado Rgnl, VOR RWY 36, Amdt 1D
Pueblo, CO, Pueblo Memorial, RNAV (GPS) RWY 35, Orig-B
Washington, DC, KDCA, RNAV (GPS) RWY 15, Orig-C
Washington, DC, Ronald Reagan Washington National, RNAV (GPS) RWY 33, Amdt 1B
Arcadia, FL, Arcadia Muni, RNAV (GPS)-A, Orig-A
Arcadia, FL, Arcadia Muni, RNAV (GPS)-B, Orig-A
Jacksonville, FL, KVQQ, RNAV (GPS) RWY 27L, Amdt 1B
Augusta, GA, Augusta Rgnl at Bush Field, ILS OR LOC RWY 17, Amdt 10
Augusta, GA, Augusta Rgnl at Bush Field, RNAV (GPS) RWY 17, Amdt 3
Augusta, GA, Augusta Rgnl at Bush Field, RNAV (GPS) RWY 35, Amdt 2D
Augusta, GA, Augusta Rgnl at Bush Field, RNAV (GPS) Z RWY 8, Amdt 1
Canton, GA, Cherokee County Rgnl, NDB RWY 5, Amdt 4B
Canton, GA, Cherokee County Rgnl, RNAV (GPS) RWY 5, Amdt 1B
Canton, GA, Cherokee County Rgnl, RNAV (GPS) RWY 23, Amdt 1B
Hilo, HI, Hilo Intl, RNAV (GPS) RWY 21, Amdt 1
Honolulu, HI, PHNL, LOC RWY 4R, Amdt 1D
Honolulu, HI, PHNL, LOC RWY 8L, Amdt 1C
Honolulu, HI, PHNL, LDA RWY 26L, Amdt 6A
Honolulu, HI, PHNL, RNAV (GPS) Y RWY 4R, Amdt 3A
Honolulu, HI, PHNL, VOR OR TACAN RWY 4R, Orig-E
Honolulu, HI, PHNL, VOR OR TACAN–A, Amdt 1D
Honolulu, HI, PHNL, VOR OR TACAN–B, Amdt 2D
Mapleton, IA, KMEY, RNAV (GPS) RWY 2, Orig-B
Mapleton, IA, KMEY, RNAV (GPS) RWY 20, Orig-D
Sioux City, IA, Sioux Gateway/Brig Gen Bud Day Field, ILS OR LOC RWY 13, Amdt 3
Sioux City, IA, Sioux Gateway/Brig Gen Bud Day Field, ILS OR LOC RWY 31, Amdt 26
Driggs, ID, Driggs-Reed Memorial, LAMON THREE, Graphic DP
Driggs, ID, Driggs-Reed Memorial, Takeoff Minimums and Obstacle DP, Amdt 3A
Belleville, IL, KBLV, ILS OR LOC RWY 14R, Orig-G
Belleville, IL, KBLV, RNAV (GPS) RWY 14R, Orig-F
Belleville, IL, KBLV, TACAN RWY 14R, Amdt 1C
Belleville, IL, KBLV, TACAN RWY 32L, Amdt 1C
Parsons, KS, Tri-City, RNAV (GPS) RWY 17, Amdt 1A
Parsons, KS, Tri-City, RNAV (GPS) RWY 35, Amdt 1A
Pittsburg, KS, Atkinson Muni, RNAV (GPS) RWY 4, Amdt 1G
Pittsburg, KS, Atkinson Muni, VOR RWY 4, Amdt 3G
Scott City, KS, Scott City Muni, Takeoff Minimums and Obstacle DP, Amdt 1
Owensboro, KY, Owensboro-Daviess County Rgnl, Takeoff Minimums and Obstacle DP, Amdt 5B
Paducah, KY, Barkley Rgnl, ILS OR LOC RWY 5, Amdt 10D
Paducah, KY, Barkley Rgnl, RNAV (GPS) RWY 5, Amdt 2
Paducah, KY, Barkley Rgnl, RNAV (GPS) RWY 14, Amdt 1
Paducah, KY, Barkley Rgnl, RNAV (GPS) RWY 23, Orig-E
Paducah, KY, Barkley Rgnl, RNAV (GPS) RWY 32, Amdt 1
Paducah, KY, Barkley Rgnl, Takeoff Minimums and Obstacle DP, Amdt 4
Paducah, KY, Barkley Rgnl, VOR RWY 5, Amdt 18C
Paducah, KY, Barkley Rgnl, VOR RWY 23, Amdt 6E
Williamsburg, KY, Williamsburg-Whitley County, Takeoff Minimums and Obstacle DP, Amdt 2A
Jennings, LA, Jennings, Takeoff Minimums and Obstacle DP, Amdt 2B
Opelousas, LA, St Landry Parish-Ahart Field, VOR RWY 36, Amdt 1B
Houlton, ME, Houlton Intl, Takeoff Minimums and Obstacle DP, Amdt 3
Lansing, MI, Capital Region Intl, RNAV (GPS) RWY 6, Amdt 1
Lansing, MI, Capital Region Intl, RNAV (GPS) RWY 10R, Amdt 1

Lansing, MI, Capital Region Intl, RNAV (GPS) RWY 24, Amdt 1
Appleton, MN, KAQP, NDB RWY 13, Amdt 1, CANCELLED
Bemidji, MN, Bemidji Rgnl, ILS OR LOC RWY 25, Amdt 2
Bemidji, MN, Bemidji Rgnl, ILS OR LOC RWY 31, Amdt 7
Benson, MN, KBBB, NDB RWY 14, Amdt 7B, CANCELLED
Cambridge, MN, KCBG, NDB RWY 34, Amdt 7A, CANCELLED
Canby, MN, Myers Field, RNAV (GPS) RWY 30, Amdt 1A
Crookston, MN, KCKN, NDB RWY 13, Amdt 9A, CANCELLED
Glencoe, MN, KGYL, NDB RWY 31, Amdt 1A, CANCELLED
Granite Falls, MN, Granite Falls Muni/Lenzen-Roe-Fagen Memorial Field, RNAV (GPS) RWY 33, Orig-A
Little Falls, MN, KLXL, NDB RWY 31, Amdt 6E, CANCELLED
Longville, MN, KXVG, NDB RWY 31, Amdt 1A, CANCELLED
Moose Lake, MN, KMZH, NDB RWY 4, Amdt 1B, CANCELLED
Mora, MN, KJMR, NDB RWY 35, Orig-A, CANCELLED
Orr, MN, KORB, NDB RWY 13, Amdt 8C, CANCELLED
Ortonville, MN, KVVV, NDB RWY 34, Amdt 2B, CANCELLED
Park Rapids, MN, KPKD, ILS OR LOC RWY 31, Amdt 2
Pipestone, MN, Pipestone Muni, RNAV (GPS) RWY 36, Amdt 1C
Staples, MN, KSAZ, NDB RWY 14, Amdt 3C, CANCELLED
Thief River Falls, MN, Thief River Falls Rgnl, RNAV (GPS) RWY 4, Orig-A
Tracy, MN, Tracy Muni, RNAV (GPS) RWY 11, Orig-B
Columbia, MO, Columbia Rgnl, ILS OR LOC RWY 2, Amdt 16B
Columbia, MO, Columbia Rgnl, RNAV (GPS) RWY 2, Amdt 2B
Columbia, MO, Columbia Rgnl, RNAV (GPS) RWY 13, Amdt 1A
Columbia, MO, Columbia Rgnl, RNAV (GPS) RWY 31, Amdt 1A
Columbia, MO, Columbia Rgnl, VOR RWY 13, Amdt 4A
Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (GPS) Y RWY 5L, Amdt 2
Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (GPS) Y RWY 5R, Amdt 4
Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (GPS) Y RWY 23L, Amdt 3
Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (RNP) Z RWY 5L, Amdt 3
Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (RNP) Z RWY 5R, Amdt 3
Raleigh/Durham, NC, Raleigh-Durham Intl, RNAV (RNP) Z RWY 23L, Amdt 3
Raleigh/Durham, NC, Raleigh-Durham Intl, VOR RWY 5R, Amdt 13F, CANCELLED
Raleigh/Durham, NC, Raleigh-Durham Intl, VOR RWY 23L, Amdt 14F, CANCELLED
Dickinson, ND, KDIK, ILS OR LOC RWY 32, Amdt 1C, CANCELLED
Dickinson, ND, KDIK, RNAV (GPS) RWY 14, Amdt 1A, CANCELLED
Dickinson, ND, KDIK, RNAV (GPS) RWY 32, Amdt 2B, CANCELLED
Dickinson, ND, Dickinson—Theodore Roosevelt Rgnl, Takeoff Minimums and Obstacle DP, Amdt 2A
Creighton, NE, Creighton Muni, RNAV (GPS) RWY 31, Orig-D
Lexington, NE, Jim Kelly Field, RNAV (GPS) RWY 32, Amdt 2
Jaffrey, NH, KAFN, RNAV (GPS)-C, Amdt 1
Millville, NJ, KMIV, RNAV (GPS) RWY 14, Orig-F
Princeton/Rocky Hill, NJ, Princeton, VOR–A, Amdt 7C
Wildwood, NJ, Cape May County, Takeoff Minimums and Obstacle DP, Amdt 3A
Ruidoso, NM, Sierra Blanca Rgnl, CAPITAN TWO, Graphic DP
Ruidoso, NM, Sierra Blanca Rgnl, Takeoff Minimums and Obstacle DP, Orig-A
Las Vegas, NV, North Las Vegas, GPS RWY 12R, Orig-E, CANCELLED
Las Vegas, NV, North Las Vegas, GPS RWY 30L, Orig-B, CANCELLED
Las Vegas, NV, North Las Vegas, RNAV (GPS) RWY 12R, Orig
White Plains, NY, Westchester County, ILS OR LOC RWY 16, ILS RWY 16 (SA CAT I), ILS RWY 16 (SA CAT II), Amdt 25C
White Plains, NY, Westchester County, ILS OR LOC RWY 34, Amdt 5C
Ketchum, OK, 1K8, RNAV (GPS) RWY 36, Orig-B
Weatherford, OK, KOJA, RNAV (GPS) RWY 17, Amdt 2A
Mc Minnville, OR, Mc Minnville Muni, Takeoff Minimums and Obstacle DP, Amdt 5
Chambersburg, PA, Franklin County Rgnl, RNAV (GPS) RWY 6, Orig-C
Chambersburg, PA, Franklin County Rgnl, RNAV (GPS) RWY 24, Orig-C
Doylestown, PA, Doylestown, VOR–A, Orig
Doylestown, PA, Doylestown, VOR/DME RWY 23, Amdt 8B, CANCELLED
Latrobe, PA, Arnold Palmer Rgnl, ILS OR LOC RWY 24, Amdt 17B
Huron, SD, Huron Rgnl, ILS OR LOC RWY 12, Amdt 11
Huron, SD, Huron Rgnl, LOC BC RWY 30, Amdt 14
Huron, SD, Huron Rgnl, RNAV (GPS) RWY 12, Orig-B
Huron, SD, Huron Rgnl, RNAV (GPS) RWY 30, Amdt 1C
Huron, SD, Huron Rgnl, VOR RWY 12, Amdt 22A, CANCELLED
Miller, SD, Miller Muni, RNAV (GPS) RWY 15, Amdt 1B
Miller, SD, Miller Muni, RNAV (GPS) RWY 33, Amdt 1B
Pierre, SD, Pierre Rgnl, RNAV (GPS) RWY 25, Amdt 2A
Pierre, SD, Pierre Rgnl, RNAV (GPS) RWY 31, Amdt 1A
Gallatin, TN, KXNX, RNAV (GPS) RWY 35, Amdt 3B
Jasper, TN, Marion County-Brown Field, Takeoff Minimums and Obstacle DP, Amdt 2A
Mountain City, TN, Johnson County, Takeoff Minimums and Obstacle DP, Amdt 1
Austin, TX, KAUS, ILS OR LOC RWY 35R, ILS RWY 35R (SA CAT I), ILS RWY 35R (SA CAT II), Amdt 4A
Austin, TX, Austin-Bergstrom Intl, RNAV (RNP) Z RWY 17R, Amdt 1A
Austin, TX, KHYI, RNAV (GPS) RWY 8, Orig-C
El Paso, TX, KELP, RADAR–1, Amdt 15C
Harlingen, TX, Valley Intl, VOR RWY 17L, Amdt 1
Marfa, TX, Marfa Muni, Takeoff Minimums and Obstacle DP, Amdt 1A
Midlothian/Waxahachie, TX, Mid-Way Rgnl, RNAV (GPS) RWY 18, Orig-B
Vernal, UT, KVEL, RNAV (GPS) Y RWY 35, Orig-B
Vernal, UT, KVEL, VOR RWY 35, Orig-B
Wise, VA, Lonesome Pine, LOC RWY 24, Amdt 1
Wise, VA, Lonesome Pine, RNAV (GPS) RWY 6, Orig-B
Wise, VA, Lonesome Pine, RNAV (GPS) RWY 24, Amdt 1
Highgate, VT, KFSO, VOR RWY 19, Amdt 5B, CANCELLED

[FR Doc. 2020–28413 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31347 Amdt. No. 3936]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

DATES: This rule is effective December 28, 2020. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of December 28, 2020.

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

For Examination

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

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

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

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

For information on the availability of this material at NARA, email *fedreg.legal@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Availability

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

FOR FURTHER INFORMATION CONTACT: Thomas J. Nichols, Flight Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29 Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

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

Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section. The material incorporated by reference describes SIAPs, Takeoff Minimums and ODPs as identified in the amendatory language for part 97 of this final rule.

The Rule

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

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

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

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

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

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on December 11, 2020.

Wade Terrell,

Aviation Safety, Manager, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

Adoption of The Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

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

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

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

Effective Upon Publication

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
28–Jan–21	NE	Lexington	Jim Kelly Field	0/3429	12/7/20	RNAV (GPS) RWY 14, Amdt 1C.
28–Jan–21	CA	Madera	Madera Muni	0/4637	12/7/20	RNAV (GPS) RWY 12, Amdt 2.
28–Jan–21	CA	Madera	Madera Muni	0/4638	12/7/20	RNAV (GPS) RWY 30, Amdt 2.
28–Jan–21	WI	La Crosse	La Crosse Rgnl	0/5484	12/7/20	RNAV (GPS) RWY 22, Orig-A.

[FR Doc. 2020–28414 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 740

[Docket No. 201120–0311]

RIN 0694–AI12

Amendment to Country Groups for Ukraine, Mexico and Cyprus Under the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: In this rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to revise the Country Group designations for Ukraine, Mexico and Cyprus. Specifically, in this rule, BIS moves Ukraine from Country Group D to Country Group B and adds Mexico and Cyprus in Country Group A:6. This rule also includes conforming changes.

DATES: Effective December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Patricia Muldonian, Office of National Security and Technology Transfer Controls, *Patricia.Muldonian@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Export Administration Regulations (EAR) designates countries in Country Groups (A, B, D and E) (Supplement No. 1 to Part 740) which reflect each country's export control policy, multilateral regime membership, system, and practice. The Country Groups generally serve as a basis for the availability of exceptions from license requirements described in part 740 (License Exceptions) of the EAR, when applicable conditions are met in part 740. Country Groups may also be used when describing license review policy and end-user and end-use based controls under part 744.

The EAR also sets forth license requirements in the Commerce Country Chart (Supplement No. 1 to Part 738). The Commerce Country Chart contains licensing requirements based on the destination to which items listed on the Commerce Control List (CCL) (Supplement No. 1 to Part 774) will be exported or reexported and their corresponding ''Reason for Control,'' which is found in the CCL entry. An ''X'' in the cell where the ''reason for control'' column intersects with the row of the destination indicates a license requirement. Licenses are required to export and reexport items under the EAR for multilateral reasons (*i.e.,* chemical and biological (CB), nuclear nonproliferation (NP), national security (NS), and missile technology (MT)); and for unilateral reasons (*i.e.,* region stability (RS), crime control (CC) and anti-terrorism (AT)), as well as to implement controls for firearms convention (FC) and United Nations Security Council purposes. Controls for United Nations Security Council purposes are identified by the abbreviation ''UN'' in the applicable CCL entries. The ''UN'' reason for control is described in § 746.2(b) of the EAR.

In combination with the CCL—the list of items classified and set-out as Export Control Classification Numbers (ECCNs) and arranged by categories—the Commerce Country Chart allows an exporter to determine whether a license is required for the export or reexport of an item on the CCL to the destinations on the Chart, unless otherwise specified in the particular ECCN entry on the CCL.

Specific Amendments in This Rule

Ukraine

Ukraine is a member of the four multilateral export control regimes (Australia Group; Missile Technology Control Regime; Nuclear Suppliers Group; Wassenaar Arrangement). In addition, Ukraine works with the United States on a variety of export control matters. As a result, this rule removes Ukraine from Country Group D:1 and places Ukraine in Country Group B. This removes Ukraine from Country Group D completely. This rule does not remove ''Xs'' in Columns CB1, NS1, NS2, MT1, RS1, RS2, CC1 and CC2 for Ukraine in the Commerce Country Chart. In addition, BIS has determined that exports to Ukraine are not eligible for License Exceptions Shipments to Country Group B countries (GBS) and Technology and software under restriction (TSR). This rule makes conforming changes in part 740 consistent with that policy. Those amendments are described further in the following section on the ''*Impact of the Amendments in this Rule*''.

Mexico

Mexico is a member of three multilateral export control regimes (Australia Group; Nuclear Suppliers Group; Wassenaar Arrangement). Mexico also has national security interests and policies compatible with those of the United States. As a result, this rule adds Mexico to Country Group A:6. This rule does not remove ''Xs'' in Columns CB1, NS1, MT1, RS1, and CC1 for Mexico in the Commerce Country Chart.

Cyprus

Cyprus is a member of the European Union. The European Union's export control regulations implement the controls of the four multilateral export control regimes and apply to all members. In addition, the Department of State recently issued a temporary final rule revising its licensing policy for Cyprus in § 126.1 (Prohibited exports, imports and sales to or from certain countries) (of the International Traffic in Arms Regulations) (85 FR 60698, 9/28/20). As a result, this final rule adds Cyprus to Country Group A:6. This rule does not remove ''Xs'' in Columns CB1, NS1, MT1, RS1, RS2 and CC1 for Cyprus in the Commerce Country Chart.

Impact of the Amendments in This Rule

Ukraine

Placing Ukraine in Country Group B and removing it from Country Group D, combined with Ukraine's existing Country Groups A:2, A:3, and A:4 status, makes certain license exceptions available for Ukraine, when applicable conditions are met, and the restrictions in § 740.2 do not apply. The available license exceptions are: Shipments of limited value (LVS)(§ 740.3); Temporary imports, exports, reexports, and transfers (in-country) (TMP)(§ 740.9); Servicing and replacement of parts and equipment (RPL) (§ 740.10); Gift parcels and humanitarian donations (GFT)(§ 740.12); Baggage

(BAG)(§ 740.14); Aircraft and vessels (AVS)(§ 740.15); Additional permissive reexports (APR)(§ 740.16); and Encryption, commodities, software, and technology (ENC)(§ 740.17).

As noted earlier, License Exceptions Shipments to Country Group B countries (GBS) (§ 740.4) and Technology and software under restriction (TSR) (§ 740.6) will not be available for exports to Ukraine. Therefore, in this rule, BIS made conforming amendments in §§ 740.4 and 740.6 to clearly set forth that license exceptions GBS and TSR are available for Country Group B countries except Ukraine.

These changes also allow a less restrictive licensing policy for the export and reexport to Ukraine of items listed on the CCL and controlled for national security reasons. Also as a result of the amendments in this rule, applications to export and reexport to Ukraine items listed on the CCL and controlled for national security reasons will no longer be subject to the case-by-case licensing policy in § 742.4(b)(2), and now will be subject to a licensing policy of approval per § 742.4(b)(1)(i). The restrictions on the export, reexport, and transfer (in-country) of certain microprocessors to military end uses and end users in Country Group D:1, pursuant to § 744.17, (Restrictions on certain exports, reexports, and transfers (in-country) of microprocessors and associated ''software'' and ''technology'' for 'military end uses' and to 'military end users') also no longer apply to Ukraine. Furthermore, § 744.7 (Restrictions on certain exports to and for the use of certain foreign vessels or aircraft) restrictions on certain exports and reexports to vessels and aircraft, located in Ukrainian ports or registered in Ukraine no longer apply to that destination. Finally, by removing Ukraine from Country Group D:1, the § 736.2(b)(3), General Prohibition Three, licensing requirements for reexports of the foreign-produced direct product of U.S.-origin technology and software to Ukraine no longer apply.

These amendments are intended to serve U.S. national security and foreign policy interests toward Ukraine. This rule does not change the status of the Crimea Region of Ukraine under the EAR.

Mexico

With the addition of Mexico to Country Group A:6, License Exception Strategic Trade Authorization (STA) is available for exports, reexports and transfer (in-country) of lesser sensitivity items controlled for NS reasons only as set forth in § 740.20(c)(2). This new Country Group status is in addition to Mexico's existing Country Group B status which includes the availability of License Exceptions GBS and TSR.

Cyprus

Adding Cyprus to Country Group A:6 makes License Exception STA available for exports, reexports and transfer (in-country) of lesser sensitivity items controlled for NS reasons only as set forth in § 740.20(c)(2). This new Country Group status is in addition to Cyprus' existing Country Group B status which includes the availability of License Exceptions GBS and TSR. As Cyprus also is in Country Group D:5 (U.S. Arms Embargoed Countries), however, consideration of license exceptions must include particular review and compliance with the restrictions on items in a 9x515 or ''600 series'' ECCN as set forth in paragraphs (a)(12) and (13) of § 740.2.

Export Control Reform Act of 2018

On August 13, 2018, the President signed into law the John S. McCain National Defense Authorization Act for Fiscal Year 2019, which included the Export Control Reform Act of 2018.

(ECRA) (50 U.S.C. 4801–4852) that provides the legal basis for BIS's principal authorities and serves as the authority under which BIS issues this rule. As set forth in Section 1768 of ECRA, all delegations, rules, regulations, orders, determinations, licenses, or other forms of administrative action that were made, issued, conducted, or allowed to become effective under the Export Administration Act of 1979 (50 U.S.C. 4601 *et seq.*) (as in effect prior to August 13, 2018, and as continued in effect pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*)), or the Export Administration Regulations, and were in effect as of August 13, 2018, shall continue in effect according to their terms until modified, superseded, set aside, or revoked under the authority of ECRA.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated to be a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866.

2. This final rule is not subject to the requirements of E.O. 13771 (82 FR 9339, February 3, 2017) because it is issued with respect to a military and foreign affairs function of the United States. In particular, this rule recognizes: (1) The Government of Ukraine's continuing engagement with regional and international export control authorities; (2) Mexico's multilateral export control regime memberships and national security approaches and interests compatible with the United States; and (3) Cyprus' European Union membership and like-minded export controls. These changes to the EAR serve U.S. foreign policy and national security interests. Accordingly, this rule meets the requirements set forth in the April 5, 2017, OMB guidance implementing E.O. 13771. See *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2017/M-17-21-OMB.pdf*.

3. This rule does not contain policies with Federalism implications as that term is defined under Executive Order 13132.

4. Pursuant to section 1762 of the Export Control Reform Act of 2018 (50 U.S.C. 4821), this action is exempt from the Administrative Procedure Act (5 U.S.C. 553) requirements for notice of proposed rulemaking, opportunity for public participation, and delay in effective date.

5. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

6. Notwithstanding any other provision of law, no person may be required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves a collection currently approved by OMB under control number 0694–0088, Simplified Network Application Processing System. The collection includes, among other things, license applications, and carries a burden estimate of 42.5 minutes for a manual or electronic submission for a total burden

estimate of 31,878 hours. BIS expects the burden hours associated with this collection to decrease slightly or have limited impact on the existing estimates. Any comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, should be sent within 30 days of publication of this notice to *http://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

List of Subjects in 15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, part 740 of the Export Administration Regulations (15 CFR parts 730–774) are amended as follows:

PART 740—LICENSE EXCEPTIONS

■ 1. The authority citation for part 740 continues to read as follows:

Authority: 50 U.S.C. 4801–4852; 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 7201 *et seq.;* E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783.

■ 2. Section 740.4 is revised to read as follows:

§ 740.4 Shipments to Country Group B countries (GBS).

License Exception GBS authorizes exports and reexports to Country Group B (see Supplement No. 1 to part 740), except Ukraine, of those commodities where the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR) indicates a license requirement to the ultimate destination for national security reasons only and identified by ''GBS—Yes'' on the CCL. See § 743.1 of the EAR for reporting requirements for exports of certain commodities under License Exception GBS.

■ 3. Section 740.6 is amended by revising paragraph (a) introductory text to read as follows:

§ 740.6 Technology and software under restriction (TSR).

(a) *Scope.* License Exception TSR permits exports and reexports of technology and software where the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR) indicates a license requirement to the ultimate destination for national security reasons only and identified by ''TSR—Yes'' in entries on the CCL, provided the software or technology is destined to Country Group B, except Ukraine. (See Supplement No. 1 to part 740.) A written assurance is required from the consignee before exporting or reexporting under this License Exception.

* * * * *

Supplement No. 1 to Part 740 [Amended]

■ 4. Supplement No. 1 to part 740 is amended by

■ a. In the Country Group A table, adding ''Cyprus'' and ''Mexico'' in alphabetical order to Column A:6.

■ b. In the Country Group B table, adding ''Ukraine'' in alphabetical order;

■ c. In the Country Group D table, removing the entry for ''Ukraine'';

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2020–26552 Filed 12–23–20; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Parts 773 and 778

Federal Railroad Administration

49 CFR Part 264

Federal Transit Administration

49 CFR Part 662

[Docket No. FHWA–2016–0037]

FHWA RIN 2125–AF73; FRA RIN 2130–AC66; FTA RIN 2132–AB32

Program for Eliminating Duplication of Environmental Review

AGENCY: Federal Highway Administration (FHWA), Federal Railroad Administration (FRA), Federal Transit Administration (FTA), U.S. Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: FHWA, FRA, and FTA are issuing this final rule to establish the regulations governing the DOT Program for Eliminating Duplication of Environmental Reviews (Pilot Program). Section 1309 of the Fixing America's Surface Transportation (FAST) Act, as further amended, directed the Secretary of Transportation to establish a pilot program authorizing up to two States to conduct environmental reviews and make approvals for projects under State environmental laws and regulations, instead of the National Environmental Policy Act (NEPA), under certain circumstances. Section 1309(c) requires the Secretary, in consultation with the Chair of the Council on Environmental Quality (CEQ), to promulgate regulations to implement the requirements of the Pilot Program, including application requirements and criteria necessary to determine whether State laws and regulations are at least as stringent as the applicable Federal law.

This final rule also implements Section 1308 of the FAST Act, which amends the corrective action period of the Surface Transportation Project Delivery Program (Section 327 Program).

DATES: This final rule is effective January 27, 2021.

FOR FURTHER INFORMATION CONTACT: For FHWA, James Gavin, Office of Project Development and Environmental Review, (202) 366–1473, or Diane Mobley, Office of Chief Counsel, (202) 366–1366. For FRA, Michael Johnsen, Office of Railroad Policy and Development, (202) 493–1310, or Chris Van Nostrand, Office of Chief Counsel, (202) 493–6058. For FTA, Megan Blum, Office of Planning and Environment, (202) 366–0463, or Mark Montgomery, Office of Chief Counsel, 202–366–1017. The Agencies are located at 1200 New Jersey Ave. SE, Washington, DC 20590. Office hours are from 9:00 a.m. to 5:00 p.m. ET, Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Section 1309 of the FAST Act (Pub. L. 114–94, 129 Stat. 1312), codified at 23 U.S.C. 330, established a pilot program that allows the Secretary to approve up to five States (to include the District of Columbia and Puerto Rico) to use one or more State environmental laws instead of the NEPA process for a State's environmental review of surface transportation projects. Section 1309 required the Secretary, in consultation with the Chair of CEQ, to promulgate regulations governing the Pilot Program. FHWA, FRA, and FTA, herein referred to as the ''Agencies'' or, when singular, the ''Agency,'' are promulgating these regulations under a delegation from the Secretary.

This final rule establishes the Pilot Program, specifies application requirements, and defines the criteria the Agencies will use to determine whether a State law or regulation is as stringent as the Federal requirements under NEPA, the procedures implementing NEPA, and NEPA-related regulations and executive orders. As a prerequisite to a State's participation in the Pilot Program, it must have assumed the Secretary's responsibilities for

environmental reviews under 23 U.S.C. 327 (the Section 327 Program).

After publication of the NPRM, Section 578 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254) amended 23 U.S.C. 330(a)(2), reducing the number of States eligible to participate in the pilot from five to two. In addition, it amended 23 U.S.C. 330 (e)(2)(A) and (e)(3)(B)(i), changing the statute of limitations from 2 years to 150 days as set forth in 23 U.S.C. 139(*l*). In addition, CEQ issued a final rule comprehensively updating the regulations implementing NEPA. 85 FR 43304 (July 16, 2020). These regulations became effective on September 14, 2020.

In addition to creating the Pilot Program authorized under Section 1309, the FAST Act also amended 23 U.S.C. 327, which authorizes DOT's Section 327 Program. Notably, section 1308(5) changed the termination procedures for the Section 327 Program by: (1) Lengthening the time the Agencies must provide to a State to take corrective action following a notice of non-compliance from 30 days to at least 120 calendar days, and (2) requiring the Agencies to provide a detailed description of each responsibility in need of corrective action, upon the request of the Governor of the State. 23 U.S.C. 327(j)(1).

Notice of Proposed Rulemaking (NPRM)

On September 28, 2017, the Agencies published their NPRM at 82 FR 45220. In the NPRM, the Agencies proposed regulations to implement the Pilot Program and its application and stringency requirements, and proposed amending the corrective action period that the Agencies must provide to a State participating in the Section 327 Program.

The public comment period closed on November 27, 2017. The Agencies considered all comments received when adopting this final rule.

Summary of Comments and Responses

The Agencies received 18 comment letters in response to the NRPM from the following groups or individuals: 1 private citizen, 4 surface transportation industry interest groups (the American Association of State Highway and Transportation Officials, the American Road and Transportation Builders Association, the Association of American Railroads, and the Associated General Contractors of America), 1 regional transportation agency (the Transportation Corridor Agencies), 2 States (California Department of Transportation and Maryland State Highway Administration (MD SHA)), 1 public transportation agency (the San Francisco Municipal Transportation Agency), 14 public interest groups (the Southern Environmental Law Center, the Natural Resources Defense Council, Earthjustice, WE ACT for Environmental Justice, Earthworks, Environmental Law & Policy Center, Waterkeeper Alliance, Western Watersheds Project Wilderness Workshop, Wyoming Outdoor Council, Center for Biological Diversity, Klamath Forest Alliance, Save EPA, Environmental Protection Information Center, and the Defenders of Wildlife), 2 resource/regulatory agencies (the Arizona Fish and Game Department and the Department of the Interior), 1 port authority (Port of Long Beach), 1 railroad company (Modesto and Empire Traction Company), 3 local governments (Orange County Public Works, Orange County Transportation Authority, and the Contra Costa Transportation Authority), and 1 anonymous commenter.

The majority of comments addressed several common issues. The following section-by-section discussion of changes identifies and addresses the significant comments received. The Agencies responded to all comments except those related to § 779.109. CEQ responded to the comments related to § 779.109 because that section addresses CEQ's mandate to develop the criteria necessary to determine whether State laws and regulations are at least as stringent as the applicable Federal law.

Discussion of Comments Received to the NPRM

Section-by-Section Discussion of Changes

Section 778.101—Purpose

An anonymous commenter noted there is no discussion on the purpose of the Pilot Program. The commenter recommended that additional information be added to 23 CFR 778.101 entitled ''Purpose.'' The Agencies decline to make the proposed change. The statute sets forth the purpose in section 1309(a) and requires the Secretary to establish the Pilot Program; therefore, the Agencies have determined a separate purpose section in the regulations is unnecessary. However, for clarity, the background section of the preamble for this final rule explains the Pilot Program's basic purpose and history.

Section 778.103—Eligibility and Certain Limitations

One public transportation agency expressed reservations about a State transportation agency having the lead role in the environmental review and approval process, including oversight. Specifically, the commenter noted that federally funded transit projects located outside State rights-of-way do not fall within the State departments of transportation (State DOT) jurisdiction, so the proposed rules could place responsibility for environmental compliance on an agency that would not otherwise have a role in developing or approving a proposed project. The commenter suggested that additional coordination and review periods would lengthen the overall time and cost to complete the Federal NEPA process for transit projects. The public transportation agency also noted that, in certain States, individual jurisdictions, not State DOTs, may implement the State's environmental laws. Under that process, the State's only involvement in the environmental review of local projects would take place when there is a pass-through of FHWA funds, or when there is an affected State-owned facility or right-of-way. The public transportation agency expressed concern that adding another reviewer to the process would add new coordination requirements, leading to a lengthened documentation schedule.

The Pilot Program, as authorized by Congress, allows a State—not local agencies or jurisdictions—to substitute an alternative environmental review and approval process for NEPA. However, in some situations a State may exercise authority under the Pilot Program on behalf of a local government pursuant to 23 U.S.C. 330(h). Consistent with § 778.107(h), a local government must request that the State exercise authority under the Pilot Program for the local government's locally administered projects. If a local government does not submit such a request, NEPA, not the State's alternative environmental review and approval process, would apply to such projects.

In addition, the Agencies anticipate learning whether implementation of the Pilot Program has resulted in more efficient review of projects and identifying any recommendations for modifications to the program.

A surface transportation industry interest group commented that in implementing the Pilot Program, the Agencies should be mindful that the Pilot Program's purpose is to reduce delay in the environmental review process. The commenter suggested that, in determining which States participate in the Pilot Program, the Agencies should consider whether a State's participation will improve the efficiency of the environmental review and approval process. In addition, the commenter suggested that, if applying a

State environmental review process would add time or complication to the review, NEPA should apply instead.

The Agencies decline to make the proposed change. The criteria for a State to receive approval to participate in the Pilot Program is established in 23 U.S.C. 330(d). The Agencies have determined that the statute does not permit the Agencies to consider a State's demonstrated ability to reduce delays in the environmental review process as part of the application approval. However, the Agencies expect a State would consider whether the Pilot Program would lead to more efficient environmental reviews when deciding whether to submit an application.

One surface transportation industry interest group proposed language that would exclude FRA or railroad projects from the Pilot Program. The surface transportation industry interest group argued that the Interstate Commerce Commission Termination Act of 1994 (ICCTA), 49 U.S.C. 10501(b), establishes a broad preemption standard preventing the application of State and local laws to rail operations.

The Agencies decline to make the proposed change. While in certain circumstances, ICCTA may preempt the application of State law under the Pilot Program, the Agencies do not believe it would do so in every case. Railroad projects are potentially eligible to participate in the Pilot Program and excluding them would be inconsistent with the statute. Prior to executing a written agreement under § 778.111(d), the applicable Agency will conduct a fact-specific review to determine the appropriateness of applying State law to a railroad project or class of railroad projects. The review will be based on the information the State submits with its application and the consideration of the law(s) a State identifies pursuant to § 778.105(b), as they may relate to ICCTA preemption. In making this determination, the applicable Agency may consult with the Surface Transportation Board. The Agencies will memorialize the types of projects to which State law will be applied in the written agreement.

A railroad company raised a similar concern and asked the Agencies to clarify that the Pilot Program would apply only to projects requiring both State and Federal environmental review, and that it would not apply to projects that are subject to Federal environmental review only. In such cases, the commenter suggests that a Federal lead Agency would be responsible for the environmental review, applying Federal law.

Similar to the Section 327 program, the Pilot Program would apply to those actions where the State's approval would normally require a Federal environmental review by one of the Agencies in the event the State was not participating in the Pilot Program. The statute does not limit the application to only those instances where both a State and Federal environmental review are required. Therefore, the Pilot Program would apply when an approval would require both a State and a Federal environmental review, as well as in cases only requiring Federal environmental review. The key question is whether the project or class of projects is within the scope of the application and the final written agreement.

A railroad company commented that the State of California would not be well-suited for the Pilot Program and further suggested that if California applies and is approved to participate in the Pilot Program, then freight rail infrastructure projects in California should be excluded.

The Agencies note that 23 U.S.C. 330 does not give the Agencies discretion to preemptively exclude a State from participation in the Pilot Program. The Agencies will make determinations on a State's participation in the Pilot Program only after receiving an application and following the process described in 23 U.S.C. 330 and 23 CFR 778.107.

Two commenters suggested that the Agencies create an ''opt-out'' provision. First, a railroad company suggested that a project proponent should be able to opt out of the Pilot Program at its discretion. Second, a public transportation agency suggested that local agencies should be allowed to opt out of the Pilot Program on a project-by-project basis in instances where participation in the Pilot Program would hinder, rather than streamline, the environmental review process.

Due to logistical and administrative complications for the approving Agency and the participating State (*e.g.,* managing, tracking, or auditing the Pilot Program, as appropriate), the Agencies decline to create an opt-out provision for project proponents or local agencies in the Pilot Program. Project sponsors concerned with how the Pilot Program would apply to their projects should coordinate with the State during the development of the application to ensure their concerns are addressed. With respect to the local agencies, the Agencies have modified § 778.107(h) by adding a new paragraph to require the State to provide the Agency with a copy of the local government's written request for the State to apply the approved alternative review and approval procedures to a locally administered project. This new prerequisite would eliminate the possibility that a State could apply the Pilot Program to a project or projects over the objections of the local agency.

In addition, the Agencies note that 23 U.S.C. 330(f) gives a State participating in the Pilot Program the discretion to apply NEPA instead of the State's alternative environmental review and approval procedures. How a State would communicate such a decision to the Agency and complete the environmental review would be further defined in the written agreement between the State and the approving Agency.

A State suggested the Agencies should use the term ''existing'' rather than ''alternative'' when describing the State's environmental review process. The commenter suggested that the Agencies assume that States applying for the Pilot Program have existing environmental review and approval procedures that will be used to substitute for the Federal NEPA process.

The Agencies decline to make the suggested change. The term ''alternative'' is consistent with the statutory language in 23 U.S.C. 330(a)(3). As described in statute, the term ''alternative environmental review and approval procedures'' means substitution of one or more State environmental laws and substitution of one or more State environmental regulations. The Agencies have modified § 778.103(a)(4) to use the term ''alternative'' rather than ''equivalent'' for consistency.

A State suggested clarifying the two limitations in § 778.103(b) to eliminate redundancy because the limitations in paragraphs (b)(1) and (b)(2) are the same. The Agencies disagree the limitations are the same and, therefore, decline to make the suggested changes. The two limitations in § 778.103(b) distinguish the conditions governing a State's participation in the Pilot Program. The limitation in paragraph (b)(1) identifies which Federal laws the State's alternative environmental review and approval procedures may substitute, whereas paragraph (b)(2) states that such procedures may not substitute for other Federal environmental laws. However, the Agencies have added a clause to (b)(2) to provide additional clarity.

One public transportation agency requested the Agencies clarify and expand the phrase ''related regulations and Executive orders'' used in § 778.103(b)(1)(iii). The Agencies

decline to provide an exhaustive list in the Pilot Program regulation since regulations and executive orders change over time. During the negotiation of the written agreement, the approving Agency will identify which executive orders are related and applicable at that time and will provide for changes in law, including by regulation or executive order.

One local government suggested that the regulation should address how the Agencies would treat (1) environmental documents started before a State participates in the Pilot Program and (2) environmental documents started during a State's participation in the Pilot Program but not completed prior to the termination of the written agreement. The Agencies intend to address those scenarios in the written agreements between the approving Agency and the State, similar to how these situations are treated under the existing Section 327 program. This approach allows for the desired flexibility.

Section 778.105—Application Requirements for Participation in the Program

A local government suggested that the regulation address whether each State that has already assumed the responsibilities under the existing Section 327 Program would have to go through an application process under this Pilot Program. The commenter further suggested that, if a separate application process is required, the regulation should clarify how this process would be undertaken and whether States would still be able to process documents under their existing Section 327 Program agreements while applying to participate in the Pilot Program.

Pursuant to 23 U.S.C. 330(a)(1) and § 778.103(a)(3), the State must already be a participant in the Section 327 Program to participate in the Pilot Program. To participate in the Pilot Program, a State must go through a separate application process, as described in §§ 778.105 and 778.107. Although the Pilot Program is intended to build on the established responsibility assumed by the State under the Section 327 Program, the programs are different and have separate application and participation requirements.

With respect to how a State should process documents during the Pilot Program application process, the Agencies expect the State will continue to follow the requirements of its executed Section 327 Program agreement. In addition, the Section 327 Program allows a State to take on broader environmental review responsibilities than can be substituted under the Pilot Program. Therefore, it is likely the State will retain some responsibilities to conduct Federal environmental reviews under the Section 327 Program, where such reviews cannot be substituted by the State's alternative environmental review and approval process under the Pilot Program.

Two surface transportation industry interest groups noted the proposed application requirements call for the applicant to provide a ''detailed explanation of how the State environmental law and regulation intended to substitute for a Federal environmental requirement is at least as stringent as the Federal requirement'' (§ 778.105(b)(4)). The commenters noted that wording in the NPRM implies that the State must separately demonstrate consistency with each Federal requirement. In addition, the commenters noted that it is more practical and consistent with the way the stringency criteria are defined to allow the application to address consistency with the Federal NEPA process and 23 U.S.C. 139 requirements together by addressing each of the stringency criteria listed in the regulations.

The commenters are correct that the application should address the criteria for determining stringency set forth in § 778.109 as part of the application requirements in § 778.105(b)(4). The States should include an explanation of how the State environmental law or regulation satisfies each of the stringency criteria in § 778.109. It is the Agencies' expectation that the application will identify how the State law or regulation meets the criteria; however, the Agencies do not expect that the State law or regulation will have to follow all of the CEQ regulations implementing the NEPA standards associated with the criteria. As an example, the explanation could be in the form of a side-by-side comparison or walk-through of the stringency requirements and the appropriate State laws and regulations that meet the requirements. However, a State could address the application requirement in § 778.105(b)(4) in a different manner if the application demonstrates how the requirement is met. The Agencies expect there will be differences on each specific detail of the various criteria, and the application process will facilitate a discussion with the respective States on the specific areas to ensure adequacy.

A State commented that the term ''classes'' in § 778.105(b)(5) needs to be better defined. The State recommended using the terms ''actions'' or ''class of actions.'' The Agencies decline to make the suggested changes because the term ''classes of projects'' is the statutory term. Further, the terms ''actions'' and ''class of actions'' have different meanings under 23 U.S.C. 139. With respect to how the Agencies will apply the term ''class of projects,'' the Agencies intend to be consistent with the Section 327 Program, which uses the same term. As defined in 23 CFR part 773, a class of projects ''means either a defined group of projects or all projects to which Federal environmental laws apply.'' For purposes of the Pilot Program, ''class of projects'' would be defined as ''either a defined group of projects or all projects to which NEPA, the procedures governing the implementation of NEPA and related procedural laws under the authority of the Secretary, including 23 U.S.C. 109 and 139, and related regulations and Executive orders would apply.'' This definition has been added to § 778.105(b)(5) to provide clarity.

One public interest group noted that, in numerous places, the proposed rule requires that the participating State's Attorney General certify that the State has certain laws in place. The commenter recommended that, in each instance, the regulation should require identification of the State law(s) that form the basis for the certification. The Agencies decline the recommendation because the Agencies intend to be consistent with the requirements in the Section 327 Program, which does not require a similar identification (see 23 CFR 773.109(a)(7)). Furthermore, no issues have arisen with the State certification process under the Section 327 Program.

One regional transportation agency noted that, according to proposed § 778.105(b)(9)(B), the State must consent to exclusive Federal court jurisdiction for the compliance, discharge, and enforcement of any responsibility under the Pilot Program. The commenter requested that the Agencies clarify that any such lawsuit would need to be brought in Federal court for Federal court jurisdiction to apply and that a lawsuit brought in State court against the State environmental document would remain in State court.

As described in the NPRM preamble, 23 U.S.C. 330(e)(1) provides Federal district courts with exclusive jurisdiction over a State's compliance, discharge, and enforcement of any responsibility under the Pilot Program.

Section 778.105(b)(9)(B) sets forth the application requirements for the Pilot Program with respect to waiver of sovereignty immunity.

One public interest group expressed support for the requirement that States must consent to the jurisdiction of the Federal courts to be eligible to participate in the Pilot Program. However, it recommended that the Agencies require that a State have laws with a standard of review at least as stringent as the Administrative Procedure Act (APA). In the alternative, if States do not have a State law as stringent as the APA, the commenter suggested that the Agencies require the State to expressly submit to the jurisdiction of the APA for judicial review. The public interest group also suggested that the Agencies clarify which laws and standards will govern the review of the State laws substituting for the NEPA process. Specifically, the commenter sought clarification on the standards for determining standing and the applicability of arbitration.

The Agencies agree that decisions under State law must be reviewable. To address the commenter's concerns, the Agencies add a new application requirement in § 778.105(b)(9)(D) requiring a State to identify the jurisdictional requirements and standard of review that will be applicable to judicial review of decisions under the environmental laws proposed for substitution under the Pilot Program. The Agencies expect the information a State provides in response to this requirement will address the commenter's concern about identifying the applicable standards and requirements under the State's laws.

One public interest group commented that the proposed language does not clearly require that a State waive its sovereign immunity before participating in the Pilot Program. The commenter recommended that the Agencies require a State to expressly waive immunity under each State law that would substitute for the Federal NEPA process. The commenter further suggested that, in some circumstances, the waiver of sovereign immunity should apply to the State's equivalent of the APA, which ''creates the basis for the cause of action.'' Similarly, 13 public interest groups commented that the rule should clarify that the right to judicial review remains when a State has assumed the responsibilities of the Secretary.

An interested State must waive its sovereign immunity under the U.S. Constitution's 11th Amendment to the extent needed to accept the jurisdiction of the Federal courts for the compliance, discharge, and enforcement of the environmental review responsibilities under the Pilot Program. A State's consent to accept the exclusive jurisdiction of the Federal courts for compliance, discharge, and enforcement of any responsibility, as required under the Pilot Program, is the functional equivalent of the State's waiver of the State's sovereign immunity. The Agencies revised § 778.103(a)(2) to clarify that a waiver of sovereign immunity is necessary to participate in this Pilot Program. The Agencies also revised § 778.105(b)(9)(B) to ensure the State includes documentation regarding the waiver of sovereign immunity as part of its application for the Pilot Program. This sovereign immunity waiver is a significant precondition for the State's participation that may require State legislative action (in some States gubernatorial action may be sufficient).

A public interest group stated that it is important the Agencies ensure a State has a law similar to the Equal Access to Justice Act. The Agencies lack the authority under Section 1309 to require a State to have a law similar to the Equal Access to Justice Act. The Pilot Program covers the substitution of the procedures governing the implementation of NEPA and related procedural laws under the authority of the Secretary, including 23 U.S.C. 109 and 139, and NEPA-related regulations and executive orders. It also identifies other laws a State must have in place—for example, a law comparable to the Freedom of Information Act (FOIA). However, since the statute does not require the State to have a law similar to the Equal Access to Justice Act, the Agencies cannot impose this requirement in a rulemaking as a condition of a State's participation in the Pilot Program.

One State DOT asked whether a State must provide a separate consent to Federal court jurisdiction in order to participate in this Pilot Program where the State has already given such consent pursuant to the Section 327 Program. The Agencies clarify that the certification and explanation required under § 778.105(b)(9) must be met separately for participation in the Pilot Program, *i.e.,* the certification and explanation must be included in a State's application to participate in the Pilot Program. The Agencies acknowledge that several States have provided this certification and explanation with applications to assume responsibilities under the Section 327 Program; however, the Agencies require the inclusion of this certification and explanation in a State's application for this Pilot Program to facilitate the approving Agency's review of a complete application package.

One public interest group supports the requirement that an interested State must demonstrate that it has a State public records law comparable to FOIA. However, the commenter suggested that the word ''comparable'' is ambiguous and suggested that the Agencies instead consider using the phrase ''at least as stringent as the Freedom of Information Act (FOIA).'' The commenter also recommended that any decision made under the State public records law must be reviewable in court. Additionally, the commenter recommended that, when evaluating a State's public records law, the Agencies ensure that the law includes a fee waiver provision, a requirement that the State respond to a request for records within a specific time frame that is no less than the Federal 20-day obligation, and a requirement that each participating State certify that it has sufficient resources to comply with the provisions of its State public records law.

The Agencies disagree with the commenter's proposal to require States to have laws (and regulations) in effect that are at least as stringent as FOIA and decline to adopt the three suggested requirements. Under 23 U.S.C. 330(d)(1)(D)(iii)(III)(bb), the Secretary must approve a State's application to participate in the Pilot Program if the State executed an agreement with the Secretary in which the State, among other requirements, ''certifies that State laws (including regulations) are in effect that . . . are comparable to [FOIA]. . . .'' This certification is consistent with that required by the Section 327 program (23 CFR 773.106(b)(7)). The statutory language does not establish factors to assess comparability. However, the Agencies have added an additional stringency requirement in § 778.109 that applicable State law must provide for public access to the documentation necessary to review the potential impacts of projects.

One resource/regulatory agency commented that there is no mention of how the States will coordinate with other agencies during environmental reviews. The resource/regulatory agency recommended that State wildlife agencies be identified as cooperating agencies based on their regulatory authority and special expertise for wildlife and wildlife resources for high-level NEPA analyses. The Agencies considered the comment, but decline to make the recommended change because the identification of cooperating agencies is a project-specific determination and not appropriate in this rulemaking. However, the Agencies

note that the stringency criteria in § 778.109 address the need for coordination with other agencies, including those that have jurisdiction by law or special expertise.

The resource/regulatory agency also noted that full public disclosure of impacts is a key component of NEPA and recommended that States be required to analyze impacts to all resources required under NEPA. Public disclosure and analysis of impacts to affected resources is considered as part of the evaluation of whether a State law or regulation is as stringent as NEPA (*see* §§ 778.109(f)–(i)).

The same resource/regulatory agency recommends revising the requirements to direct that environmental review and analyses be documented in one all-encompassing report in accordance with NEPA standards. The CEQ regulations implementing NEPA (40 CFR parts 1500–1508) encourage the concurrent preparation and integration of the Federal NEPA process with other environmental impact analyses and surveys and studies required by other Federal laws. The CEQ regulations also encourage combining documents and processes to eliminate duplication and reduce paperwork (*see* 40 CFR 1506.2 and 1506.4). However, these are best practices allowed under the CEQ regulations and are appropriately addressed in State applications. The Agencies, therefore, decline to make the commenter's recommended change.

Section 778.107—Application Review and Approval

A regional transportation agency and a port authority suggest the Agencies consider streamlining the application and approval process by eliminating the separate requirements for a State to seek public comment on its application before submittal to the Agencies and for the Agencies to seek public comment before approving or disapproving an application. Instead, the commenters suggest requiring a State and the Agencies to seek one set of public comments. Similarly, one State questioned the need for two public comment periods, noting that § 778.105(b)(7) requires that the State seek public input on the application prior to submitting it to the approving Agency.

The Agencies decline to make the suggested change. Two public comment periods are required by 23 U.S.C. 330. As reflected in § 778.105(b)(7), 23 U.S.C. 330(b)(7) requires that the application include evidence that the State sought and addressed public comments on its application. Additionally, as reflected in § 778.107(a), 23 U.S.C. 330(c)(1) and (d)(1)(A)–(B) require the Secretary to accept and consider public comments on applications submitted. These requirements are separate; the pre-submission comment period provides the public an opportunity to inform the State's application, while the post-submission comment period provides the public an opportunity to inform the approving Agency's consideration of the application and the terms of the agreement with the State. Additionally, the second opportunity for public comment ensures transparency during the approval process.

A regional transportation agency and a port authority recommended that the regulations require an approving Agency to approve the application within 60 days instead of 120 days. The Agencies decline the suggested change because the timeframe in § 778.107(b) is prescribed in the statute. Under 23 U.S.C. 330(c)(2), the Secretary must approve or disapprove an application not later than 120 days after the date of receipt of an application that the Secretary determines is complete.

A State commented that the requirement that a written agreement be made between the Governor or Senior Transportation Official and the approving Agency prior to approval of the application appears to be out of sequence. The State commented that the Agency should approve the application before the written agreement between the State and the approving Agency is finalized. The State also expressed confusion with the assertion in § 778.107(f) that the approving Agency's execution of the agreement will constitute approval of the application and the assertion in § 778.111(b) that, after making a decision on an application, the approving Agency must transmit the decision in writing to the State with a statement explaining the decision.

The Agencies decline the commenter's recommendation to approve the application prior to finalizing the written agreement. Section 330(d) of Title 23, U.S.C., authorizes approval of an application only if the State has executed an agreement with the approving Agency that memorializes the State's responsibilities under the Pilot Program. The Agencies interpret this provision to require States to sign a written agreement prepared by the approving Agency during the approving Agency's application review process to demonstrate the State's ability to comply with all Pilot Program requirements. The approving Agency will sign and execute the agreement after the State, and only when it has determined approval of the State's application is appropriate. The Agencies clarify the approving Agency's signature on and execution of the agreement constitutes approval of a State's application. The approving Agency's transmittal of the agreement with the approving Agency's signature will serve as the notice of approval required under 23 U.S.C. 330(c). For clarity, the Agencies modify the text of § 778.107(f).

In a joint letter, 13 public interest groups recommended changes to clarify the role of the Agencies in the review and approval of a State's application to the Pilot Program. The commenters noted concerns about the lack of a requirement for the Agencies to respond to comments received during the public comment period following the State's submission of an application. In addition, they noted concerns about the public's ability to participate in the project-specific review and comment process once State environmental laws and regulations are substituted for the NEPA process under the Pilot Program.

The Agencies read the statute to require the Agency receiving an application to accept and consider public comments on a State's application, but the statute does not require the Agencies to respond to these public comments. The Agencies will seek and consider public comments before taking action on a State's application, consistent with how the Agencies seek and consider public comments under the Section 327 Program, and the written agreement approving a State's participation in the Pilot Program will address, as appropriate, these comments. In addition, the Agencies confirm that the public will retain the same ability to review and comment on projects as currently provided under the NEPA process per § 778.109(i). Under the Section 327 Program, a State that assumes responsibility must meet the same procedural and substantive requirements as if the responsibility was carried out by the Secretary. Any environmental documentation developed under State environmental laws and regulations under this Pilot Program would still be required to comply with the notification, publication, and comment procedures as would be required under NEPA.

The public interest groups also suggested that the final rule should require the Agencies to publish approval of the State's application and a copy of the executed agreement in the **Federal Register** and clarify that such approval is a final Agency action subject to judicial review under the APA. The Agencies intend to approve applications

for participation in the Pilot Program in a manner consistent with that used by the Section 327 Program (*see* 23 U.S.C. 327(b)(3)), which includes providing public notice as required by 23 U.S.C. 330(c)(1).

Section 778.109—Criteria for Determining Stringency

A State commented that the § 778.109 requirements ''are overly detailed and may prohibit States from participating'' in the Pilot Program. Rather than detailing an exhaustive list of separate requirements, the State suggested that the State law be evaluated for equivalency to the NEPA process as a whole, with provisions included in the NPRM to address shortcomings or deficiencies, should any be identified. The State indicated that most of such issues could be easily addressed through the written agreement. Similarly, two surface transportation industry interest groups expressed concern that the requirement to satisfy 14 distinct criteria as a ''minimum'' requirement could end up disqualifying States from participating in the Pilot Program even when the State law is ''equally as stringent or more stringent than NEPA overall.'' They commented that even a State law with extremely stringent requirements, such as the California Environmental Quality Act (CEQA), may require a lower level of detail than NEPA in some specific areas. These commenters cited CEQ's handbook on NEPA–CEQA integration where it points out that the alternative analysis and cumulative impact analysis under NEPA may need more detail than in the CEQA process. The surface transportation industry interest groups recommended that the final rule include language stating that the Agencies will base the stringency determination on an assessment of the State law as a whole, so that minor differences in the level of detail required on specific issues do not prevent the stringency requirement from being met.

Section 1309(c)(2)(A) of the FAST Act requires CEQ to develop the criteria the Secretary will use to determine whether the State law or regulation is at least as stringent as the Federal requirements. At a minimum, the criteria for determining stringency must provide for protection of the environment, provide opportunity for public participation and comment, allow access to the documentation necessary to review the potential impacts of projects, and ensure consistency of review of projects. A broad criterion based on an assessment of the State law as a whole would fail to establish an objective way to compare the State and Federal requirements. For example, the State commenters point to CEQA as an example of a statute that is more stringent than NEPA, but did not explain how they arrived at this conclusion. In the absence of specific criteria to make a comparison, a similar conclusory statement could be said for many, if not all, of the other State laws or regulations that are comparable to NEPA.

The Agencies clarify the expectations with regards to policies and guidance developed for NEPA for each of these criteria. The CEQ analyzed NEPA, the Regulations for Implementing the Procedural Provisions of NEPA, and 23 U.S.C. 139 to determine the core elements that would ensure protection of the environment and consistency of review. The CEQ also took into account the existing State laws and regulations that are comparable to the NEPA process. A State law or regulation that meets each of the listed general criterion would meet the stringency required by the statute. The State law or regulation would meet the test if the statutory text, implementing regulations, policies, or guidance address each general criterion in § 778.109. The State law or regulation does not have to adopt or follow the Federal guidance, policy, and interpretation used for implementing the standard under NEPA. For example, the alternatives analysis criterion (§ 778.109(e)) would be met if the State law or regulation requires alternatives evaluation consistent with the criterion, but would not need to follow the CEQ guidance and interpretation on alternatives for NEPA such as those available in the 40 Most Asked Questions (46 FR 18026 (March 23, 1981)) or based on NEPA case law. The same approach would follow for cumulative effects consideration. The Agencies do not require the State to follow CEQ guidance on cumulative effects analyses that is applicable to NEPA reviews, nor do they expect the cumulative effects case law under NEPA to apply to the State law or regulation implementation of its cumulative effects analysis expectations.

Proposed Rule § 778.109(a)

A public interest group expressed concerns that subsection (a) of the stringency criteria requires States to ''define the types of actions that normally require an environmental impact statement.'' By using the term ''environmental impact statement,'' a term of art under NEPA, the commenter asserts it is unclear whether the rule is requiring States to define what types of projects would be subject to NEPA review overall, or which projects would rise to the level of impact necessitating an environmental impact statement (EIS) rather than an environmental assessment (EA) or categorical exclusion (CE). The commenter recommended the rule make clear that States must first define the types of actions that are subject to NEPA review and then specify the level of documentation that will be required for different categories of projects.

The Agencies, revised the language for additional clarity. Section 778.109(a) does not address the various levels of environmental impact evaluations or documentation that may be acceptable for particular types of projects. Proposed section 778.109(a) did not use the NEPA-specific term ''environmental impact statement'' to refer to the various types of environmental evaluations and documents required and produced under different State laws and regulations. The Agencies expect the State laws or regulations to be substituted for NEPA to establish which actions trigger environmental review. Actions requiring environmental review should include government-sponsored actions, including those receiving Federal financial assistance or permits. The classification of the appropriate environmental impact evaluations or documentation required for particular types of projects is addressed as part of § 778.109(b).

Proposed Rule § 778.109(b)

A public interest group recommended amending the last sentence in § 778.109(b) by changing the word ''should'' to ''must'' to ensure that scoping for actions that may result in significant impacts on the human environment is guaranteed to be an ''open and public process.'' The commenter also suggested the rule require participating States to provide public notification and public involvement, to the extent practicable, during the scoping process for State environmental reviews equivalent to EAs.

The Agencies agree to change ''should'' to ''must'' in the last sentence of § 778.109(b) to mirror the CEQ regulations scoping requirements for actions with potential significant impacts. The Agencies decline to require the State to provide public notification and public involvement during the scoping process for State environmental reviews equivalent to EAs. The CEQ regulations do not include similar requirements for EAs.

Proposed Rule § 778.109(d)

A public interest group commended the effort in § 778.109(d) to ensure a participating State's objective analysis

by preventing conflicts of interest from affecting environmental reviews and by requiring States to certify all environmental reviews performed and compiled for a project analysis. The commenter recommended the Agencies further safeguard against State reliance on substandard work from outside contractors by requiring States to ensure the ''professional integrity,'' including ''scientific integrity,'' of the discussions and analyses in environmental evaluations and documents and to document the methodologies used, as required under 40 CFR 1502.24 (these requirements are now set forth in 40 CFR 1502.23). The Agencies agree States participating in the Pilot Program should be required to comply with the intent of 40 CFR 1502.23 to protect the scientific integrity of environmental analyses and methodologies. Accordingly, the Agencies are adding language to paragraph (f) to address this comment.

Proposed Rule § 778.109(e)

A public interest group commented that, although § 778.109(e) properly tailors the evaluation of reasonable alternatives to a proposed action's purpose and need, it does not ensure that the purpose and need for a project will be defined reasonably—a key first step in the NEPA process. To ensure that environmental reviews under State programs are not rendered meaningless by purpose and need statements drawn so narrowly that the proposed project is a foregone conclusion, or so broadly to be meaningless, the public interest group recommended the Agencies revise the rule to clarify that the same rule of reason applies to the definition of purpose and need and selection of a range of alternatives under State programs. The commenter also asserted it is essential that any State program include a requirement similar to CEQ's regulations that mandate a brief discussion of the reasons for eliminating any alternatives not explored in detail in an environmental review document. The commenter stressed that only through this procedure will the public be able to determine if a ''reasonable range'' of alternatives has been considered.

The Agencies decline to make changes because the Agencies believe the existing language adequately addresses the commenter's concern.

Proposed Rule § 778.109(f)

A public interest group commented that § 778.109(f) suggests that an assessment of reasonably foreseeable direct, indirect, and cumulative impacts of a proposed action (and any reasonable alternatives) should be compared with ''existing environmental conditions.'' The commenter noted that courts have been clear that the environmental effects of the proposed action and alternative solutions should not be compared with existing environmental conditions, but rather with the ''baseline'' or ''no action'' condition described in 40 CFR 1502.14(d) (now set out at 40 CFR 1502.14(c)). The public interest group added that the proposed rule, therefore, requires further clarification, noting that where § 778.109(e) does describe the baseline ''no action'' alternative as essential to NEPA compliance, the introduction in § 778.109(f) of a comparison with ''existing environmental conditions'' could result in considerable confusion and departure from the legal requirements of NEPA. While initially a ''no action'' alternative may be the same as ''existing conditions,'' the future analysis that NEPA requires will likely require the projection of a future ''no action'' baseline that is distinct from ''existing conditions.'' The public interest group suggested that the rule be rewritten to clarify that the necessary comparison is to the ''no action'' alternative.

The Agencies agree with the public interest group comments that including in the criteria the need for comparison between the environmental impacts and existing environmental conditions was confusing. The Regulations for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500–1508) do not have this requirement; rather they require comparison among alternatives. Therefore, the Agencies revise § 778.109(f) to make this clarification.

Proposed Rule § 778.109(h)

A public interest group commended the mandate in § 778.109(h), which properly requires States to coordinate and consult with interested parties. However, the public interest group noted the words ''adequate'' and ''appropriate'' leave the proposed rule vague as to the degree of coordination and consultation required. The commenter recommended deleting both words. The Agencies believe that retaining ''adequate'' is warranted in this context. The need for and level of participation will depend on the type of analysis involved and the specific circumstances of the proposed project. Similarly, the Agencies believe that retaining ''appropriate'' is warranted because the review would not always require coordination with all the parties mentioned in the paragraph.

A public interest group expressed particular concern that Federal agencies should continue to fulfill the independent obligation to determine whether there is a Tribal interest in an undertaking and consult with Tribal authorities. The public interest group suggested that the regulation should make clear that participating States' obligations to consult with Tribal authorities are additional to the Federal obligation to do so and that the efforts should be coordinated. Similarly, in a joint letter, 13 public interest groups recommended that the proposed rule should explicitly acknowledge the Federal obligation to consult with Tribes regardless of any delegation of other responsibilities to States.

The Agencies agree with the comments related to coordination and consultation with Tribes. The Federal Government's responsibility to engage in government-to-government consultation with Tribes is a requirement independent of NEPA and, therefore, it is not subject to assignment under the Pilot Program. It is also excluded from the Section 327 Program. States must coordinate with Tribes as part of their responsibilities to assess environmental impacts, but this should not be interpreted as assigning the Federal Government's unique responsibility to consult with Tribes when needed.

One resource/regulatory agency recommended that the term ''appropriate coordination and consultation'' in § 778.109(h) be strengthened to ensure that Federal agencies with jurisdiction by law or special expertise be invited as cooperating agencies to ensure that interagency consultation occurs early and throughout the environmental review process. The Agencies decline to make the recommended change. Requiring the establishment of cooperating agency relationships would be overly prescriptive. A State law or regulation may provide for establishing coordination relationships that are as equally effective as the concept of cooperating agency under the NEPA process.

In their joint letter, 13 public interest groups noted that Congress did not authorize delegation of the review responsibility of the Environmental Protection Agency (EPA). The public interest groups recommended that the final rule explicitly address the requirement that, if a State does not incorporate EPA's review into its NEPA process, the applicable Agency will have to do so before it can finalize project approval. The statue does not address the delegation of EPA's review responsibility and it would be inappropriate for the Agencies to

determine the limitations of another Federal Agency's authority. Therefore, the Agencies decline the commenters' proposed edit on this point.

Proposed Rule § 778.109(i)

A public interest group commented that § 778.109(i) requires that States ''provide an opportunity for public participation and comment that is commensurate with the significance of the proposal's impacts on the human environment.'' The public interest group commented that this statement is overly vague and suggested that the rule must establish the bare minimum required for public participation, namely: (1) The right to notice and comment on draft EISs; (2) the right to notice and comment on draft EAs where the proposed project is controversial or where mitigation is relied upon to avoid potential significant impacts; and (3) the right to view all environmental review documents prior to a decision being made, including those supporting the application of CEs. The commenter also suggested that the rule make clear that, beyond simply providing an opportunity for the public to comment, States will ''affirmatively solicit comments from persons or organizations who may be interested or affected.'' The commenter recommended that the proposed rule refer States to the 2016 report of the Federal Interagency Working Group on Environmental Justice and its NEPA Committee titled, ''Promising Practices for Environmental Justice Methodologies in NEPA Reviews,'' and subsequent guidance from these bodies. The public interest group further noted that the rule should stress that a State's duty is not limited to allowing for public comment, but that it also encompasses a duty to carefully consider public comment and respond to all comments—including opposing viewpoints—in subsequent NEPA documents.

The Agencies decline to make the recommended changes. State law or regulations may create different categories of analysis that would not be the same as an EIS, EA, or CE. The criteria should be flexible enough to allow differences in the categorization of environmental analyses. The Agencies also do not find it necessary to require the same public comment standard as NEPA since the State law or regulations must have adequate public involvement procedures that are as equally effective and are consistent with State law.

In their joint letter, 13 public interest groups commented that the proposed rule should identify specific requirements for notice and comment that a State must provide to meet the guarantees of public participation currently provided by NEPA, including the right to notice and comment on draft EAs and draft EISs, and the right to all environmental review documents in time for non-expert members of the public to understand, assess, and provide informed comment on the decision being made.

The Agencies agree with the commenters that public participation procedures under NEPA are worth emulating. However, requiring that a State law or regulation adopt the same public requirements applicable to NEPA ignores the fact that States have their own public involvement procedures and applicable laws. The State law or regulation may have adequate public involvement procedures that are equally effective.

The public interest groups also requested that a State's use of CEs be limited to those established by Federal transportation agencies after public notice and comment. The Agencies decline this request. If the States in the Pilot Program choose to propose and develop additional categories of projects to exclude from detailed environmental analysis under the applicable State law, that process would be handled consistent with the State's legal authority that was determined to be as stringent as NEPA. Once a State is in the Pilot Program, it would no longer apply Agencies' CEs.

Proposed Rule § 778.109(j)

In their joint letter, 13 public interest groups noted that, under existing law, other Federal agencies can refer environmental reviews to CEQ (see 40 CFR 1504.3). The public interest groups commented that the final rule should also address the requirement that, if a Federal agency refers concerns about a proposed project to CEQ, CEQ must resolve those concerns before the project is approved. The Agencies agree that a referral process should be part of the stringency criteria and revise the regulation in § 778.109(j) to add a referral process. However, the Agencies believe that requiring the same referral process as required for the Federal NEPA process would be overly prescriptive. A State law or regulation may provide for a referral process that is as equally effective as the referral process under 40 CFR part 1504.

Proposed Rule § 778.109(l)

A public interest group noted the rule should make clear that supplemental environmental documents must be ''prepared and circulated in a similar fashion'' to the original environmental documents. The Agencies believe that this proposed change would be overly restrictive. Requiring that a State law or regulation adopt the same circulation requirement applicable to NEPA ignores the fact that States have their own public involvement procedures and applicable laws. The State law or regulation may have adequate public involvement procedures that are equally effective. Although the Agencies are not making changes in response to the commenter, the Agencies intend to consider each State application's treatment of this issue by evaluating the alternative environmental review and approval procedures that States propose in their applications to the Pilot Program and through the review process established in § 778.111.

Proposed Rule § 778.109(m)

A public interest group noted that § 778.109(m) risks seriously undermining the effectiveness of the proposed rule because it requires procedures to ''facilitate process efficiency'' without requiring that any such abbreviated procedures be at least as protective as their Federal equivalents. The public interest group commented that this subsection has the potential to become a large loophole for a State inclined to avoid environmental reviews by, for example, designating excessively large categories of actions exempt, conducting overly broad programmatic reviews, or similar actions. The commenter suggested that § 778.109(m) should be removed entirely, or at least any requirement to adopt abbreviated procedures should be separated from the stringency analysis. Beyond that, the commenter recommended the rule should make clear that any procedures set in place to ''facilitate process efficiency'' must be at least as stringent as their Federal equivalents.

The Agencies decline to make the proposed changes. The Agencies and CEQ have pursued measures to make the process more efficient, starting with Executive Order 11514 onward to the latest efforts captured in Executive Order 13807, as well as regulations implementing the Moving Ahead for Progress in the 21st Century Act (MAP–21) and the FAST Act. The public comment process on State guidance and procedures, along with judicial review, provide the appropriate check on attempts to avoid compliance with applicable environmental reviews. Furthermore, as part of ongoing monitoring, the Agencies maintain the opportunity to provide oversight of any updated State environmental review procedures.

Additional Requirements

In their joint letter, 13 public interest groups recommended that 2 additional elements that are part of the current NEPA process be added to what is required in a State submission: (1) A requirement that the State review address disproportionate impacts on low-income and minority populations, and (2) an enforceable requirement that, when avoiding potentially significant impacts, any mitigation measures identified in the State review be incorporated as conditions of approval in the Federal decision that the State review supports. Similarly, a public interest group commented that the rule should make clear that States have a responsibility to address disproportionate impacts on minority and low-income communities.

The Agencies decline to make the proposed changes. First, the Agencies acknowledge the commenter's concern regarding the consideration of disproportionate impacts on minority and low-income communities and note they must be evaluated as part of the environmental review process per Executive Order 12898. While this is a process typically integrated into the NEPA process, it is not one that may be substituted under this Pilot Program. However, State agencies continue to have this responsibility and must comply with the Federal standard. Second, allowing a project with potential significant impacts to proceed with an EA and a Finding of No Significant Impact instead of an EIS, if there are mitigation commitments that reduce the impacts below the threshold of significance, is a NEPA-specific concept. There may be some State laws or regulations that allow a similar process, but this would be subject to State law. The Agencies are not requiring the adoption of the same concepts of EIS, EA, and CE as in the NEPA process and, therefore, do not believe that there is a need to require this NEPA-specific concept from State law or regulations.

The public interest groups also requested clarification on the role of Federal agencies in project approval. The commenters noted that Congress provided States the opportunity to stand in the shoes of the Secretary for compliance with other Federal environmental laws as well as NEPA (23 U.S.C. 327(a)(2)(B)(i)). This could include, for example, the obligation to consult with U.S. Fish & Wildlife Service under the Endangered Species Act. It could also possibly include compliance with the National Historic Preservation Act. The project approval, however, remains with the Secretary. The commenters recommended that the proposed rule should explicitly state so to avoid any confusion.

The Agencies agree with the commenters regarding project approval, but do not find that any additional clarification is needed. The procedures for the Section 327 Program make clear that the only assignable responsibilities under the Section 327 Program are the environmental review responsibilities; project approvals are not authorized to be assigned under the Section 327 Program (see 23 CFR 773.105(b)(5)). With regard to the Pilot Program, §§ 778.101 and 778.103(b) make clear that the only requirements being substituted are those related to NEPA.

One local government recommended that the Pilot Program regulations include an allowance for granting environmental review exemptions for categories of projects that have been determined not to have a significant effect on the environment. The Agencies find that this suggestion is addressed in § 778.109(b) (classification of the appropriate assessment of environmental impacts) and § 778.109(m) (categories of action). However, the Agencies want to highlight that, as with a CE under NEPA, these are not exemptions from the applicability of the State law or regulation, but rather are situations where the analysis is more limited and where consideration of extraordinary circumstances evaluation is warranted.

Section 778.111—Review and Terminations

One local government suggested that the proposed rule should provide what the compliance and reporting measures would be for States participating in the Pilot Program. The Agencies acknowledge the comment and agree States participating in the Pilot Program should be informed about required compliance and reporting measures. The Agencies believe that the appropriate place to do this is the written agreement consistent with the Section 327 Program. In addition, the Agencies want to further clarify that the frequency of review of the State's performance in implementing the requirements of the Pilot Program will be determined as necessary by the approving Agency and included in the written agreement.

One public interest group noted concerns about the mechanisms for ensuring State compliance with the proposed review and the termination requirements, including the public's opportunity to provide input, and recommended many changes. The Agencies agree that monitoring and auditing each approved State's performance implementing the Pilot Program is critical to its success, and the Agencies possess the right and responsibility to terminate a State's participation in the Pilot Program early (see § 778.111(c)). The Agencies will provide the necessary compliance and reporting measures as part of the written agreement required between the approving Agency and the State.

In their joint letter, 13 public interest groups noted that the proposed rule fails to provide the public an opportunity to petition the Secretary to rescind approval for a State to participate in the Pilot Program, stating that such opportunity is a fundamental aspect of delegation of other authority to States to implement and enforce environmental laws. The Agencies determine that a public or formal petition process is not necessary or supported by statute. However, the public can submit concerns regarding a State's implementation of the Pilot Program to the Secretary at any time. In addition, the Agencies note that, under § 778.111(b), the Agencies must review each participating State's performance in implementing the requirements of the Pilot Program at least once every 5 years and must provide notice and an opportunity for public comment during that review.

Section 778.111—Review and Terminations

One State noted concerns with termination of the Pilot Program after 12 years of enactment of the FAST Act. Specifically, the commenter indicated participation in the Pilot Program would likely require it to revise its processes and procedures for completing applicable environmental review under existing regulations and, therefore, the definable and finite termination of the Pilot Program after 12 years under § 778.111 would place a burden on the State to revise its regulations again to account for Pilot Program termination. The commenter also noted termination of the Pilot Program after 12 years could confuse staff and resource agencies required to switch between legal standards. The Agencies acknowledge the concern; however, the termination provision is prescribed by the statute. Congress mandated in 23 U.S.C. 330(k) that the Pilot Program terminate 12 years after the date the FAST Act was signed into law. The Agencies have added a new section to address the termination of the Pilot Program and a sunset of the regulations absent Congressional action to extend the program.

Locally Administered Projects

A public transportation agency and a port authority requested that the Agencies clarify that States can change the local governments that participate in the Pilot Program, as needed, provided the total number of local governments participating at one time does not exceed 25. The Agencies decline to provide additional clarification in the regulation. Under § 778.107(h), a State is responsible for ensuring that the requirements of the approved alternative State procedures are met when applying the alternative procedures to locally administered projects. Procedures for identifying the local governments participating in the Pilot Program will be defined in the written agreement between the State and the approving Agency.

One State requested that the provision that limits the application to only 25 local government agencies be eliminated, noting that other State-administered Federal programs, such as the Recreational Trails Program, do not include this limitation. Section 778.107(h) is consistent with the statute. Accordingly, the Agencies decline the suggested change. The number of local governments participating in the Pilot Program is limited by 23 U.S.C. 330(h)(1), which specifies that a State with an approved Pilot Program, at the request of a local government, may exercise authority under that program for *up to* 25 local governments for locally administered programs.

One public interest group noted that the proposed rule provides little detail beyond the text of 23 U.S.C. 330(h) about how States and local governments might apply the alternative environmental review and approval procedures to locally administrated projects. The commenter noted the proposed rule does not describe or limit which projects or local governments may qualify for or be eligible to implement the State's alternative environmental review and approval procedures, nor does the proposed rule define ''locally administered project'' or ''local government.''

The Agencies decline to provide additional clarification of the terms ''locally administered project'' and ''local government'' in the regulation due to differing program definitions and requirements among the Agencies, but may define expectations regarding locally administered projects and local governments in the written agreement. Under the Pilot Program, the State is the responsible party that must meet the Pilot Program requirements. Any local governments participating in the Pilot Program may conduct the environmental analyses or reviews, but the State is responsible for ensuring that the requirements of the approved alternative State procedures are met for those projects (see § 778.107(h)).

A local government suggested that the Agencies consider requiring States to participate in the Pilot Program so that local agencies, which are responsible for delivering local transportation projects, can benefit from the Pilot Program. The commenter also noted that, if State participation in the Pilot Program is optional, local agencies should be given the opportunity to demonstrate their ability to participate in the Pilot Program. Similarly, another local government commented that the Pilot Program should provide administrative delegation of the proposed regulations to a local agency to further streamline the process and review of environmental documents.

The Agencies acknowledge the commenters' interest in the Pilot Program and concerns with the proposed rule. However, 23 U.S.C. 330(a) only allows, and does not require, States to participate in the Pilot Program. The scope of the Pilot Program in relation to locally administered projects is established by 23 U.S.C. 330(h). It provides that a State with an approved program, at the request of a local government, may exercise authority under that program on behalf of up to 25 local governments for locally administered projects and, for up to 25 local governments selected by a State participating in the Pilot Program, the State shall be responsible for ensuring compliance with Federal and State law and the Pilot Program.

Statutes of Limitations

Several commenters raised concerns with the statute of limitations in the proposed rule. A public transportation agency commented that the 2-year statute of limitations established under Section 1309 of the FAST Act is a deterrent to participation in the Pilot Program. A surface transportation industry interest group noted the statute of limitations for any claims challenging actions taken by a State under the Pilot Program is different from the 150-day period that otherwise would apply to claims challenging actions taken by State agencies approving a highway or transit project under the Section 327 Program. The surface transportation industry interest group commented that the disparity between these two statutes of limitations means that a lawsuit challenging a single State decision approving a highway or transit project could be subject to two different limitations periods; a 2-year period relative to a State's action under the State law substituted for NEPA, and a 150-day period relative to State's action under other Federal laws not covered by the Pilot Program (*e.g.,* 49 U.S.C. 303, commonly known as ''Section 4(f)''). To provide clarity for applicants and for States participating in the Pilot Program, the commenter recommended that the Agencies include a section in the regulations specifically addressing the issuance of statute of limitations notices under the Pilot Program. The surface transportation industry interest group commented that the regulations should confirm that the State can still issue a 150-day statute of limitations notice for all actions taken by the State or other Federal agencies under other Federal laws.

Similarly, a State seeks clarification on whether the statute of limitations is two years following the publication in the **Federal Register** of the Notice of Final Federal Agency Action. The commenter also noted that, if the statute of limitations under the Pilot Program is set at two years, this is significantly longer than the 150-day period currently afforded to other surface transportation projects by MAP–21. The State DOT commented that, in order to streamline project delivery, the statute of limitations under the Pilot Program should be the same period established by the State law that will be used to substitute for NEPA, or the 150-day period established by MAP–21, whichever period is shorter. A local government also suggested the Pilot Program consider adopting the 150-day statute of limitations for NEPA actions and decisions, provided a Notice of Final Agency Action is placed in the **Federal Register**. A local government, a regional transportation agency, and a port authority all commented that, since the Pilot Program would allow States to substitute their environmental review procedures for Federal procedures, the State's statute of limitations should apply to legal challenges related to the environmental review. Finally, a public interest group sought clarification on the applicable statute of limitations.

After publication of the NPRM, Section 578 of the FAA Reauthorization Act of 2018 (Pub. L. 115–254) amended 23 U.S.C. 330(a)(2), reducing the number of States eligible to participate in the pilot from five to two. In addition, it amended 23 U.S.C. 330 (e)(2)(A) and (e)(3)(B)(i), changing the statute of limitations from two years to 150 days as set forth in 23 U.S.C. 139(*l*). This statutory change regarding the applicable statute of limitations is reflected in the rulemaking and

otherwise responds to and clarifies the comments received regarding the applicable statute of limitations.

Environmental Permits

A regional transportation agency and a port authority commented that there were benefits to be realized from State and local governments using State environmental review procedures to satisfy the NEPA process. However, these two commenters expressed concerns that the State and local governments may not be able to obtain required permits from Federal resource agencies if the State reviews are not given the required deference. The two commenters stated that approved State and local governments in the Pilot Program should be treated the same as a Federal participating agency. Under the Pilot Program, the Agencies intend for the approved State agency to have the same standing as would a lead Federal agency under the NEPA process. This intent also applies to those local governments or locally administered projects that are subject to the approved Pilot Program application and written agreement, though the State will retain the responsibility for ensuring the requirements of the approved alternative State procedures are met.

One local government noted that Federal environmental resource agency review and approvals to obtain environmental permits continue to be a challenge and suggested the Pilot Program consider streamlining Federal environmental resource agency approvals and potentially assign environmental permitting to the State. Similarly, a public transportation agency recommended that States look for ways to maximize and utilize a project's environmental document for not only NEPA, but also for other Federal agency reviews and permitting requirements, in order to minimize duplicative efforts and streamline the environmental review process. While these comments are outside the scope of this rule, the Agencies direct the commenters to Executive Order 13807 and its corresponding One Federal Decision memorandum of understanding, which aim to condense Federal environmental review and authorization (*e.g.,* permitting) decisions to the maximum extent practicable.

Performance Measurement

A surface transportation industry interest group and a local government suggested that the Agencies establish a system for tracking and benchmarking the performance of the Pilot Program. The two commenters noted this system would allow DOT and Congress to compare the Pilot Program's timelines with those of States and the Federal Government applying NEPA requirements. Similarly, a private citizen noted the Pilot Program can provide key data regarding the possibility of saving money, whether State laws can substitute Federal environmental laws, and whether this program impacts project delivery. The private citizen recommended that DOT be sure to maintain careful records about the successes and failures of the Pilot Program to help determine whether the Pilot Program should be extended to more States.

Per 23 U.S.C. 330(j), the Agencies must submit a report to Congress that describes the administration of the Pilot Program. As such, the Agencies will collect the necessary data and information needed to comply with these requirements. However, the Agencies do not believe it is necessary to address data collection for the Pilot Program in regulation.

Miscellaneous

A private citizen expressed support for the proposed rulemaking and its attempt to aid in the reduction of duplicative environmental reviews at the State and Federal levels. The citizen also noted that the reduction in environmental reviews and subsequent potential cost savings could lead to a reallocation of increased transportation funding for infrastructure. The individual requested that the Agencies seek to expand the Pilot Program beyond five States to gain a better understanding of the efficacy of the Pilot Program across the country since limiting it to only five States could create a limited data set to analyze. The Agencies note that the limit of State participation is based upon a statutory mandate in 23 U.S.C. 330(a)(2), which the FAA Reauthorization Act of 2018 reduced to two States. This rulemaking is consistent with that statute.

49 CFR Part 264

The Agencies are modifying the heading and list of authorities to align with the Final Rule published on October 29, 2018 (83 FR 54480). These changes are administrative in nature.

Rulemaking Analyses and Notices

Statutory/Legal Authority for This Rulemaking

The Agencies have the authority for this rulemaking action under 49 U.S.C. 322(a), which provides authority to ''[a]n officer of the Department of Transportation [to] prescribe regulations to carry out the duties and powers of the officer.'' The Secretary delegated this authority to the Agencies' Administrators in 49 CFR 1.81(a)(3), which provides that the authority to prescribe regulations contained in 49 U.S.C. 322(a) is delegated to each Administrator ''with respect to statutory provisions for which authority is delegated by other sections in [49 CFR part 1].''

Rulemaking Analyses and Notices

The Agencies considered all comments received before the close of business on the comment closing date indicated above. The comments are available for examination in the docket (FHWA–2017–20561) at *www.regulations.gov.* The Agencies also considered comments received after the comment closing date to the extent practicable.

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and DOT Regulatory Policies and Procedures

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Agencies have determined that this action would not be a significant regulatory action under section 3(f) of Executive Order 12866 and would not be significant within the meaning of U.S. Department of Transportation Regulatory Policies and Procedures. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This action complies with Executive Orders 12866 and 13563.

Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

This final rule is considered an E.O. 13771 deregulatory action. The Agencies expect minor cost savings from this rulemaking that cannot be quantified.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601–612), the Agencies have evaluated the effects of this rule on small entities and anticipate that this action would not have a significant economic impact on a substantial number of small entities. ''Small entities'' include small

businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations under 50,000. The proposed rule addresses application requirements for States wishing to participate in the Pilot Program. As such, it affects only States, and States are not included in the definition of small entity set forth in 5 U.S.C. 601. Therefore, the Regulatory Flexibility Act does not apply, and the Agencies certify that this action would not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This final rule would not impose unfunded mandates as defined by the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48). This final rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $155 million or more in any one year (2 U.S.C. 1532). In addition, the definition of ''Federal mandate'' in the Unfunded Mandates Reform Act excludes financial assistance of the type in which State, local, or Tribal governments have authority to adjust their participation in the program in accordance with changes made in the program by the Federal Government.

Executive Order 13132 (Federalism Assessment)

Executive Order 13132 requires agencies to ensure meaningful and timely input by State and local officials in the development of regulatory policies that may have a substantial, direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. The Agencies analyzed this action in accordance with the principles and criteria contained in Executive Order 13132 and determined that it would not have sufficient Federalism implications to warrant the preparation of a federalism assessment. The Agencies have also determined that this final rule would not preempt any State law or State regulation or affect the States' ability to discharge traditional State governmental functions.

Executive Order 13175 (Tribal Consultation)

The Agencies have analyzed this action under Executive Order 13175, and determined that it would not have substantial direct effects on one or more Indian Tribes; would not impose substantial direct compliance costs on Indian Tribal governments; and would not preempt Tribal law. Therefore, a Tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

The Agencies have analyzed this action under Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.* The Agencies have determined that this action is not a significant energy action under Executive Order 13211 because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects under Executive Order 13211 is not required.

Executive Order 12372 (Intergovernmental Review)

DOT's regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities (49 CFR part 17) apply to this program. The Agencies solicited comments on this issue with the proposed rulemakings but did not receive any comments pertaining to Executive Order 12372.

Paperwork Reduction Act

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget for each collection of information they conduct, sponsor, or require through regulations. The Agencies have determined that this final rule does not contain collection of information requirements for the purposes of the PRA.

Executive Order 12988 (Civil Justice Reform)

This action meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, *Civil Justice Reform,* to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 12630 (Taking of Private Property)

The Agencies do not anticipate that this action would affect a taking of private property or otherwise have taking implications under Executive Order 12630, *Governmental Actions and Interference with Constitutionally Protected Property Rights.*

National Environmental Policy Act

Agencies are required to adopt implementing procedures for NEPA that establish specific criteria for, and identification of, three classes of actions: Those that normally require preparation of an EIS; those that normally require preparation of an EA; and those that are categorically excluded from further NEPA review (40 CFR 1507.(e)(2)).

This action qualifies for CEs under 23 CFR 771.116(c)(15) (promulgation of rules), 23 CFR 771.117(c)(20) (promulgation of rules, regulations, and directives) and 771.117(c)(1) (activities that do not lead directly to construction), 23 CFR 771.118(c)(4) (planning and administrative activities which do not involve or lead directly to construction). The Agencies have evaluated whether this action would involve unusual or extraordinary circumstances and have determined that this action would not involve such circumstances.

Under the Pilot Program, a selected State may conduct environmental reviews and make approvals for projects under State environmental laws and regulations instead of NEPA. These State environmental laws and regulations must be at least as stringent as the Federal requirements. As a result, the Agencies find that this rulemaking would not result in significant impacts on the human environment.

Regulation Identifier Number

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects

23 CFR Part 773

Environmental protection, Surface Transportation Project Delivery Program application requirements and termination, Highways and roads

23 CFR Part 778

Environmental protection, eliminating duplication of environmental reviews pilot program, Highways and roads

49 CFR Part 264

Environmental protection, Eliminating duplication of environmental reviews pilot program, Railroads

49 CFR Part 622

Environmental protection, Environmental impact and related procedures, Public transportation, Transit

Issued in Washington, DC, under authority delegated in 49 CFR 1.81(a)(5), 1.85, and 1.91:

Nicole R. Nason,

Administrator, Federal Highway Administration.

Quintin C. Kendall,

Deputy Administrator, Federal Railroad Administration.

K. Jane Williams,

Deputy Administrator, Federal Transit Administration.

For the reasons set out in the preamble the Federal Highway Administration mends title 23, chapter I of the Code of Federal Regulations as follows:

TITLE 23—HIGHWAYS

PART 773—SURFACE TRANSPORTATION PROJECT DELIVERY PROGRAM APPLICATION REQUIREMENTS AND TERMINATION

■ 1. The authority citation for part 773 continues to read as follows:

Authority: 23 U.S.C. 315 and 327; 49 CFR 1.81(a)(4)–(6); 49 CFR 1.85.

■ 2. Amend § 773.117 by revising paragraph (a)(2) and adding paragraph (a)(3) to read as follows:

(a) * * *

(2) The Operating Administration(s) may not terminate a State's participation without providing the State with notification of the noncompliance issue that could give rise to the termination, and without affording the State an opportunity to take corrective action to address the noncompliance issue. The Operating Administration(s) must provide the State a period of no less than 120 days to take corrective actions. The Operating Administration(s) is responsible for making the final decision on whether the corrective action is satisfactory.

(3) On the request of the Governor of the State (or in the case of the District of Columbia, the Mayor), the Operating Administration(s) shall provide a detailed description of each responsibility in need of corrective action regarding an inadequacy identified by the Operating Administration(s).

* * * * *

■ 3. Add part 778 to read as follows:

PART 778—PILOT PROGRAM FOR ELIMINATING DUPLICATION OF ENVIRONMENTAL REVIEWS

Sec.

778.101 Purpose.
778.103 Eligibility and Certain Limitations.
778.105 Application requirements for participation in the Pilot Program.
778.107 Application review and approval.
778.109 Criteria for Determining Stringency.
778.111 Review and Termination.
778.113 Program Termination and Regulations Sunset

Authority: 23 U.S.C. 330; 49 CFR 1.81.

§ 778.101 Purpose.

The purpose of this part is to establish the requirements for a State to participate in the Pilot Program for eliminating duplication of environmental reviews (''Pilot Program''), authorized under 23 U.S.C. 330. The Pilot Program allows States to conduct environmental reviews and make approvals for projects under State environmental laws and regulations instead of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*).

§ 778.103 Eligibility and Certain Limitations.

(a) *Applicants.* To be eligible for the Pilot Program, a State must:

(1) Act by and through the Governor or top-ranking State transportation official who is charged with responsibility for highway construction;

(2) Consent to a waiver of its sovereign immunity for the compliance, discharge, and enforcement of any responsibility under this Pilot Program;

(3) Have previously assumed the responsibilities of the Secretary under 23 U.S.C. 327 related to environmental review, consultation, or other actions required under certain Federal environmental laws; and

(4) Identify laws authorizing the State to take the actions necessary to carry out the alternative environmental review and approval procedures under State laws and regulations.

(b) *Certain Limitations.* (1) State environmental laws and regulations may only be substituted as a means of complying with:

(i) NEPA;

(ii) Procedures governing the implementation of NEPA and related procedural laws under the authority of the Secretary, including 23 U.S.C. 109, 128, and 139; and

(iii) Related regulations and executive orders.

(2) Compliance with State environmental laws and regulations may not substitute for the Secretary's responsibilities regarding compliance with any other Federal environmental laws other than those set forth in (b)(1).

§ 778.105 Application requirements for participation in the Pilot Program.

(a) To apply to participate in the Pilot Program, a State must submit an application to the applicable Operating Administration(s) (*i.e.,* FHWA, FRA, or FTA).

(b) Each application submitted must contain the following information:

(1) A full and complete description of the alternative environmental review and approval procedures, including:

(i) The procedures the State uses to engage the public and consider alternatives to the proposed action; and

(ii) The extent to which the State considers environmental consequences or impacts on resources potentially impacted by the proposed actions (such as air, water, or species).

(2) Each Federal environmental requirement the State is seeking to substitute, within the limitations of § 778.103(b);

(3) Each State environmental law and regulation the State intends to substitute for a Federal environmental requirement, within the limitations of § 778.103(b);

(4) A detailed explanation (with supporting documentation, incorporated by reference where appropriate and reasonably available) of the basis for concluding the State environmental law or regulation intended to substitute for a Federal environmental requirement is at least as stringent as that requirement;

(5) A description of the projects or classes of projects (defined as either a defined group of projects or all projects to which NEPA, the procedures governing the implementation of NEPA and related procedural laws under the authority of the Secretary, including 23 U.S.C. 109 and 139, and related regulations and Executive orders would apply) for which the State would exercise the authority that may be granted under the Pilot Program;

(6) Verification that the State has the financial and personnel resources necessary to fulfill its obligations under the Pilot Program;

(7) Evidence that the State has sought public comments on its application prior to the submittal and the State's response to any comments it received;

(8) A point of contact for questions regarding the application and a point of contact regarding potential implementation of the Pilot Program (if different);

(9) Certification and explanation by the State's Attorney General or other State official empowered by State law to issue legal opinions that bind the State:

(i) That the State has legal authority to enter into the Pilot Program;

(ii) That the State waives its sovereign immunity to the extent necessary to consent to exclusive Federal court jurisdiction for the compliance, discharge, and enforcement of any responsibility under this Pilot Program;

(iii) That the State has laws that are comparable to the Freedom of Information Act, 5 U.S.C. 552 (FOIA), including laws that allow for any decision regarding the public availability of a document under those laws to be reviewed by a court of competent jurisdiction;

(iv) Identifying within the State's laws the jurisdictional requirements and standards of review applicable to judicial review of decisions under the environmental laws proposed for substitution under the Pilot Program; and

(10) The State Governor's (or in the case of the District of Columbia, the Mayor's) or the State's top-ranking transportation official's signature approving the application.

§ 778.107 Application review and approval.

(a) The Operating Administration must solicit public comments on the application and must consider comments received before making a decision to approve or disapprove the application. Materials made available for this public review must include the State's application and supporting materials.

(b) After receiving an application the Operating Administration deems complete, the Operating Administration must make a decision on whether to approve or disapprove the application within 120 calendar days. The Operating Administration must transmit the decision in writing to the State with a statement explaining the decision.

(c) The Operating Administration will approve an application only if it determines the following conditions are satisfied:

(1) The State is party to an agreement with the Operating Administration under 23 U.S.C. 327;

(2) The Operating Administration has determined, after considering any public comments received, the State has the capacity, including financial and personnel, to undertake the alternative environmental review and approval procedures; and

(3) The Operating Administration, in consultation with the Office of the Secretary, with the concurrence of the Chair of CEQ, and after considering public comments received, has determined that the State environmental laws and regulations described in the State's application are at least as stringent as the Federal requirements for which they substitute.

(d) The State must enter into a written agreement with the Operating Administration.

(e) The written agreement must:

(1) Be executed by the Governor (or in the case of the District of Columbia, the Mayor) or top-ranking transportation official in the State charged with responsibility for highway construction;

(2) Provide that the State agrees to assume the responsibilities of the Pilot Program, as identified by the Operating Administration;

(3) Provide that the State, in accordance with the sovereign immunity waiver process required by State law, expressly consents to and accepts Federal court jurisdiction with respect to compliance, discharge, and enforcement of any responsibility undertaken as part of the Pilot Program;

(4) Certify that State laws and regulations exist that authorize the State to carry out the responsibilities of the Pilot Program;

(5) Certify that State laws and regulations exist that are comparable to FOIA (5 U.S.C. 552), including a provision that any decision regarding the public availability of a document under the State laws and regulations is reviewable by a court of competent jurisdiction;

(6) Contain a commitment that the State will maintain the personnel and financial resources necessary to carry out its responsibilities under the Pilot Program;

(7) Have a term of not more than 5 years, the term of a State's agreement with the Operating Administration in accordance with 23 U.S.C. 327, or a term ending on December 4, 2027, whichever is sooner; and

(8) Be renewable.

(f) The State must execute the agreement before the Operating Administration executes the agreement. The Operating Administration's execution of the agreement and transmittal to the State will constitute approval of the application.

(g) The agreement may be renewed at the end of its term, but may not extend beyond December 4, 2027.

(h) A State approved to participate in the Pilot Program may apply the approved alternative environmental review and approval procedures to locally administered projects, for up to 25 local governments at the request of those local governments. For such locally administered projects, the State shall be responsible for ensuring that the requirements of the approved alternative State procedures are met.

§ 778.109 Criteria for determining stringency.

To be considered at least as stringent as a Federal requirement under this Pilot Program, the State laws and regulations, must, at a minimum:

(a) Define the types of actions that normally require an assessment of environmental impacts, including government-sponsored projects such as those receiving Federal financial assistance or permit approvals. (42 U.S.C. 4332(2)(C); 40 CFR 1501.1(a)(4), 1501.3, 1507.3(e)(2)(i), 1508.1(q);

(b) Ensure an early process for determining the scope of the action and issues that need to be addressed, identifying the significant issues, and for the classification of the appropriate assessment of environmental impacts in accordance with the significance of the likely impacts. For actions that may result in significant impacts on the environment, the scoping process must be an open and public process. (23 U.S.C. 139(e); 40 CFR 1501.5, 1501.9, 1506.6, 1507.3(c), 1507.3(e), 1508.1(y), and 1508.1(cc));

(c) Prohibit agencies and nongovernmental proponents from taking action concerning the proposal until the environmental impact evaluation is complete when such action would:

(1) Have adverse environmental impacts or

(2) Limit the choice of reasonable alternatives. (40 CFR 1506.1 and 1506.11(b)).

(d) Protect the integrity and objectivity of the analysis by requiring the agency to take responsibility for the scope and content of the analysis, and by preventing conflicts of interest among the parties developing the analysis and the parties with financial or other interest in the outcome of the project. (42 U.S.C. 4332(2)(D); 40 CFR 1506.5);

(e) Based on a proposed action's purpose and need, require objective evaluation of reasonable alternatives to the proposed action (including the alternative of not taking the action) if it may result in significant impacts to the environment or, for those actions that may not result in significant impacts, consideration of alternatives if they will involve unresolved conflicts concerning alternative uses of available resources (42 U.S.C. 4332(2)(C)(iii); 42U.S.C. 4332(2)(E); 23 U.S.C. 330(b)(1)(A); 40 CFR 1502.13, and 1502.14);

(f) Using procedures that ensure professional and scientific integrity of the discussions and analysis, require an assessment of the changes to the human environment from the proposed action or alternatives that are reasonably foreseeable and have a reasonably close causal relationship to the proposed action or alternatives. (42 U.S.C. 4332(2)(C); 23 U.S.C. 330(b)(1)(B); 40 CFR 1501.5(c)(2), 1502.16, 1502.23, and 1508.1(g);

(g) Require the consideration of appropriate mitigation for the impacts associated with a proposal and reasonable alternatives (including avoiding, minimizing, rectifying, reducing or eliminating the impact over time, and compensating for the impact) (40 CFR 1502.14(e), 1502.16(a)(9), and 1508.1(s));

(h) Provide for adequate interagency participation, including appropriate coordination and consultation with State, Federal, Tribal, and local agencies with jurisdiction by law, special expertise, or an interest with respect to any environmental impact associated with the proposal, and for collaboration that would eliminate duplication of reviews. For actions that may result in significant impacts to the environment, the process should allow for the development of plans for interagency coordination and public involvement, and the setting of timetables for the review process (42 U.S.C. 4332(2)(C); 23 U.S.C. 139(d) and 139(g); 40 CFR 1500.5(g), 1501.8, 1501.9(b), 1502.174, and part 1503);

(i) Provide an opportunity for public participation and comment that is commensurate with the significance of the proposal's impacts on the environment, and require public access to the documentation developed during the environmental review and a process to respond to public comments (42 U.S.C. 4332(2)(C); 23 U.S.C. 330(b)(1)(A); FAST Act, Sec. 1309(c)(2)(B)(ii); 40 CFR 1502.20, part 1503, and 1506.6; and Executive Order 11514, Sec.1(b));

(j) Provide for public access to the documentation necessary to review the potential impacts of projects;

(k) Include procedures for the elevation, resolution, and referral of interagency disputes prior to a final decision on the proposed project (23 U.S.C. 139(h); 40 CFR part 1504);

(l) For the conclusion of the environmental review process, require a concise documentation of findings (for actions that would not likely result in significant impacts to the environment) or, for actions that may result in significant impacts, a concise record that states the agency decision that:

(1) Identifies all alternatives considered (specifying which were environmentally preferable),

(2) Identifies and discusses all factors that were balanced by the agency in making its decision and states how those considerations entered into the decision,

(3) States whether all practicable means to avoid or minimize environmental harm have been adopted, and if not, why they were not; and

(4) Describes the monitoring and enforcement program that is adopted, where applicable, for any mitigation (40 CFR 1501.6(c), 1505.2, and 1505.3).

(m) Require the agency to supplement assessments of environmental impacts if there are substantial changes in the proposal that are relevant to environmental concerns or significant new circumstances or information relevant to environmental concerns and have a bearing on the proposed action or its impacts. (23 U.S.C. 330(e)(3); 40 CFR 1502.9(d)); and

(n) Allow for the use of procedures to facilitate process efficiency, such as tiering, programmatic approaches, adoption, incorporation by reference, approaches to eliminate duplication with other Federal requirements, and special procedures to address emergency situations. Where the procedures allow for the identification and establishment of categories of actions that normally do not have a significant impact on the environment and are therefore excluded from further review, ensure that the procedures require the consideration of extraordinary circumstances that would warrant a higher level of analysis in which a normally excluded action may have a significant environmental effect. (23 U.S.C. 139(b)(3); 40 CFR 1500.4, 1500.5, 1501.4, 1501.11, 1501.12, 1502.24, 1506.2, 1506.3, and 1506.4).

§ 778.111 Review and termination.

(a) *Review.* The Operating Administration must review each participating State's performance in implementing the requirements of the Pilot Program at least once every 5 years.

(1) The Operating Administration must provide notice and an opportunity for public comment during the review.

(2) At the conclusion of its last review prior to the expiration of the term, the Operating Administration may extend a State's participation in the Pilot Program for an additional term of not more than 5 years (as long as such term does not extend beyond the termination date of the Pilot Program) or terminate the State's participation in the Pilot Program.

(b) *Early Termination.* (1) If the Operating Administration, in consultation with the Office of the Secretary and the Chair of CEQ, determines that a State is not administering the Pilot Program consistent with the terms of its written agreement, or the requirements of this part or 23 U.S.C. 330, the Operating Administration must provide the State notification of that determination.

(2) After notifying the State of its determination under paragraph (c)(1), the Operating Administration must provide the State a maximum of 90 days to take the appropriate corrective action. If the State fails to take such corrective action, the Operating Administration may terminate the State's participation in the Pilot Program.

§ 778.113 Program termination and regulations sunset.

(a) *In General.* The Pilot Program shall terminate December 4, 2027, unless Congress extends the authority under 23 U.S.C. 330.

(b) *Sunset.* Unless Congress extends the authority for the Pilot Program that sunsets 12 years after the date of enactment, this rule shall expire on December 4, 2027.

For the reasons set out in the preamble the Federal Railroad Administration amends 49 CFR part 264 as follows:

TITLE 49—TRANSPORTATION

PART 264—ENVIRONMENTAL IMPACT AND RELATED PROCEDURES

■ 4. The authority citation for part 264 is revised to read as follows:

Authority: 42 U.S.C. 4321 *et seq.;* 49 U.S.C. 303; 23 U.S.C. 139, 327, 330; 40 CFR parts 1500–1508; 49 CFR 1.81; Pub. L. 112–141, 126 Stat. 405, Section 1319; and Pub. L. 114–94, 129 Stat. 1312, Sections 1309, 1432, 11502, and 11503.

■ 5. Revise § 264.101 to read as follows:

§ 264.101 Cross reference to environmental impact and related procedures.

The procedures for complying with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and related statutes, regulations, and orders are set forth in part 771 of title 23 of the Code of Federal Regulations. The procedures for complying with 49 U.S.C. 303, commonly known as ''Section 4(f),'' are set forth in part 774 of title 23 of the Code of Federal Regulations. The procedures for complying with the Surface Transportation Project Delivery Program application requirements and termination are set forth in part 773 of title 23 of the CFR. The procedures for participating in and complying with the program for eliminating duplication of environmental reviews are set forth in part 778 of title 23 of the CFR.

For the reasons set forth in the preamble, the Federal Transit Administration amends 49 CR part 622 as follows:

PART 622—ENVIRONMENTAL IMPACT AND RELATED PROCEDURES

Subpart A—Environmental Procedures

■ 7. The authority citation for subpart A of part 622 is revised to read as follows:

Authority: 42 U.S.C. 4321 *et seq.;* 49 U.S.C. 303 and 5323(q); 23 U.S.C. 139, 326, 327, and 330; Pub. L. 109–59, 119 Stat. 1144, Sections 6002 and 6010; 40 CFR parts 1500–1508; 49 CFR 1.81; Pub. L. 112–141, 126 Stat.405, Sections 1315, 1316, 1317, and 1318; and Pub. L. 114–94, Section 1309.

■ 8. Revise § 622.101 to read as follows:

§ 622.101 Cross-reference to procedures.

The procedures for complying with the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), and related statutes, regulations, and Executive Orders are set forth in part 771 of title 23 of the CFR. The procedures for complying with 49 U.S.C. 303, commonly known as ''Section 4(f),'' are set forth in part 774 of title 23 of the CFR. The procedures for complying with the Surface Transportation Project Delivery Program application requirements and termination are set forth in part 773 of title 23 of the CFR. The procedures for participating and complying with the program for eliminating duplication of environmental reviews are set forth in part 778 of title 23 of the CFR.

[FR Doc. 2020–26395 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 0

[Docket No. OAG 162; AG Order No. 4926–2020]

Approval of Civil Consent Decrees With State and Local Governmental Entities

AGENCY: Office of the Attorney General, Justice.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations of the Department of Justice (''Department'') setting forth the approval procedures to be used when a civil action against a State or local governmental entity is resolved by consent decree, prior to the finalization of that agreement.

DATES: This rule is effective December 28, 2020.

FOR FURTHER INFORMATION CONTACT: J. Taylor McConkie, Deputy Associate Attorney General, Department of Justice, Washington, DC 20530; telephone: (202) 514–9500 (not a toll-free number).

SUPPLEMENTARY INFORMATION: In enforcing Federal law, the Department may bring lawsuits against State and local governmental entities. State governments are sovereigns with special and protected roles under our constitutional order. Accordingly, the Department must ensure that its practices in such cases are in the interests of justice, transparent, and consistent with the impartial rule of law and fundamental constitutional principles, including federalism and democratic control and accountability.

On November 7, 2018, Attorney General Jeff Sessions issued a memorandum (''November 7 memorandum'' or ''memorandum'') to the heads of the Department's civil litigating components and the United States Attorneys addressing many of the particular considerations arising when a civil action against a State or local government is resolved by consent decree or settlement agreement. Principles and Procedures for Civil Consent Decrees and Settlement Agreements with State and Local Government Entities (Nov. 7, 2018) (available at *https://www.justice.gov/opa/press-release/file/1109681/download*).

As that memorandum explained, while consent decrees may be necessary and appropriate to secure compliance with Federal law, Federal court decrees that impose wide-ranging and long-term obligations on, or require ongoing judicial supervision of, State or local governments are extraordinary remedies that ''raise sensitive federalism concerns.'' *Id.* at 2 (*citing Horne* v. *Flores,* 557 U.S. 433, 448 (2009)). It is appropriate that the Department should exercise special caution before entering into a consent decree with a State or local governmental entity. While such consent decrees can be appropriate settlement vehicles in limited circumstances, they should be employed carefully and only after review and approval of senior leadership of the Department. *Id.* at 3–4.

To that end, the November 7 memorandum set forth important principles to guide the development of consent decrees with State or local governmental entities, including limitations on the circumstances in which a consent decree with a State or local governmental entity may be appropriate, the substantive requirements for such consent decrees, internal notification requirements regarding the initiation of negotiation for consent decrees, and a requirement of review and approval of senior leadership of the Department before a consent decree is agreed to by the United States or submitted to the court for entry.

The principles of the November 7 memorandum are applicable, by its terms, to all civil litigation conducted by the Department that involves any civil consent decrees or settlement agreements with State or local governmental entities. However, it is appropriate to amend the Department's settlement regulations to effectuate one aspect addressed by the memorandum, *i.e.,* the requirement for leadership approval of consent decrees prior to the agreement or submission to a court for entry. As noted in the memorandum (pages 2 n.3 and 3 n.4), the Department's existing regulations on the delegation of settlement authority govern the requirements for certain settlements to be approved by the Department's senior leadership. This final rule amends the existing settlement regulations to add a new paragraph codifying the requirement for the relevant Assistant Attorney General of the civil litigating division (or the United States Attorney to whom settlement authority has been redelegated under 28 CFR 0.168) to approve and submit consent decrees involving State or local government entities for approval by the Deputy Attorney General or the Associate Attorney General if the consent decree would (1) place a court in a long-term position of monitoring compliance by a State or local governmental entity; (2) create long-term structural or programmatic obligations, or long-term, indeterminate financial obligations, for a State or local governmental entity; or (3) otherwise raise novel questions of law or policy that merit review by senior Department leadership. However, consistent with the November 7 memorandum at page 3 n.5, this new approval requirement does not apply where use of a consent decree is required by statute or regulation or the consent decree is limited to the payment of a sum certain of money or performance of a specific environmental removal action.

Accordingly, to achieve the foregoing objectives, before a consent decree that comes within one of the categories set forth above is agreed to by the United States or submitted to a court for entry, it must be approved by the United States Attorney or the Assistant Attorney General for the litigating component responsible for the subject matter of the consent decree and by the Deputy Attorney General or the

Associate Attorney General, in accordance with the standard reporting structure of the Department.

Regulatory Certifications

Administrative Procedure Act

This rule relates to a matter of agency management or personnel and is a rule of agency organization, procedure, or practice. As such, this rule is exempt from the usual requirements of prior notice and comment and a 30-day delay in effective date. *See* 5 U.S.C. 553(a)(2), (b), (d).

Regulatory Flexibility Act

This regulation will not have an impact on small entities because it pertains to personnel and administrative matters affecting the Department. A Regulatory Flexibility Analysis was not required for this final rule because the Department was not required to publish a general notice of proposed rulemaking for this matter. *See* 5 U.S.C. 601(2), 604(a).

Executive Orders 12866, 13563, and 13771—Regulatory Review

This regulation has been drafted and reviewed in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), ''The Principles of Regulation,'' and Executive Order 13563, ''Improving Regulation and Regulatory Review,'' section 1, ''General Principles of Regulation.''

This final rule is ''limited to agency organization, management, or personnel matters'' and thus is not a ''rule'' for purposes of review by the Office of Management and Budget. *See* Executive Order 12866, section 3(d)(3). Accordingly, this rule has not been reviewed by the Office of Management and Budget.

This rule is not subject to the requirements of Executive Order 13771 because it is ''related to agency organization, management, or personnel'' and thus not a ''rule'' under Executive Order 13771, section 4(b).

Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132—Federalism

This rule provides for appropriate leadership review by the Department prior to the finalization of consent decrees involving State or local governmental entities, in order to better ensure their special sovereign and protected roles under our constitutional order. This is not a substantive rule but is a rule of internal agency management, practice, and procedure regarding the delegation of the Attorney General's litigation authority for the internal review of certain consent decrees in litigation being conducted under the authority of the Attorney General. This rule will not have substantial direct effects on the States, on the relationship between the Federal Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, Federalism, the Department has determined that this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120 million or more (adjusted for inflation) in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Congressional Review Act, 5 U.S.C. 804. This action pertains to agency management, personnel, and organization and does not substantially affect the rights or obligations of non-agency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act, 8 U.S.C. 804(3)(B)–(C). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 28 CFR Part 0

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

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

PART 0—ORGANIZATION OF THE DEPARTMENT OF JUSTICE

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

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

■ 2. Section 0.160 is amended by:
■ a. Removing the word ''or'' at the end of paragraph (d)(1);
■ b. Removing the word ''or'' at the end of paragraph (d)(4);
■ c. Removing the period at the end of paragraph (d)(5) and adding in its place ''; or''; and
■ d. Adding paragraphs (d)(6) and (e).

The additions read as follows:

§ 0.160 Offers that may be accepted by Assistant Attorneys General.

* * * * *

(d) * * *

(6) When a proposed settlement of a civil action includes a consent decree with a State or local governmental entity that would:

(i) Place a court in a long-term position of monitoring compliance by a State or local governmental entity;

(ii) Create long-term structural or programmatic obligations, or long-term, indeterminate financial obligations, for a State or local governmental entity; or

(iii) Otherwise raise novel questions of law or policy that merit review by senior Department leadership.

(e) As used in paragraph (d)(6) of this section, ''long-term'' means that the obligations, on their face or in practice, are reasonably likely to take 24 months or longer to satisfy. Paragraph (d)(6) of this section does not apply where use of a consent decree is required by statute or regulation or the consent decree is limited to the payment of a sum certain of money or performance of a specific environmental removal action.

Dated: December 4, 2020.

William P. Barr,

Attorney General.

[FR Doc. 2020–27190 Filed 12–23–20; 8:45 am]

BILLING CODE 4410–12–P

DEPARTMENT OF THE INTERIOR

Bureau of Safety and Environmental Enforcement

30 CFR Part 250

[Docket ID: BSEE–2020–0002; EEEE500000 21XE1700DX EX1SF0000.EAQ000]

RIN 1014–AA46

Oil and Gas and Sulfur Operations in the Outer Continental Shelf—Reaffirmation of Standard Editions Related to the Manual of Petroleum Measurement Standards

AGENCY: Bureau of Safety and Environmental Enforcement, Interior.

ACTION: Direct final rule; request for comments.

SUMMARY: This direct final rule incorporates by reference American Petroleum Institute's (API's) reaffirmation of 21 production measurement publications (each referred to herein as a ''standard''). This direct final rule updates the reaffirmation date of industry standards already incorporated in regulations administered by the Bureau of Safety and Environmental Enforcement (BSEE). This rule does not include any new editions of incorporated standards, nor does it incorporate any new standards. Rather, it merely acknowledges API's subsequent reaffirmation, without change, of standards previously incorporated by reference. Incorporation of these reaffirmed documents will ensure that the citations to standards for the measurement of oil and gas production flow rates and volumes incorporated into the regulations are up to date. This rule will update incorporated measurement standards, thereby eliminating confusion in identifying the correct measurement standards required to be used.

DATES: This rule is effective February 26, 2021 without further action, unless adverse comment is received by January 27, 2021. If adverse comment is received, BSEE will publish a timely withdrawal of the rule in the **Federal Register**. BSEE may not fully consider comments received after the comment due date. The incorporation by reference of the publications listed in the regulation is approved by the Director of the Federal Register as of February 26, 2021.

ADDRESSES: You may submit comments on the rulemaking using the Federal eRulemaking portal which is located at *www.regulations.gov.* Please use the regulation identifier number (RIN) 1014–AA46 as an identifier for your comment.

Public Availability of Comments—Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. In order for BSEE to withhold from disclosure your personal identifying information, you must identify any information contained in the submittal of your comments that, if released, would constitute a clearly unwarranted invasion of your personal privacy. You must also briefly describe any possible harmful consequence(s) of the disclosure of the information, such as embarrassment, injury, or other harm. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. Availability of documents for public viewing: The reaffirmed standards are available online for review for free, and hardcopies and printable versions are available for purchase. The API website where the standards can be viewed is: *http://publications.api.org/.* This API website provides a free online reading room for users after creating an account.

For the convenience of the public who may not wish to view documents online, all documents incorporated in this rule may be viewed by appointment at the BSEE Houston office, 1919 Smith Street, Suite 14042, Houston, Texas 77002. An appointment is required because of agency resources, natural disasters, public health situations and the like, *e.g.,* personnel availability, hurricanes, pandemics, etc. To make an appointment, please call 1–844–259–4779.

These documents, if incorporated, will continue to be made available to the public for viewing when requested. Specific information on where these documents can be inspected or purchased can be found at 30 CFR 250.198, *documents incorporated by reference.*

FOR FURTHER INFORMATION CONTACT: For technical or procedural questions contact Alton Payne at 713–220–9204, or David Izon at 703–787–1706, or by email: *standards@bsee.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

BSEE derives its authority primarily from the Outer Continental Shelf Lands Act (OCSLA), 43 U.S.C. 1331–1356a. Congress enacted OCSLA in 1953, authorizing the Secretary of the Interior (Secretary) to lease the Outer Continental Shelf (OCS) for mineral development, and to regulate oil and gas exploration, development, and production operations on the OCS. The Secretary has delegated authority to perform certain of these functions to BSEE. To carry out its responsibilities, BSEE regulates oil and gas exploration, development, and production operations on the OCS. Among other purposes, regulations administered by BSEE seek to prevent injury, loss of life, as well as damage to property, natural resources, and the environment. The Department of the Interior (Department) incorporates by reference in its regulations many oil and gas industry standards in order to require compliance with those standards in offshore operations.

BSSE uses standards, specifications, RPs, and other documents developed by standard development organizations (SDO) as a means of establishing requirements for activities on the OCS. This practice, known as ''incorporation by reference,'' allows the Department to incorporate the requirements of technical documents into the regulations without increasing the volume of the Code of Federal Regulations (CFR). The Department currently incorporates by reference 125 documents into its offshore operating regulations administered by BSEE.

The National Technology Transfer and Advancement Act (NTTAA) [1] requires BSEE to ''use technical standards that are developed or adopted by voluntary consensus standards bodies . . . to carry out policy objectives or activities[,]'' including those on the OCS. According to the relevant definitional guidance from the Office of Management and Budget (OMB), standards include those developed by SDOs that are currently incorporated into regulations administered by BSEE (*e.g.,* industry standards, codes, specifications, and RPs).[2]

Where appropriate, the Department incorporates industry standards into its regulations by reference without republishing the standards in their entirety. The legal effect of incorporation by reference is that the incorporated standards become regulatory requirements. This incorporated material, like any other regulation, has the force and effect of law. Operators, lessees, and other regulated parties must comply with the documents incorporated by reference in the regulations.

The Office of the Federal Register's (OFR) regulations, at 1 CFR part 51, govern how BSEE and other Federal agencies incorporate documents by reference. Agencies may incorporate a document by reference by publishing in the **Federal Register** the document title, edition, date, author, publisher, identification number, and other specified information. The preamble of the rule must contain a summary of each document incorporated by reference, as well as discuss the ways that the incorporated materials are reasonably available to interested parties and how interested parties can

[1] Public Law 104–113, sec. 12(d), Mar. 7, 1996, 15 U.S.C. 272 note.

[2] *See,* OMB Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities'' (pp. 15–16) *https://www.nist.gov/system/files/revised_circular_a-119_as_of_01-22-2016.pdf*

obtain those materials. The Director of the Federal Register must also approve the incorporation by reference of a publication.

Incorporation by reference of a document or publication is limited to the version of the document or publication cited in the regulations. This means that newer editions, versions, amendments, or revisions to documents already incorporated by reference in regulations are not part of the regulations until the Department promulgates a rulemaking in the **Federal Register** that incorporates the new, updated, or revised version of the document.

BSSE reviewed API reaffirmations of documents already incorporated into the regulations BSEE administers and determined that it is appropriate to update the regulations to reflect the reaffirmed documents. Based on this review, BSEE has concluded that the use of these reaffirmed standards will not impose additional costs on any stakeholder, including the offshore oil and gas industry. In fact, the substance of the standards incorporated here is the same as that presently incorporated because this rulemaking merely incorporates by reference the reaffirmation by the SDO, namely API, of standards already incorporated by reference. Therefore, the Department is incorporating these reaffirmed documents through a direct final rule. The Department determined under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) that ''notice and public procedure thereon are . . . unnecessary . . .'' because the Department does not propose to make any actual substantive changes to the regulations—the changes are merely administrative updates to the citations to the standards previously incorporated into the regulations. Additionally, because the reaffirmed versions of the standards being incorporated are identical to the requirements of the standards already contained in the regulations, incorporation of these versions will not impose undue costs on the affected parties.

BSEE's Functions and Authority

BSEE promotes safety, protects the environment, and conserves offshore oil and gas resources through vigorous regulatory oversight and enforcement. BSEE derives its authority primarily from OCSLA.

Congress enacted OCSLA in 1953, establishing Federal control over the OCS and authorizing the Secretary to regulate oil and natural gas exploration, development, and production operations on the OCS. The Secretary authorized BSEE to perform certain of these functions (*see* 30 CFR 250.101, *Authority and applicability*). In addition to developing and implementing such regulatory requirements, BSEE participates in activities of relevant SDOs and the international community to develop and revise safety and environmental standards, which the Department may incorporate into BSEE's regulatory program. BSEE also conducts onsite inspections to ensure compliance with regulations, including the subject matter of the standards incorporated by reference in regulations administered by BSEE. Detailed information concerning regulations and guidance for the offshore industry may be found on BSEE's website at: *www.bsee.gov/Regulations-and-Guidance/index.*

Public Participation and Availability of Comments

BSEE encourages public participation in this direct final rulemaking through the submission of written comments, as discussed in the **ACTION**, **ADDRESSES**, and **DATES** sections of this direct final rule. This direct final rule provides 30 days for public comment to ensure the public has an opportunity to raise concerns regarding the incorporation of these reaffirmed standards. If no adverse comment is received within the 30-day comment period, this final rule will become effective 60 days after its publication in the **Federal Register**. If an adverse substantive comment is received within the 30-day comment period, then the Department will withdraw the final rule before its effective date and issue a separate proposed rule document on the same subject. The reaffirmed standards the Department is incorporating were previously incorporated in its regulations. Industry is currently working with the reaffirmed versions of these incorporated standards.

Procedures for Incorporation by Reference and Availability of Incorporated Documents for Public Viewing

BSEE frequently uses standards (*e.g.,* codes, specifications, recommended practices, and bulletins) developed through a consensus process, facilitated by SDOs, with input from the oil and gas industry and the public generally, as a means of establishing requirements for activities on the OCS. The Department may incorporate these standards into its regulations without republishing the standards in their entirety in the CFR, a practice known as incorporation by reference. The legal effect of incorporation by reference is that the incorporated standards become regulatory requirements (*see* 30 CFR 250.115). This incorporated material, like any other properly issued regulation, has the force and effect of law, and BSEE holds operators, lessees, and other regulated parties accountable for complying with the documents incorporated by reference in the regulations. There are 125 consensus standards currently incorporated by reference in the regulations governing offshore oil and gas operations administered by BSEE (*see* 30 CFR 250.198).

When a copyrighted industry standard is incorporated by reference into the regulations, BSEE is obligated to observe and protect that copyright. BSEE provides members of the public with website addresses where these standards may be accessed for viewing—sometimes for free and sometimes for a fee. The decision to charge a fee is made by each SDO. API provides free online public viewing access to more than 160 technical and other key industry standards. Those standards represent almost one-third of all API standards and include all that are safety-related or are incorporated into Federal regulations. These standards are available for viewing online, while hard copies and printable versions will continue to be available for purchase through API. To review such standards online, go to the API publications website at: *http://publications.api.org.* You must then log-in or create a new account, accept API's ''Terms and Conditions,'' click on the ''Browse Documents'' button, and then select the applicable category (*e.g.,* ''Exploration and Production'') for the standard you wish to review.

For the convenience of the viewing public who may not wish to purchase or view the incorporated documents online, the documents may be inspected at BSEE's office at: 1919 Smith Street, Suite 14042, Houston, Texas 77002 (phone: 1–844–259–4779) by appointment only. An appointment is required because of agency resources, natural disasters, public health situations and the like, *e.g.,* personnel availability, hurricanes, pandemics, etc. BSEE will make documents incorporated in the final rule available for viewing at the time and date agreed upon for the appointment. Additional information on where these documents can be inspected or purchased can be found at 30 CFR 250.198, *Documents incorporated by reference.*

Background Information for Proposed Incorporation by Reference of Reaffirmed API Standards

In addition to the legal requirement under the NTTAA for Federal agencies to use standards where appropriate, there are a number of benefits to incorporating these documents into the regulations. Standards increase consistency for employee training, equipment compatibility, processes, and testing during operations. Standards help ensure that operators and their contractors take proper precautions during operations resulting in safety performance improvements through the reduction of lost time from injuries and incidents, work environment safety standards, proper training, product failure reporting, quality control and assurance requirements, addressing safety issues, and improved communications between user and supplier. Global adoption of standards is a compelling reason for the most updated version to be part of the regulatory framework, since standards drive consistency, promote competition, and reduce the burden of compliance.

OMB Circular A–119 indicates that Federal agencies ''should undertake a standards-specific review of such incorporated standards every three-to-five years, or when stakeholders otherwise provide adequate information that a standards-specific review is necessary due to . . . the need to remain current with technological changes. . . .'' [3] This standard-specific rulemaking is part of the Department's effort to keep the standards in the regulations up-to-date. The American National Standards Institute (ANSI) generally contemplates that industry standards will be updated at least every five years by the SDOs. However, the regulations administered by BSEE incorporate several standards that are updated by SDOs more frequently than every five years, and are therefore appropriate for updating in the regulations.

Typically, standards cite other documents as normative. When documents are cited as normative, the normative document is indispensable for the application of the standard citing it. Thus, the normative document must be followed in order to comply with the requirements of the underlying standard.

This rulemaking updates the specific versions defined by the reaffirmation dates of the incorporated editions of the following API documents:

[3] OMB Circ. A–119 at p. 26.

1. API MPMS Chapter 2—Tank Calibration, Section 2A—Measurement and Calibration of Upright Cylindrical Tanks by the Manual Tank Strapping Method, First Edition, February 1995, Reaffirmed August 2017.

This standard describes the procedures for calibrating upright cylindrical tanks used primarily for the storage of petroleum liquids. Section 2A, *Tank Calibration,* first addresses procedures for making necessary measurements to determine the total and incremental tank volumes, and then presents the recommended procedures for computing volumes. The standard also provides guidelines for recalibration and computerization of capacity tables. Both the International System of Units (SI), or metric, and U.S. customary units are presented where appropriate. SI and U.S. customary conversions may not necessarily be exact. The SI units often reflect what is available in commercial equipment. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in August 2017.

2. API MPMS Chapter 2—Tank Calibration, Section 2B—Calibration of Upright Cylindrical Tanks Using the Optical Reference Line Method (ORLM), First Edition, March 1989, Reaffirmed April 2019.

This standard describes measurement and calculation procedures for determining the diameters of upright welded (lap/butt) cylindrical tanks, or vertical cylindrical tanks, with a smooth outside surface and either floating or fixed roofs. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in April 2019.

3. API MPMS Chapter 3—Tank Gauging, Section 1B—*Standard Practice for Level Measurement of Liquid Hydrocarbons in Stationary Tanks by Automatic Tank Gauging (ATG);* Second Edition, June 2001, Reaffirmed February 2016.

This incorporated standard discusses automatic tank gauging in general, calibration of ATGs for custody transfer and inventory control, and the requirements for data collection, transmission, and receiving. The appendices discuss the operation and installation of the most commonly used ATG equipment and of the less commonly used electronic ATGs. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in February 2016.

4. API MPMS Chapter 4—Proving Systems, *Section 1—Introduction*—Third Edition, February 2005, Reaffirmed June 2014.

Section 1, Proving Systems, is a general introduction to the subject of proving. The requirements in Chapter 4 are based on customary practices that evolved for crude oils and products covered by API MPMS Ch. 11.1. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in June 2014.

5. API MPMS Chapter 4—Proving Systems, *Section 4—Tank Provers,* Second Edition, May 1998, Reaffirmed May 2015.

Chapter 4 specifies the characteristics of stationary (fixed) or portable tank provers that are in general use and the procedures for their calibration. Guidelines are provided for the design, manufacture, calibration, and use of new or replacement tank provers and are not intended to make any existing tank provers obsolete. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in May 2015.

6. API MPMS, Chapter 4—Proving Systems, Section 6—*Pulse Interpolation,* Second Edition, May 1999, Reaffirmed October 2013.

Chapter 4 describes how the double-chronometry method of pulse interpolation, including system operating requirements and equipment testing, is applied to meter proving. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in October 2013.

7. API MPMS, Chapter 5—Metering, *Section 2—Measurement of Liquid Hydrocarbons by Displacement Meters,* Third Edition, September 2005, Reaffirmed July 2015.

This section of API MPMS Chapter 5 covers the unique performance characteristics of displacement meters in liquid hydrocarbon service. The Department incorporated this standard by reference into the regulations on April 28, 2010 [75 FR 22223], and API reaffirmed the standard without substantive change in July 2015.

8. API MPMS Chapter 5—Metering, *Section 3—Measurement of Liquid Hydrocarbons by Turbine Meters,* Fifth Edition, September 2005, Reaffirmed August 2014.

Section 3 of API MPMS Chapter 5 covers the unique installation requirements and performance characteristics of turbine meters in liquid-hydrocarbon service. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in August 2014.

9. API MPMS, Chapter 5—Metering, *Section 4—Accessory Equipment for Liquid Meters,* Fourth Edition, September 2005, Reaffirmed August 2015.

Section 4 of API MPMS Chapter 5 describes the characteristics of accessory equipment that may be used with meters in liquid hydrocarbon service. Having a knowledge of these characteristics helps designers and operators of meter installations provide satisfactory quantity measurement results. Certain minimum requirements for devices that monitor temperature, density, and pressure are discussed in this section. Most system hardware, such as non-control valves, vents, and manifolding, is not discussed in this section. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in August 2015.

10. API MPMS, Chapter 5—Metering, *Section 5—Fidelity and Security of Flow Measurement Pulsed-Data Transmission Systems,* Second Edition, August 2005, Reaffirmed August 2015.

The recommendations set forth in this publication are concerned only with the fidelity and security of pulsed-data, cabled transmission systems between a flow meter or flow meter transducer and a remote totalizer. The Department incorporated this standard by reference into the regulations on March 15, 2007 [72 FR 12093], and API reaffirmed the standard without substantive change in August 2015.

11. API MPMS Chapter 5—Metering, *Section 6—Measurement of Liquid Hydrocarbons by Coriolis Meters,* First Edition October 2002, Reaffirmed November 2013.

This standard is applicable to custody transfer applications for liquid hydrocarbons. Topics covered are:

(1) Applicable API standards used in the operation of Coriolis meters,

(2) Proving and verification using both mass-based and volume-based methods,

(3) Installation,

(4) Operation, and

(5) Maintenance.

The mass-based and volume-based calculation procedures for proving and quantity determination are included in Appendix E. Although the Coriolis meter is capable of simultaneously determining density, this document does not address its use as a stand-alone densitometer. See API MPMS Chapter 14.6 for density matters. The Department incorporated this standard by reference into the regulations on March 29, 2012 [77 FR 18921], and API reaffirmed the standard without substantive change in November 2013.

12. API MPMS, Chapter 6—Metering Assemblies, Section 1—Lease Automatic Custody Transfer (LACT) Systems, Second Edition, May 1991, Reaffirmed May 2012.

This publication describes the metering function of a Lease Automatic Custody Transfer (LACT) unit and is intended to complement API Specification II N, Specification for Lease Automatic Custody Transfer (LACT) Equipment. The Department incorporated this standard by reference into the regulations on December 28, 1999 [64 FR 72791], and API reaffirmed the standard without substantive change in May 2012.

13. API MPMS, Chapter 6—Metering Assemblies, Section 6—Pipeline Metering Systems, Second Edition, May 1991, Reaffirmed December 2017.

This publication deals with the operation and special arrangements of meters, provers, manifolding, instrumentation, and accessory equipment used to measure the loading and unloading of marine bulk carriers. The information provided in this publication is applicable to shore-to-carrier-to-shore measurements of crude oils and refined products. These procedures are not intended to apply to hydrocarbons that require specialized measurements and handling equipment, such as liquefied natural gas (LNG). The Department incorporated this standard by reference into the regulations on December 28, 1999 [64 FR 72791], and API reaffirmed the standard without substantive change in December 2017.

14. API MPMS, Chapter 6—Metering Assemblies, Section 7—Metering Viscous Hydrocarbons, Second Edition May 1991, Reaffirmed March 2018.

This chapter defines viscous hydrocarbons and describes the difficulties that arise when viscous hydrocarbons are raised to high temperatures. The effects of such temperatures on meters, auxiliary equipment, and fittings are discussed. Further, advice and warnings to overcome or mitigate difficulties are included. The Department incorporated this standard by reference into the regulations on December 28, 1999 [64 FR 72791], and API reaffirmed the standard without substantive change in March 2018.

15. API MPMS, Chapter 10—Sediment and Water, Section 1—Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method, Third Edition November 2007, Reaffirmed October 2012.

This test method determines the sediment in crude oils and fuel oils by extraction with toluene. The Department incorporated this standard by reference into the regulations on April 28, 2010 [75 FR 22224], and API reaffirmed the standard without substantive change in October 2012.

16. API MPMS, Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 1—Introduction, Second Edition May 1995, Reaffirmed March 2014.

This document provides standardized calculation methods for the quantification of liquids and the determination of base prover volumes under defined conditions, regardless of the point of origin or destination or the units of measure required by governmental customs or statute. The criteria contained in this document allow different entities using various computer languages on different computer hardware (or manual calculations) to arrive at identical results using the same standardized input data. The Department incorporated this standard by reference into the regulations on December 28, 1999 [64 FR 72791], and API reaffirmed the standard without substantive change in March 2014.

17. API MPMS, Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 2—Measurement Tickets, Third Edition, June 2003, Reaffirmed February 2016.

This document provides standardized calculation methods for the quantification of liquids and the determination of base prover volumes under defined conditions, regardless of the point of origin or destination or the units of measure required by governmental customs or statute. The criteria contained in this document allow different entities using various computer languages on different computer hardware (or manual calculations) to arrive at identical results using the same standardized input data. The Department incorporated this standard by reference into the regulations on March 15, 2007

[72 FR 12094], and API reaffirmed the standard without substantive change in February 2016.

18. API MPMS Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 3—Proving Reports, First Edition, October 1998, Reaffirmed May 2014.

This document provides standardized calculation methods for the determination of meter factors under defined conditions, regardless of the point of origin or destination or units of measure required by governmental customs or statute. The criteria contained here will allow different entities using various computer languages on different computer hardware (or by manual calculations) to arrive at identical results using the same standardized input data. This document also specifies the equations for computing correction factors, including the calculation sequence, discrimination levels, and rules for rounding to be employed in the calculations. The Department incorporated this standard by reference into the regulations on March 29, 2012 [77 FR 18921], and API reaffirmed the standard without substantive change in March 2014.

19. API Manual of Petroleum Measurement Standards (MPMS) Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 4—Calculation of Base Prover Volumes by the Waterdraw Method, First Edition, December 1997, Reaffirmed September 2014.

This document provides standardized calculation methods for the quantification of liquids and the determination of base prover volumes under defined conditions, regardless of the point of origin or destination or units of measure required by governmental organizations. The criteria contained in this document allow different individuals, using various computer languages on different computer hardware (or manual calculations), to arrive at identical results using the same standardized input data. This publication rigorously specifies the equations for computing correction factors, rules for rounding, the sequence of the calculations, and the discrimination levels of all numbers to be used in these calculations. The Department incorporated this standard by reference into the regulations on March 29, 2012 [77 FR 18921], and API reaffirmed the standard without substantive change in September 2014.

20. API MPMS, Chapter 14.5/GPA Standard 2172–09, Calculation of Gross Heating Value, Relative Density, Compressibility and Theoretical Hydrocarbon Liquid Content for Natural Gas Mixtures for Custody Transfer, Third Edition, January 2009, Reaffirmed February 2014.

This standard provides criteria and procedures for designing, installing, and operating continuous density measurement systems for Newtonian fluids in the petroleum, chemical, and natural gas industries. The Department incorporated this standard by reference into the regulations on April 28, 2010 [75 FR 22224], and API reaffirmed the standard without substantive change in February 2014.

21. API MPMS Chapter 21—Flow Measurement Using Electronic Metering Systems, Section 2—Electronic Liquid Volume Measurement Using Positive Displacement and Turbine Meters, First Edition, June 1998, Reaffirmed October 2016.

This standard provides guidance for effective utilization of electronic liquid measurement systems for custody transfer measurement of liquid hydrocarbons:

(1) Within the scope and field of application of API MPMS Chapter 12.2.,

(2) Which are single-phase liquids at measurement conditions,

(3) For systems utilizing turbine or positive displacement meters, and

(4) For systems using on-line CTL and CPL compensation.

The Department incorporated this standard by reference into the regulations on March 29, 2012 [77 FR 18921], and API reaffirmed the standard without substantive change in October 2016.

Procedural Matters

Regulatory Planning and Review (E.O. 12866, 13563, and 13771)

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

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. E.O. 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 further emphasizes that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements in that the continued use of the reaffirmed standards promotes predictability, reduces uncertainity, and provides no additional burden.

E.O. 13771 of January 30, 2017, directs Federal agencies to reduce the regulatory burden on regulated entities and control regulatory costs. E.O. 13771, however, applies only to significant regulatory actions, as defined in Section 3(f) of E.O. 12866. Thus, E.O. 13771 does not apply to this rulemaking.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis for rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish notice of a proposed rule. (*See* 5 U.S.C. 603(a) and 604(a)). For the reasons described above, this rule is exempt from the notice publication requirement of the APA, therefore, the RFA does not apply.

Small Business Regulatory Enforcement Fairness Act

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

(1) Does not have an annual effect on the economy of $100 million or more;

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

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

Unfunded Mandates Reform Act of 1995

This rule does not impose an unfunded mandate on State, local, or tribal governments, or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments or the private sector. Therefore, a statement containing the information required by the Unfunded

Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

Takings Implication Assessment (E.O. 12630)

This rule does not effect a taking of private property or otherwise have takings implications under E.O. 12630. Therefore, a takings implication assessment is not required.

Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. To the extent that State and local governments have a role in Outer Continental Shelf activities, this rule will not affect that role. Therefore, a federalism summary impact statement is not required.

Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(1) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(2) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. This rule has been evaluated under the Department of the Interior's consultation policy, under Departmental Manual Part 512 Chapters 4 and 5, and under the criteria in E.O. 13175. It has been determined that the rule will have no substantial direct effects on Federally-recognized Indian tribes or Alaska Native Claims Settlement Act (ANCSA) Corporations, and that consultation under the Department of the Interior's tribal and ANCSA consultation policies is not required.

Paperwork Reduction Act (PRA) of 1995

This rule does not contain new information collection requirements, and a submission to the OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act of 1969 (NEPA) is not required because, as a regulation of an administrative nature, this rule is covered by a categorical exclusion (*see* 43 CFR 46.210(i)). BSEE also determined that the rule does not implicate any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. Therefore, a detailed statement under NEPA is not required.

Data Quality Act

In developing this rule, we did not conduct or use a study, experiment, or survey requiring peer review under the Data Quality Act (Pub. L. 106–554, app. C, sec. 515, 114 Stat. 2763, 2763A–153–154).

Effects on the Nation's Energy Supply (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. The rule is not likely to have a significant adverse effect on the supply, distribution, or use of energy. A Statement of Energy Effects is not required.

Clarity of This Regulation

We are required by E.O. 12866, E.O. 12988, and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in the **ADDRESSES** section. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that you find unclear, which sections or sentences are too long, the sections where you feel lists or tables would be useful, *etc.*

List of Subjects in 30 CFR Part 250

Administrative practice and procedure, Continental shelf, Environmental impact statements, Environmental protection, Incorporation by reference, Investigations, Oil and gas exploration, Penalties, Pipelines, Reporting and recordkeeping requirements, Sulfur.

Casey Hammond,

Principal Deputy Assistant Secretary, Land and Minerals Management.

For the reasons stated in the preamble, BSEE amends 30 CFR part 250 as follows:

PART 250—OIL AND GAS AND SULFUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for part 250 continues to read as follows:

Authority: 30 U.S.C. 1751, 31 U.S.C. 9701, 33 U.S.C. 1321(j)(1)(C), 43 U.S.C. 1334.

Subpart A—General

■ 2. Amend § 250.198 by revising paragraphs (e)(8), (9), (11), (12), (14), and (16), (e)(20) through (24), (e)(26) through (28), (e)(34), (e)(43) through (46), and (e)(50) and (55) to read as follows:

§ 250.198 Documents incorporated by reference.

* * * * *

(e) * * *

(8) API MPMS Chapter 2—Tank Calibration, Section 2A—Measurement and Calibration of Upright Cylindrical Tanks by the Manual Tank Strapping Method, First Edition, February 1995; reaffirmed August 2017; incorporated by reference at § 250.1202;

(9) API MPMS Chapter 2—Tank Calibration, Section 2B—Calibration of Upright Cylindrical Tanks Using the Optical Reference Line Method, First Edition, March 1989; reaffirmed April 2019 (including Addendum 1, October 2019); incorporated by reference at § 250.1202;

* * * * *

(11) API MPMS Chapter 3—Tank Gauging, Section 1B—Standard Practice for Level Measurement of Liquid Hydrocarbons in Stationary Tanks by Automatic Tank Gauging, Second Edition, June 2001; reaffirmed February 2016; incorporated by reference at § 250.1202;

(12) API MPMS Chapter 4—Proving Systems, Section 1—Introduction, Third Edition, February 2005; reaffirmed June 2014; incorporated by reference at § 250.1202;

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(14) API MPMS Chapter 4—Proving Systems, Section 4—Tank Provers, Second Edition, May 1998, reaffirmed May 2015; incorporated by reference at § 250.1202;

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(16) API MPMS Chapter 4—Proving Systems, Section 6—Pulse Interpolation,

Second Edition, May 1999; Errata April 2007; reaffirmed October 2013; incorporated by reference at § 250.1202;

* * * * *

(20) API MPMS Chapter 5—Metering, Section 2—Measurement of Liquid Hydrocarbons by Displacement Meters, Third Edition, September 2005; reaffirmed July 2015; incorporated by reference at § 250.1202;

(21) API MPMS Chapter 5—Metering, Section 3—Measurement of Liquid Hydrocarbons by Turbine Meters, Fifth Edition, September 2005; reaffirmed August 1, 2014; incorporated by reference at § 250.1202;

(22) API MPMS Chapter 5—Metering, Section 4—Accessory Equipment for Liquid Meters, Fourth Edition, September 2005; reaffirmed August 2015; incorporated by reference at § 250.1202;

(23) API MPMS Chapter 5—Metering, Section 5—Fidelity and Security of Flow Measurement Pulsed-Data Transmission Systems, Second Edition, August 2005; reaffirmed August 2015; incorporated by reference at § 250.1202;

(24) API MPMS Chapter 5—Metering, Section 6—Measurement of Liquid Hydrocarbons by Coriolis Meters; First Edition, October 2002; reaffirmed November 2013; incorporated by reference at § 250.1202;

* * * * *

(26) API MPMS Chapter 6—Metering Assemblies, Section 1—Lease Automatic Custody Transfer (LACT) Systems, Second Edition, May 1991; reaffirmed May 2012; incorporated by reference at § 250.1202;

(27) API MPMS Chapter 6—Metering Assemblies, Section 6—Pipeline Metering Systems, Second Edition, May 1991; reaffirmed December 2017; incorporated by reference at § 250.1202;

(28) API MPMS Chapter 6—Metering Assemblies, Section 7—Metering Viscous Hydrocarbons, Second Edition, May 1991; reaffirmed March 2018; incorporated by reference at § 250.1202;

* * * * *

(34) API MPMS Chapter 10—Sediment and Water, Section 1—Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method, Third Edition, November 2007; reaffirmed October 2012; incorporated by reference at § 250.1202;

* * * * *

(43) API MPMS, Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 1—Introduction, Second Edition, May 1995; reaffirmed March 2014; incorporated by reference at § 250.1202;

(44) API MPMS, Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 2—Measurement Tickets, Third Edition, June 2003; reaffirmed February 2016; incorporated by reference at § 250.1202;

(45) API MPMS Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 3—Proving Reports; First Edition, October 1998, reaffirmed March 2014; incorporated by reference at § 250.1202(a) and (g);

(46) API MPMS Chapter 12—Calculation of Petroleum Quantities, Section 2—Calculation of Petroleum Quantities Using Dynamic Measurement Methods and Volumetric Correction Factors, Part 4—Calculation of Base Prover Volumes by the Waterdraw Method, First Edition, December 1997; reaffirmed September 2014; incorporated by reference at § 250.1202(a), (f), and (g);

* * * * *

(50) API MPMS, Chapter 14.5/GPA Standard 2172–09; Calculation of Gross Heating Value, Relative Density, Compressibility and Theoretical Hydrocarbon Liquid Content for Natural Gas Mixtures for Custody Transfer; Third Edition, January 2009; reaffirmed February 2014; incorporated by reference at § 250.1203;

* * * * *

(55) API MPMS Chapter 21—Flow Measurement Using Electronic Metering Systems, Section 2—Electronic Liquid Volume Measurement Using Positive Displacement and Turbine Meters; First Edition, June 1998; reaffirmed October 2016; incorporated by reference at § 250.1202(a);

* * * * *

Subpart L—Oil and Gas Production Measurement, Surface Commingling, and Security

§ 250.1203 [AMENDED]

■ 3. In § 250.1203(b)(4), at the end of the last sentence, add ''(incorporated by reference as specified in § 250.198)''.

[FR Doc. 2020–27238 Filed 12–23–20; 8:45 am]

BILLING CODE 4310–VH–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 44

[Docket ID: DOD–2020–OS–0041]

RIN 0790–AL00

Screening the Ready Reserve

AGENCY: Office of the Under Secretary of Defense, Personnel & Readiness (Manpower and Reserve Affairs), Department of Defense (DoD).

ACTION: Interim final rule.

SUMMARY: In light of the Administration's continuing response to COVID–19, DoD is amending the CFR to aid civilian employers in more quickly identifying key employees so the Department can better understand the capacity and capability available to support the response to the current pandemic and to avoid military-civilian manpower conflicts in future Declarations of National Emergency or in military mobilizations.

DATES: This rule is effective December 28, 2020. Comments must be received by February 26, 2021.

ADDRESSES: You may submit comments, identified by docket number and/or Regulatory Information Number (RIN) number and title, through the Federal Rulemaking Portal at *http://www.regulations.gov.* Follow the instructions for submitting comments. DoD cannot receive written comments at this time due to the COVID–19 pandemic. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing as they are received, without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: CAPT Daryl P. Schaffer, 703–697–3837.

SUPPLEMENTARY INFORMATION: DoD's internal policy, DoD Directive 1200.7, Screening the Ready Reserve, at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/120007p.pdf*) establishes requirements for federal government employers and this rule parallels those requirements for application to non-federal employers, *i.e.,* all employers not of the federal government (state, local, non-profit, private, self-employed, etc.), hereafter referred to as ''employer.''

Legal Authority

10 U.S. Code 12302 authorizes the President to recall up to one million reservists for up to two years in times of national emergency 10 U.S.C. 10149,

''Ready Reserve: continuous screening'' requires the Secretary to provide a system of continuous screening of units and members of the Ready Reserve to ensure:

(1) No significant attrition of those members or units during a mobilization.

(2) a proper balance of military skills.

(3) those with military skills for which there is an overriding requirement, members having critical civilian skills are not retained in numbers beyond the need for those skills.

(4) recognition will be given to participation in combat and national security and military requirements.

(5) members whose mobilization in an emergency would result in an extreme personal or community hardship are not retained in the Ready Reserve.

Background

The Ready Reserve.is the category of reservists most often called to active duty. It consists of three subcategories: Selected Reserve, Individual Ready Reserve, and Inactive National Guard.

The Selected Reserve are the first to be activated. Most reservists are in this category.

The Individual Ready Reserve (IRR) is made up mainly of those who have had training and served in an active component.

The Inactive National Guard are those who leave active drilling status in the Army National Guard before completing their enlistment and will be put in this category unless they specifically request a transfer to the IRR. Only the Army maintains an Inactive National Guard.

If a reservist is unable to meet the requirements to be recalled, the respective Military Service shall discharge, retire, or transfer the member to the Standby Reserve. The Standby Reserve are reservists who maintain their military affiliation but are not members of the Ready Reserve. This may include reservists who fill key federal positions as well as members whose civilian employers designate their job as crucial to national security.

Recall consideration will include length and nature of previous service, family responsibilities, and necessary national interest employment.

For example, if a health care professional can do society more good as a civilian, that individual may be exempted from recall. If reservists has serious family responsibilities, they may be exempted. The law may also exempt veterans with some disabilities, medical conditions, or certain separation codes from any involuntary recall.

On March 27, 2020, the Administration issued E.O. 13912, *National Emergency Authority To Order the Selected Reserve and Certain Members of the Individual Ready Reserve of the Armed Forces to Active Duty* at *https://www.federalregister.gov/documents/2020/04/01/2020-06985/national-emergency-authority-to-order-the-selected-reserve-and-certain-members-of-the-individual*. While other authorizations are available for recall of the Ready Reserve, this E.O. was required to allow the Secretary of Defense the maximum flexibility for this national emergency to call up Ready Reserve members to help in the country's response to COVID–19. On April 2, 2020, the Secretary of Defense issued *Guidance on Activating the National Guard, Reserve, and Individual Ready Reserve for Coronavirus Disease Response,* at *https://prhome.defense.gov/Portals/52/Guidance%20on%20Activating%20the%20National%20Guard%20Reserve%20and%20IRR%20for%20COVID-19%20OSD003539-20%20RES%20Final%201.pdf* describing how the Military Services can activate the National Guard and the Ready Reserve to support the domestic response to COVID–19.

Expected Impact of the Changes by This Interim Rule

DoD's revisions are meant to support military mobilization without diminishing the civilian national coronavirus response. The publication of this rule is meant to enhance civilian employer awareness of the need to provide early identification of critical civilian positions within their organizations and, in coordination with the Military Services, allow the service member to be considered for service not as a Ready Reserve member who is factored into military mobilization planning.

This rule only discusses employee and employer actions before a mobilization. After a mobilization is ordered, no deferment, delay, or exemption from mobilization will be granted because of civilian employment. The Uniformed Services Employment and Reemployment Rights Act (USERRA), 1994 Public Law 103–353, as amended at 38 U.S.C. 4301–4335, affords reservists and employers various rights and responsibilities regarding reemployment of their civilian position. Employers must ensure key position determinations are not undertaken in a manner that would violate USERRA, its implementing regulations at 20 CFR part 1002, or other federal statutes and regulations.

Civilian employers, usually through their onboarding programs, identify key employees to ensure the Military Services have an accurate assessment of Ready Reserve members. This assessment of employees who have a Ready Reserve affiliation is meant to preclude conflicts between a member's mobilization requirements and non-Federal civilian employment obligations during times of war or national emergency. Ready Reserve members with critical civilian skills should work with their employer before mobilization. The efforts of civilian employers and their employees pre-mobilization will help identify employees who are required for the ongoing civilian response to the pandemic. While Ready Reserve members are already required to be screened by their respective Military Service per 10 U.S.C. 10149 and to work with their employer to ensure those with critical civilian skills are identified, these updates to the CFR will ensure a more accurate accounting of capability and capacity of the specialties required for COVID–19 response.

This rule updates the naming of current offices within the Office of the Secretary of Defense (OSD), provides current information on service points of contact, and removes previous language pertaining to federal government employers to more succinctly clarify employer responsibilities to petition the respective Military Service of Ready Reserve members that may have a conflict with their employment prior to a military mobilization. These changes highlight how a civilian employer, based on their capability and capacity during either normal or extenuating circumstances such as the ongoing COVID–19 response, petitions a Military Service on behalf of a Ready Reserve employee who occupies a key position within a company or occupies a position where military mobilization would create an extreme personal or community hardship. Employers are encouraged to assess the internal capabilities of their own positions and the organic capacity to sustain emergency manpower needs prior to a military mobilization which can produce an accurate listing of what they consider key positions to their organization.

DoD last modified this section of the CFR, *Screening the Ready Reserve* on December 23, 1999 (64 FR 72027). Many of the changes support a recommendation of the DoD Regulatory Reform Task Force to redact parts related to Federal Employers as the current rule contains the entire content of DoD's internal Directive which is unnecessary for civilian employers. The

revisions remove all text not applicable to the public and the retained text was updated or edited for clarity.

The following is a summary of changes by section:

Section 44.1 Purpose. Updated U.S. Code.

Section 44.2 Applicability. Removed all text and replaced with non-Federal employers statement.

Section 44.3 Definitions. Removed ''Extreme personal hardship'' as this request is submitted by the member, not the employer. Added ''Inactive National Guard.'' Removed all Federal implications in ''Key position'' and retained only the first statement for non-Federal applicability. Removed internal process text from ''Mobilization.'' Removed internal process text from ''Selected Reserve.'' Removed ''Standby Reserve'' as non-applicable to the public.

Section 44.4 Policy. Retained (a), merged (a)(1) and (a)(2), renumbered (a)(3) to (a)(2). Renumbered (b) to (d) and removed internal process text. Renumbered (f) to (b). Renumbered (g) to (c). Removed (c), (d), (e), (h), (i), (j), and (k) as internal processes text and non-applicable to the public.

Section 44.5 Responsibilities. Adjusted responsibilities based on OSD restructure. Renamed (a) to USD(P&R) and retained text with edits for clarity. Renamed (b) to ASD(M&RA), retained (b)(5) text with edits for clarity, and removed (b)(1–4) as internal processes text and non-applicable to the public. Retained (c), added USCG, retained (c)(2–4) text with edits for clarity, removed (c)(1, 5–10) as internal processes text and non-applicable to the public.

Appendix A to Part 44—Guidance. Adjusted title for public applicability. Removed Deputy Secretary of Defense as internal processes text and non-applicable to the public. Merged and renamed with edits (a) and (b) to (a). Retained with edits for clarity and text non-applicable to the public (a)(1) to (b). Retained (a)(1)(i) to (b)(3) with edits for clarity and text non-applicable to the public. Removed (a)(1)(ii) as internal processes and text non-applicable to the public. Retained (a)(1)(iii) to (b)(1) with edits for clarity and text non-applicable to the public. Retained (a)(1)(iv)(A–F) to (b)(2)(i–vi). Removed (2). Retained (b) to (a). Retained (c) and merged ''List of . . .'' into (c). Updated contact information and added website.

When this rule is published, DoD will also update and publish its internal instruction—DoD Instruction 1200.07, ''Screening the Ready Reserve''—for all applicable changes.

Costs

As this is an administrative update to an existing Rule, DoD believes the economic impact to civilian employers is de minimis, estimating a cumulative total of $11K across all employers nationwide. Under the existing Rule, employers are already required to identify employees who are Ready Reserve members and this rulemaking does not alter that requirement. The cost to employers of screening is already imbedded in their HR processes. The estimated costs if an employer submits a petition to a Military Service is calculated below and will vary based on the automation of human resource processes and the number of employees of an organization who are Ready Reserve members with critical skills. Ready Reserve members are already required to be screened by their respective Military Service per 10 U.S.C. 10149 and to work with their employers to address any concerns. The benefit of screening to the employer is to ensure those with critical civilian skills are identified in order to prevent conflicts between the emergency manpower needs of civilian and military activities during a mobilization.

The following describes how the estimated sum total of $11K was derived using existing costs to project costs of a petition. Using data from the U.S. Bureau of Labor Statistics, U.S. Census, DoD Total Military Strength report, and the DoD Status of Forces survey, less than 0.3% of the U.S. population is in the Reserve, including the National Guard, with 51% employed by the public [Federal (36%), State (9%), or Local (6%)]. There were 1,020,156 Military Service members in the Ready Reserve as of March 2020 and over 782,000 of those members are estimated to have civilian employment. Approximately 0.3% of the 782,000, or 2,346 members, may be identified as key civilian employees and may require a petition. The 2019 median hourly wage for an HR professional or manager is $34.92 an hour. The cost to screen one employee as part of an onboarding process questionnaire or through an annual recertification process, which is estimated at less than 10 minutes or $5.82, is already imbedded in their HR processes and thus not included here. The cost to prepare a petition on one employee is estimated at 2 hours, or $69.84. Applying a more appropriate and realistic planning factor of 0.3% to reflect key positions in civilian organizations reflects a projected annual cost, collectively from all employers, of $11,095.

Cost Benefit Analysis Assumptions and Sources

It should be noted, not every Ready Reserve member in a company would be considered in a ''key position'' and therefore, a petition would not be needed on every member. The estimated cost presented encompasses all 1,020,156 Ready Reserve members and a 0.3% planning factor. Assumptions in cost calculation include: U.S. population: 329,648,880 (as of May 14, 2020, source: *https://www.census.gov/*); Ready Reserve: 1,020,156 (as of March 31, 2020, source: Total Military Strength report obtained from the Defense Manpower Data Center (DMDC) from each Military Service HR system of record); Percent of U.S. population in the Ready Reserve (Reserve/US population): 0.0030947 or 0.3%. Based on these data points, a projected 0.3% of employers in the country employ a Ready Reserve member. The Bureau of Labor Statistics at the end of March 2020 reported a U.S. working population of 155,167,000 with 16,294,000 working office/admin (human resources/HR). Applying the projected 0.3% of employers with Ready Reserve members (HR*0.3%) reflects 48,882 HR employees to address Ready Reserve members for their employer. With a median salary for HR Manager/Specialist of $34.92/hour, an annual screening is estimated to take 10 min (Rate/6) or $5.82 and to prepare a petition package to take 2 hours (Rate*2) or $69.84. Only the petition calculation is include as the annual screening is already imbedded in HR processes.

Data from 2018 DoD Status of Forces Survey reflects the following breakdown of principal civilian employment before most recent activation: Federal Government 36%; State government 9%; Local government 6%; Private/public company 43%; Non-profit 3%; Self-employed 2%; and Family business/farm/unemployed 1%. The below table reflects the costs of the 48,882 HR employees who would be preparing petitions on the Ready Reserve members in their organization.

SCREENING READY RESERVE/NATIONAL GUARD COST ANALYSIS

	%	# Employees	2-hr at 0.3% planning factor
Private	49	23,952	$5,018.46
Federal	36	17,598	3,687.03
State	9	4,399	921.76
Local	6	2,933	614.51
Grand Total	100	48,882	11,095.24

Cost to the DoD. These estimates (0.3% of 782,000 Ready Reserve members fill key positions) indicate the Military Services would adjudicate approximately 2,346 members, a number well within the normal processing by all Military Service Reserve centers and therefore would not add additional costs.

Interim Final Rule Justification

DoD is issuing this rulemaking as an interim final rule and has determined that, under the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), it would be impracticable and contrary to the public interest to delay a final regulation until a public notice and comment process has been completed.

Since March 2020, DoD's response to the pandemic has grown from a few thousand Ready Reserve members deployed primarily to states in the northwest and northeast to currently over 40,000 members deployed throughout the United States. The conclusion of a public notice and comment period before the rule is finalized would be impracticable because it would impede agile and timely execution of DoD's response to current pandemic and ongoing natural disaster support. Requests for DoD support to all states has evolved and grown over the last 7 months and the Department anticipates it will continue through the development and deployment of a vaccine over the next two years. Additionally, the Military Services continue to support other domestic response actions such as providing local protection during civil disturbances throughout the country, supporting disaster response for wildfires and hurricanes and continuing to support election requirements. Given these competing requests and the length of time required for pandemic response involving DoD personnel, the Department needs to continue to consider the proper balance of a civilian employees responsibilities within their communities for pandemic and disaster response and increasing requests from States for additional DoD resources. Given the pandemic's evolution and increasing request for DoD resources over the last seven months, the effort to begin rulemaking in this area was delayed at the start of the pandemic. The current requirements and the need to support both the military and civilian response for the pandemic, natural disasters, and social unrest has left DoD with insufficient time to prepare and complete a full public notice and comment rulemaking proceeding to timely complete a final rule.

Early in the response to pandemic, limited information from employers regarding Ready Reserve members in key positions created an initial delay in understanding true capacity and capability of civilian medical providers who are also Ready Reserve members and could be factored into military mobilization planning. The publication of the rule will encourage the early identification of critical civilian employees and, in coordination with the Military Services, allow the service member to be counted in the Ready Reserve. Given the nature of the COVID–19 pandemic and an anticipated requests for resources through vaccine deployment, delaying this notice to employers through a proposed rule may hinder DoD's ability to determine the size of medical personnel available for deployment which would impede immediate action to protect the public health.

For these reasons, DoD has determined that the public notice and participation that the APA ordinarily requires would, in this case, be impracticable, unnecessary, and contrary to the public interest and that good cause exists for waiving proposed rulemaking and delaying its solicitation of comments from the public until after it issues an interim final rule. DoD will consider those comments received upon its interim final rulemaking in a subsequent final rule. Additionally, and for the same reasons discussed above, DoD has determined there is good cause to make the rule effective immediately, pursuant to 5 U.S.C. 553(d)(3).

Regulatory Analysis

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a significant regulatory action, although, not determined to be economically significant, under section 3(f) of Executive Order 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget (OMB) under the requirements of these Executive Orders.

Executive Order 13771, ''Reducing Regulation and Controlling Regulatory Costs''

This interim final rule is not subject to the requirements of Executive Order 13771 as its costs to Non-federal civilian employers are de minimis.

Costs

Additional details on the cost of this rule are discussed in the costs section of this preamble.

Benefits

Civilian Employer processes and military screening actions ensure civilian employers and the Military Services have the appropriate balance of civilian and military skills required for both parties in case of a mobilization. The challenges faced today in communities as well as in the DoD require dynamic and timely employment of our service members while reducing the conflict of those members to meet both military and or civilian requirements. Ultimately, the

response to military mobilization and civilian planning will be greatly enhanced when the essential projected response needs have been equitably calculated for a Ready Reserve member and employee. Military Service annual screening provides a vital Ready Reserve force composed of members who meet Military Service readiness standards of mental, moral, professional, and physical fitness and possess the military qualifications required in the various grades, ratings, and specialties of their Military Service; and are available immediately for active duty during a mobilization or as otherwise required by law. The tasking of a Ready Reserve member who is known to be critical to civilian response in a key position that was not previously adjudicated through the Military Service could create a delay in the civilian response and in turn create potential harm to the local community. The benefit of this Rule fosters a partnership in the appropriate balance of civilian and military assessments to meet needed requirements for a response while not decrementing each other's capacity and capability.

Alternatives

If no action were taken to update the current rule, the ability to identify medical employees with critical civilian skills needed for the COVID–19 response and to petition those critical employees to the Military Services for consideration would be reduced thus greatly impacting both military and civilian responses and creating inefficiencies in awareness and planning of medical capacity and capability. Additionally, if no action were taken, the current names of OSD officials with screening the Ready Reserve responsibilities would not be communicated to employers. This lack of action is not preferred as it would cause inefficiencies in providing medical capacity for COVID–19 response and cause confusion for employers because the list of offices to which petitions must be submitted is extremely outdated. The results of this alternative are not preferred. The preferred alternative is to publish this interim final rule for public comment.

Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The Department of Defense certifies that this interim final rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact creating a substantial cost to a number of small entities. There are a small percentage of defined critical employees in the civilian sector, regardless of the national emergency, that are required to support their civilian employer. As the response to the pandemic evolved, the need for certain specialties in the response evolved. In the case of COVID–19, the immediate need was for medical providers and the situation evolved requiring additional specialties for support. In other non-federal employment areas, a critical employee may stay consistent, as in the example of a sole nuclear reactor chief within a plant who should not be in the Ready Reserve as he or she would be required to mobilize if called upon and not be able to perform the critical civilian skill. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Congressional Review Act

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

Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $167 million in 2019 dollars, updated annually for inflation. It is estimated this interim final rule will not substantially affect State, local, or tribal governments and private sector costs any more than the previous rule requirements.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

It has been determined that 32 CFR part 44 does not impose reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995.

Executive Order 13132, ''Federalism''

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates an interim final rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Like the current rule, it is estimated this interim final rule will not have a substantial effect on State and local governments, where 9% and 6% respectively employ Ready Reserve, including the National Guard, members.

List of Subjects in 32 CFR Part 44

Armed forces reserves.

For the reasons stated in the preamble, the Department of Defense revises 32 CFR part 44 to read as follows:

PART 44–SCREENING THE READY RESERVE

Sec.
44.1 Purpose.
44.2 Applicability.
44.3 Definitions.
44.4 Policy.
44.5 Responsibilities.

Appendix A to Part 44—Guidance for Employers of Ready Reservists

Authority: 10 U.S.C. 10149.

§ 44.1 Purpose.

This rule updates Department of Defense (DoD) policy and responsibilities for the screening of Ready Reservists under 10 U.S.C. 10149.

§ 44.2 Applicability.

This rule applies to non-Federal employers of Ready Reservists filling key positions.

§ 44.3 Definitions.

For purposes of this part, the following definitions apply:

Extreme community hardship. A situation that, because of a Reserve member's mobilization, may have a substantially adverse effect on the health, safety, or welfare of the community. Any request for a determination of such hardship will be made by the Reserve member and must be supported by documentation, as required by the Secretary of the Military Department concerned.

Inactive National Guard (ING). Members of the National Guard in an inactive status in the Ready Reserve and attached to a specific National Guard unit. These members do not participate in training activities but mobilize with their unit of assignment or with other units within their State on partial or full

mobilization. They are not subject to a call-up pursuant to 10 U.S.C. 12304.

Individual Ready Reserve (IRR). A manpower pool within the Ready Reserve of each of the RCs consisting of individuals who have had some training or who have served previously in the AC or in the Selected Reserve, and may have some period of their MSO remaining pursuant to 10 U.S.C. 651. The IRR consists of members of the Ready Reserve who are not in the Selected Reserve or the ING. Additionally, the IRR also includes some personnel who are participating in officer training programs or in the Armed Forces Health Professions Scholarship and Financial Assistance Programs.

Key employee. Any non-federal employee occupying a key position within an agency, company, local government, or organization.

Key position. A public or private civilian position, not a job series, designated by the employer and approved by the Secretary of the Military Department concerned) that cannot be vacated during war or national emergency.

Mobilization. The process by which the Armed Forces of the United States, or part of them, are brought to a state of readiness for war or other national emergency.

Ready Reserve. The Selected Reserve and Individual Ready Reserve liable for active duty as prescribed by law.

Selected Reserve. Those units and individuals within the Ready Reserve designated by their respective Military Service and approved by the Joint Chiefs of Staff as so essential to initial wartime missions that they have priority over all other reserves.

§ 44.4 Policy.

It is DoD policy that:

(a) Members of the Ready Reserve shall be screened (see the appendix to this part for specific screening guidance) at least annually to meet the provisions of 10 U.S.C. 10149 and to provide a Ready Reserve force composed of members who:

(1) Meet Military Service readiness standards of mental, moral, professional, and physical fitness and possess the military qualifications required in the various ranks, ratings, and specialties.

(2) Are available immediately for active duty (AD) during a mobilization or as otherwise required by law.

(b) Ready Reserve members whose immediate recall to AD during an emergency would create an extreme personal or community hardship shall be transferred to the Standby Reserve or the Retired Reserve, or shall be discharged, as applicable.

(c) Ready Reserve members who occupy key positions shall be transferred to the Standby Reserve or the Retired Reserve, or shall be discharged, as appropriate.

(d) After a mobilization is ordered, no deferment, delay, or exemption from mobilization will be granted to Ready Reserve members because of their civilian employment.

§ 44.5 Responsibilities.

(a) The Under Secretary of Defense for Personnel and Readiness (USD(P&R)) adjudicates, before mobilization, conflicts the Ready Reserve screening process has identified, but has not resolved, between the mobilization manpower needs of the civilian sector and the Military Services.

(b) The Assistant Secretary of Defense for Manpower and Reserve Affairs (ASD(M&RA)), under the USD(P&R), coordinates resolution of conflicts between the mobilization manpower needs of the civilian sector and the Military Services identified but not resolved through the Ready Reserve screening process.

(c) The Secretaries of the Military Departments and Commandant, United States Coast Guard, ensure coordination with the ASD(M&RA) to resolve conflicts (identified, but not resolved through the Ready Reserve screening process) between the mobilization manpower needs of the civilian sector and the military. They will review petitions submitted by employers, take applicable action, and promptly transmit the results of that determination to the reservist concerned and their employer after making a determination in response to the petition. Materials provided or produced with regard to the petition will be retained by the Secretary Concerned.

Appendix A to Part 44—Guidance for Employers of Ready Reservists

(a) Employers of Ready Reserve members. Prior to any mobilization action, employers of Ready Reserve members are encouraged to adopt personnel management procedures designed to prevent conflicts between the emergency manpower needs of civilian and military activities that may occur during a military mobilization requiring Ready Reserve participation. Employers are encouraged to assess the internal capabilities of their own positions and the organic capacity to sustain emergency manpower needs prior to a military mobilization which can produce an accurate listing of what they consider key positions to their organization. Employers, via the head of or suitable designee within an agency, company, local government, or organization, are encouraged to use the below key position guidelines as a reference for considering designations and, when applicable, petitioning the respective Military Service if a Ready Reserve member fills a key position. Nothing in this part shall reduce, limit, or eliminate in any manner any right or benefit provided by USERRA. Employers must ensure that key position determinations are not undertaken in a manner that would violate USERRA.

(b) Key position guidelines:

(1) Designate individual positions that are essential in nature to, and within, the organization as ''key positions,'' and require they will not be filled by Ready Reserve members to prevent such positions from being vacated during a mobilization.

(2) Consider the following questions to determine whether an individual position should be designated as a key position:

(i) Can the position be filled in a reasonable time after mobilization? (Note that this factor must not be the sole factor relied on in making a key position determination.)

(ii) Does the position require technical or managerial skills that are possessed uniquely by the incumbent employee?

(iii) Is the position associated directly with defense mobilization?

(iv) Does the position include a mobilization or relocation assignment in a federal agency that has emergency functions, as designated by E.O. 12656?

(v) Is the position directly associated with industrial or manpower mobilization, as designated in E.O.s 12656 and 12919?

(vi) Are there other factors related to the national defense, health, or safety that will make the incumbent of the position unavailable for mobilization? These factors should not be applied more broadly than intended as to encompass an entire class of workers, nor misapplied to conflict with USERRA, its implementing regulations at 20 CFR part 1002, or other federal statutes and regulations.

(3) Conduct an annual review of key positions and employees as noted herein.

(4) Petition to the respective Military Service any findings for adjudication of specific Ready Reserve members filling critical positions, as needed.

(5) When employers consider a Ready Reserve member as filling a key position within their organization, they should petition the applicable Reserve personnel center for discussion and adjudication. An employer may not take any employment action with regard to the position for which approval is sought based upon an employee or potential employee's military service until such time as the petition for approval has been approved by the relevant Service Secretary. Below is the list of Reserve personnel centers to which petitions shall be forwarded:

Army Reserve: U.S. Army Human Resources, Command 1600 Spearhead Division, Avenue ATTN: AHRC–ROR–PPA, Fort Knox, KY 40122–5100, *https://www.hrc.army.mil/*

Navy Reserve: Commander, Naval Military Personnel Command (Pers 91), 5720 Integrity Drive, Millington, TN 38055–9100, *https://www.public.navy.mil/bupers-npc/Pages/default.aspx*

Marine Corps Reserve: Director, Marine Corps Individual Reserve Support Activity (MCIRSA), 2000 Opelousas Ave., New Orleans, LA 70114, *https://www.marforres.marines.mil/Major-Subordinate-Commands/Force-Headquarters-Group/Marine-Corps-Individual-Reserve-Support-Activity/*

Air Force Reserve: Commander, Air Reserve Personnel Center/DPAM, 18420 E. Silver Creek Ave., Bldg. 390, MS 68, Buckley AFB, CO 80011, *https://www.arpc.afrc.af.mil/*

Coast Guard Reserve: Commander (PSC–RPM), U. S. Coast Guard Personnel Service Center, 2703 Martin Luther King Jr Ave. SE, Stop 7200, Washington, DC 20593–7200, *https://www.dcms.uscg.mil/Our-Organization/Assistant-Commandant-for-Human-Resources-CG-1/Personnel-Service-Center-PSC/Reserve-Personnel-Management-PSC-RPM/*

Army and Air National Guard: Submit petitions to the Adjutant General of the appropriate State, Territory, or the District of Columbia.

Dated: December 21, 2020.

Patricia L. Toppings,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–28646 Filed 12–22–20; 4:15 pm]

BILLING CODE 5001–06–P

LIBRARY OF CONGRESS

U.S. Copyright Office

37 CFR Part 210

[Docket No. 2020–5]

Music Modernization Act Notices of License, Notices of Nonblanket Activity, Data Collection and Delivery Efforts, and Reports of Usage and Payment

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

ACTION: Supplemental interim rule with request for comments.

SUMMARY: The U.S. Copyright Office is amending its regulations governing certain reporting requirements of digital music providers and significant nonblanket licensees pursuant to title I of the Orrin G. Hatch-Bob Goodlatte Music Modernization Act. This amendment will create a temporary exception to certain provisions concerning the reporting of information about permanent download pass-through licenses in light of recent requests that an accommodation to current reporting rules be made to avoid potential market disruption. Based on these requests received following the adoption of the current requirements, the Copyright Office has determined that there is a legitimate need to make this amendment effective immediately to govern these matters while it considers further potential adjustments. The Copyright Office solicits public comment on how, or whether, it should further adjust these particular reporting requirements.

DATES: The supplemental interim rule is effective December 28, 2020. Written comments must be received no later than 11:59 p.m. Eastern Time on January 27, 2021.

ADDRESSES: For reasons of Government efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments are therefore to be submitted electronically through *regulations.gov.* Specific instructions for submitting comments are available on the Copyright Office's website at *https://www.copyright.gov/rulemaking/mma-notices-reports/.* If electronic submission of comments is not feasible due to lack of access to a computer and/or the internet, please contact the Copyright Office using the contact information below for special instructions.

FOR FURTHER INFORMATION CONTACT: Regan A. Smith, General Counsel and Associate Register of Copyrights, by email at *regans@copyright.gov,* Jason E. Sloan, Assistant General Counsel, by email at *jslo@copyright.gov,* or Cassandra G. Sciortino, Attorney-Advisor, by email at *csciortino@copyright.gov.* Each can be contacted by telephone by calling (202) 707–8350.

SUPPLEMENTARY INFORMATION:

I. Background

On October 11, 2018, the President signed into law the Orrin G. Hatch-Bob Goodlatte Music Modernization Act (''MMA'') which, among other things, substantially modifies the compulsory ''mechanical'' license for making and distributing phonorecords of nondramatic musical works under 17 U.S.C. 115.[1] It does so by switching from a song-by-song licensing system to a blanket licensing regime that will become available on January 1, 2021 (the ''license availability date''), and will be administered by a mechanical licensing collective (''MLC'') designated by the Copyright Office (the ''Office''). Digital music providers (''DMPs'') will be able to obtain the new compulsory blanket license to make digital phonorecord deliveries (''DPDs'') of musical works, including in the form of permanent downloads, limited downloads, or interactive streams (referred to in the statute as ''covered activity'' where such activity qualifies for a compulsory license), subject to compliance with various requirements, including reporting obligations.[2] DMPs may also continue to engage in those activities solely through voluntary, or direct, licensing with copyright owners, in which case the DMP may be considered a significant nonblanket licensee (''SNBL'') under the statute, subject to separate reporting obligations.

On September 17, 2020, the Office issued an interim rule adopting regulations concerning certain types of reporting required under the statute after the license availability date: Notices of license and reports of usage by DMPs, and notices of nonblanket activity and reports of usage by SNBLs.[3] Those interim regulations include requirements to report certain information about certain permanent download licenses.[4] They were adopted to help ensure that the MLC receives sufficient information to be able to fulfill its statutory obligations, including under section 115(d)(3)(G)(i)(I)(bb), and to effectuate the reporting requirements of section 115(d)(4)(A)(ii)(II). The Office assumes familiarity with the interim rule and all related **Federal Register** documents.

After the adoption of these rules, which involved multiple rounds of public comments through a notification of inquiry,[5] notice of proposed rulemaking,[6] and an *ex parte* communications process,[7] the DLC raised a new concern with respect to the applicability of these particular reporting provisions to ''pass-through'' licenses for permanent downloads.[8] The DLC explained that ''all [DMPs operating] download stores operate exclusively under so-called 'pass-through' licenses received from record labels, where the label obtains the

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

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

[3] 85 FR 58114 (Sept. 17, 2020).

[4] 37 CFR 210.24(b)(8), 210.25(b)(6), 210.27(c)(5), 210.28(c)(5).

[5] 84 FR 49966 (Sept. 24, 2019).

[6] 85 FR 22518 (Apr. 22, 2020).

[7] Guidelines for *ex parte* communications, along with records of such communications, including those referenced herein, are available at *https://www.copyright.gov/rulemaking/mma-implementation/ex-parte-communications.html.* All rulemaking activity, including public comments, as well as educational material regarding the Music Modernization Act, can currently be accessed via navigation from *https://www.copyright.gov/music-modernization/.*

[8] *See* DLC *Ex Parte* Letter Nov. 10, 2020 at 4–7.

mechanical licenses from musical work copyright owners and then authorizes downstream distributors to make and distribute permanent downloads.'' [9] The Office notes that this reflects that the scope of ''pass-through'' licensing under section 115 shrank under the MMA, which eliminated the ability of record labels to ''pass-through'' section 115 licenses for streaming or limited downloads.[10]

The underlying mechanical license pursuant to which the DMP has been given authority for permanent downloads by a record label can be a compulsory license or a voluntary license. Under the MMA, the compulsory version is defined as an ''individual download license,'' which is ''a compulsory license obtained by a record company to make and distribute, or authorize the making and distribution of, permanent downloads embodying a specific individual musical work.'' [11] The non-compulsory version (a ''voluntary pass-through license'') does not appear to be directly addressed by the MMA, but in general the MMA provides for preexisting voluntary licenses to remain in effect after the license availability date.[12]

The DLC raised the concern that the relevant reporting requirements set forth in the interim regulations require DMPs and SNBLs operating under the authority of pass-through licenses to report certain information about such licenses, including identification and contact information for relevant musical work copyright owners that they do not have.[13] The DLC stated that:

> This information is not provided by record labels to download stores through existing reporting mechanisms . . . and for this to occur would require record labels and digital music providers to invest resources to build entirely new systems. The reality is that services are not likely to make those investments, especially because purchases of permanent downloads, while still significant, are declining. It is far more likely that download stores would simply cease operations.[14]

The DLC submitted proposed regulatory amendments to address their concerns, which the MLC does not object to.[15] The MLC and DLC are in agreement that ''allowing the existing rules to go into effect without alteration would cause market disruption for permanent download offerings.'' [16] The DLC's proposal is available in Addendum B of the *ex parte* letter available at: *https://www.copyright.gov/rulemaking/mma-implementation/ex-parte/mlc-and-dlc.pdf.*

II. Supplemental Interim Rule and Request for Comments

The Office tentatively agrees that this issue needs to be addressed and is therefore noticing the matter for public comment. In the meantime, the Office finds it necessary and appropriate under its authority pursuant to 17 U.S.C. 115 and 702 to adjust the interim rule, effective immediately, to prevent potential market disruption that the MLC and DLC are concerned about occurring while the Office solicits comments and continues to consider how best to proceed with respect to this issue.[17] The supplemental interim rule creates a temporary exception to the previously adopted reporting requirements with respect to individual download licenses and voluntary pass-through licenses, such that the failure to report that particular information will not otherwise impact a DMP's or SNBL's compliance with their various requirements under the MMA and the Office's related regulations (*e.g.,* the MLC cannot use the failure to provide that particular information as a basis to reject an otherwise compliant notice of license or serve a notice of default on an otherwise compliant blanket licensee). The supplemental interim rule further provides that after the temporary exception is no longer in effect, the MLC can take action against a DMP or SNBL who benefitted from the exception if any amended reporting requirements adopted by the Office are not complied with by the DMP or SNBL within 45 days after the effective date of such an amendment (or an alternate date subsequently adopted by the Office, whichever is later). The MLC and DLC indicated that they respectively do not oppose the Office employing this approach while considering this matter.[18]

With respect to the DLC's concerns, the Office solicits comments on the DLC's proposal. As the Office understands it, the proposal would basically exempt individual download licenses and voluntary pass-through licenses from the relevant reporting requirements under the interim regulations, and would instead impose alternative requirements that the DLC views as more appropriate but that still ensure that the MLC has sufficient information to fulfill its statutory duties. In particular, the Office seeks comments regarding its authority to adopt the DLC's proposal in light of 17 U.S.C. 115(d)(4)(A)(ii)(II), which requires DMPs to ''identify and provide contact information for all musical work copyright owners for works embodied in sound recordings as to which a voluntary license, rather than the blanket license, is in effect with respect to the uses being reported.'' While the DLC argues that the statute is ''at least . . . ambiguous'' and that the Office can ''exercise its general regulatory authority to clarify this issue,'' [19] the Office is cautious about potentially concluding that the term ''voluntary license'' in that provision excludes voluntary pass-through licenses, and thus seeks further comments to aid its statutory analysis.[20] Relatedly, the Office seeks comments as to whether there are any concerns, as a matter of statutory interpretation, with interpreting the term ''voluntary license'' in section 115(d)(4)(A)(ii)(II) in the manner the DLC requests while reading the same term more broadly elsewhere in section 115, such as in the introductory paragraph of section 115(d)(4)(A)(ii).

The Office seeks clarification from the MLC and DLC, and comments from other interested stakeholders, regarding their proposed inclusion of language seeming to qualify the proposed exceptions to ''where [the DMP's] authority applies to the exclusion of the blanket license authority pursuant to 17

[9] *Id.* at 4.

[10] *See* H.R. Rep. No. 115–651, at 4 (2018) (''Subsection (b)(3) maintains the 'pass-through' license for record labels to obtain and pass through mechanical license rights for individual permanent downloads. Under the Music Modernization Act, a record label will no longer be eligible to obtain and pass through a Section 115 license to a digital music provider to engage in activities related to interactive streams or limited downloads.''); S. Rep. No. 115–339, at 4 (2018); Report and Section-by-Section Analysis of H.R. 1551 by the Chairmen and Ranking Members of Senate and House Judiciary Committees, at 3 (2018), *https://www.copyright.gov/legislation/_conference_report.pdf;* U.S. Copyright Office, *Copyright and the Music Marketplace* at 27–28 (2015), *https://www.copyright.gov/policy/musiclicensingstudy/copyright-and-the-music-marketplace.pdf* (describing previous pass-through licensing practices).

[11] 17 U.S.C. 115(e)(12).

[12] *See id.* at 115(d)(9)(C).

[13] DLC *Ex Parte* Letter Nov. 10, 2020 at 4–6.

[14] *Id.* at 5–6.

[15] DLC & MLC *Ex Parte* Letter Dec. 9, 2020 at 4, add. B.

[16] *Id.* at 4.

[17] Because of the short amount of time remaining before the January 1, 2021 license availability date, the Office finds there is good cause to adopt the temporary supplemental interim rule without public notice and comment, and to make it effective immediately upon publication. *See* 5 U.S.C. 553(b)(3)(B), (d)(3); *see also* DLC & MLC *Ex Parte* Letter Dec. 9, 2020 at 4 (supporting adoption of a temporary rule while the Office further considers this issue and agreeing that ''allowing the existing rules to go into effect without alteration would cause market disruption for permanent download offerings'').

[18] DLC & MLC *Ex Parte* Letter Dec. 9, 2020 at 4.

[19] DLC *Ex Parte* Letter Nov. 10, 2020 at 6–7.

[20] A ''voluntary license'' is a defined term under 17 U.S.C. 115(e)(36).

U.S.C. 115(d)(1)(C)(i).'' [21] This proposed language seems to suggest that the DLC and MLC believe there are types of voluntary licenses, authorizing DMPs to make and distribute permanent downloads, that would *not* apply to the exclusion of the blanket license. It is not entirely clear to the Office what is meant by this aspect of the proposal, but the Office observes that section 115(d)(1)(C) says ''[a] voluntary license for covered activities entered into by or under the authority of 1 or more copyright owners and 1 or more digital music providers, or authority to make and distribute permanent downloads of a musical work obtained by a digital music provider from a sound recording copyright owner pursuant to an individual download license, shall be given effect in lieu of a blanket license under this subsection with respect to the musical works (or shares thereof) covered by such voluntary license or individual download authority.'' [22]

Beyond the DLC's proposal, the Office invites comments more generally on how to address, or whether the Office should address, the pass-through license issue that has been raised, including whether a different approach should be taken. One potential alternative approach the Office seeks comment on could be for the Office to adopt a rule providing that any failure to comply with the previously adopted reporting requirements in 37 CFR 210.24(b)(8), 210.25(b)(6), 210.27(c)(5), or 210.28(c)(5) with respect to individual download licenses or voluntary pass-through licenses may not be construed as material noncompliance with the statute or regulations, but rather would be considered to be harmless errors, if appropriate alternative information—perhaps the information the DLC proposed—is timely reported instead. This would mean that in such cases, the harmless error provisions in place for notices of license (§ 210.24(e)), notices of nonblanket activity (§ 210.25(e)), and SNBL-submitted reports of usage (§ 210.28(k)) would apply to protect the DMP or SNBL; the statutory default provision in 17 U.S.C. 115(d)(4)(E)(i)(III) would similarly protect a DMP from being in default under the blanket license with respect to its reports of usage.

List of Subjects in 37 CFR Part 210

Copyright, Phonorecords, Recordings.

[21] *See* DLC & MLC *Ex Parte* Letter Dec. 9, 2020 add. B at 2, 3, 10.

[22] 17 U.S.C. 115(d)(1)(C).

Interim Regulations

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

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

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

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

■ 2. Add § 210.30 to read as follows:

§ 210.30 Temporary exception to certain reporting requirements about certain permanent download licenses.

(a) Subject to paragraph (b) of this section, where a requirement of § 210.24(b)(8), § 210.25(b)(6), § 210.27(c)(5), or § 210.28(c)(5) has not been satisfied with respect to an individual download license or voluntary pass-through license, such failure shall not:

(1) Render an otherwise compliant notice of license, notice of nonblanket activity, or report of usage invalid; or

(2) Provide a basis for the mechanical licensing collective to reject an otherwise compliant notice of license, serve a notice of default on an otherwise compliant blanket licensee, terminate an otherwise compliant blanket license, or engage in legal enforcement efforts against an otherwise compliant significant nonblanket licensee.

Note 1 to paragraph (a): Paragraph (a) of this section is a transitional exception that shall cease to apply in accordance with such further regulations as the Copyright Office may adopt.

(b) After paragraph (a) of this section is no longer applicable, the mechanical licensing collective may take such action(s) against a beneficiary of paragraph (a) of this section as had been prohibited by paragraph (a) when it was applicable, if an amendment adopted by the Copyright Office to a requirement of § 210.24(b)(8), § 210.25(b)(6), § 210.27(c)(5), or § 210.28(c)(5) with respect to individual download licenses or voluntary pass-through licenses is not complied with by such a beneficiary within 45 calendar days after the effective date of such an amendment, or an alternate date subsequently adopted by the Office, whichever is later. Any deadline otherwise applicable to any such action by the mechanical licensing collective shall be tolled with respect to a beneficiary of paragraph (a) of this section until the conclusion of such 45-day or alternate period.

(c) For purposes of this section, a *voluntary pass-through license* is a voluntary license obtained by a licensor of sound recordings to make and distribute, or authorize the making and distribution of, permanent downloads embodying musical works through which a digital music provider or significant nonblanket licensee has obtained authority from such licensor of sound recordings to make and distribute permanent downloads of musical works embodied in such sound recordings.

Dated: December 16, 2020.

Shira Perlmutter,

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

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2020–28505 Filed 12–23–20; 8:45 am]

BILLING CODE 1410–30–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AP46

Prosthetic and Rehabilitative Items and Services

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This rulemaking adopts as final, with changes, proposed amendments to VA's regulations governing the provision of prosthetic and rehabilitative items and services as medical services to veterans. This rulemaking establishes a new section for the provision of prosthetic and rehabilitative items and services, clarifies eligibility for such items and services, and defines the types of prosthetic and rehabilitative items and services available to eligible veterans.

DATES: This rule is effective on January 27, 2021.

FOR FURTHER INFORMATION CONTACT: Penny Nechanicky, National Program Director for Prosthetic and Sensory Aids Service (10P4RK), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420; *penny.nechanicky@va.gov;* (202) 461–0337. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

Background

On October 16, 2017, VA published a proposed rule in the **Federal Register** (82 FR 48018) to revise VA's regulations governing the provision of prosthetic and rehabilitative items and services to eligible veterans. The proposed rule set forth revisions to reorganize and update

the regulations on prosthetic and rehabilitative items, and define the types of items and services available to eligible veterans. The proposed rule also put forward the elimination of existing prosthetics regulations at § 17.150 of title 38, Code of Federal Regulations (CFR) and the establishment of entirely new sections at §§ 17.3200 through 17.3250. VA provided a 60-day comment period for the public to respond to the proposed rule. The comment period for the proposed rule ended on December 15, 2017, and VA received 305 comments.

Based on a review of the public comments received on the proposed rule, VA drafted and published a Supplemental Notice of Proposed Rulemaking (SNPRM) in the **Federal Register** (83 FR 61137) on November 28, 2018. The SNPRM provided clarification about provisions of the proposed rulemaking, included additional proposed amendments to § 17.3240 as proposed, and provided a 30-day comment period for the public to respond to the SNPRM and summit comments. The comment period for the SNPRM ended on December 28, 2018, and VA received 8 comments on the SNPRM. The SNPRM also provided notice regarding certain communications between VA and external parties regarding the proposed rule, and a summary of those communications were added to the public docket of the rulemakings.

We appreciate the comments we received on the proposed rule and SNPRM, and have considered them when adopting this rulemaking as final.

Several comments commended and supported revisions to the regulations identified in the proposed rule and the SNPRM. VA appreciates these comments for their support of these rules. All of the issues raised by the comments that concerned at least one portion of the rule can be grouped together by similar topic, and we have organized our discussion of the comments accordingly. For the reasons set forth in the proposed rule, in the SNPRM, and in further detail below, we are adopting the proposed rule as modified by the SNPRM and with additional changes as final.

Medical Alert Devices and Medical Identification Bracelets

Several comments opposed the proposed elimination of the provision of medical alert devices. One comment stated that emergency assistance through cell phones is limited among the elderly population, which may not have cell phones and may have limited ability in making a cell phone call and identifying their location. This comment noted that the Freedom Alert device allows for easier and quicker notification of a medical emergency to emergency services or a family member than a cell phone, in particular because the device can be used to answer a call, and would also reduce costs of emergency services. Additionally, this comment suggested that the Freedom Alert device would be a small investment that would allow many veterans to remain in their homes, thus reducing the costs for institutionalized care, home health aide care, and assisted living. Another comment also noted that life alerts do not directly provide medical information, but rather allow a veteran to stay in their home with some safety measure versus having to be placed in a facility which is more costly. One comment also opined that these devices should not be eliminated as veterans may not have alternative technology or financial resources available to them. Additional comments noted other benefits of providing these devices, including that the device can: Be used to answer phone calls; be programmed to contact family first (thus reducing emergency response costs); allow those with limited dexterity to push a simple button; ensure the well-being of veterans and reduce anxiety; be used as a substitute for cell phones in rural areas with unreliable cell service; and prevent exacerbation of serious falls or health conditions. Comments also noted that eliminating these devices under this regulation would reduce quality of life and pose potential risk to veterans to everyday hazards, medical complications, and life-threatening situations; and comments further asserted that if a treating physician requests such a device, it should be provided.

Similarly, some comments opposed elimination of the provision of medical identification bracelets pursuant to the proposed rule. A comment opined that no longer providing such items would reduce a veteran's quality of life and may result in those who need monitoring or who have communication limitations being unable to convey medical issues. This inability to communicate medical information can affect an individual's peace of mind and emotional and mental functioning. Additionally, in response to the SNPRM, another comment expressed high concern about the elimination of medical identification bracelets, as veterans have been provided these bracelets for years, and these bracelets help veterans receive better care and better outcomes in emergencies when a veteran may not be able to communicate about conditions, allergies, etc. This comment also noted that in a survey of VA clinicians, 97 percent of them believed VA should continue to provide medical identification bracelets to veterans.

We agree with the comments that medical alert devices as well as medical identification bracelets can be an important component of ensuring prompt medical response to emergency situations a veteran may encounter outside a hospital or clinic environment. However, when such devices and bracelets are purely communication devices that do not actively or directly treat or rehabilitate a veteran's health condition or limitation, they do not meet the direct and active component standard as described in the proposed rule. Medical identification bracelets particularly are entirely passive and do not actively communicate any information about a veteran, but merely provide a source of information about the existence of a condition of a veteran. Although many of the comments identified general benefits of providing medical alert devices and identification bracelets, such comments also failed to provide examples of how these devices would meet the direct and active component standard, and one comment averred that these devices do not contribute directly to an individual's treatment or rehabilitation. However, there were also some comments that did provide examples of benefits in providing these devices that may, in fact, rise to the level of meeting the direct and active component test. For example, some comments noted that some individuals need to be safe in their homes due to medical conditions, it may be possible for a clinician to determine that a medical alert device is the appropriate item to directly and actively contribute to the treatment of that medical condition. Therefore, in response to comments, we now revise the definition of the term home medical equipment in § 17.3210 as proposed to remove the restriction on medical alert devices, and we further delete the proposed definition of medical alert device as it will no longer be needed. This revision will allow the prescribing clinician to assess a medical alert device under the same direct and active component standard as all other prosthetic and rehabilitative items and services. We note that this change will permit a clinician to assess clinical needs on a case by case basis as with all other types of home medical equipment as provided in the definition under § 17.3210 as

revised in this final rule, this change does not ensure that medical alert devices will be prescribed merely if they are requested or thought needed by a veteran. This change also does not reverse VA's rationale as stated in the proposed and supplemental proposed rules for not prescribing or approving the furnishing of these items in any case in which they serve merely in a monitoring or preventive function, as opposed to actively and directly contributing to treatment. When such devices and bracelets are purely communication devices that do not actively or directly treat or rehabilitate a veteran's health condition or limitation, they would not meet the direct and active component standard established in this rule and therefore would not be provided.

As a result of this change, VA will ensure that applicable Veterans Health Administration (VHA) policy or guidance is revised or rescinded accordingly. For example, VHA Directive 2009–007, Provision of Medical Identification (ID) Bracelets and Pendants, provides that medical identification bracelets or pendants containing pertinent medical information (allergies or diagnoses) must be available, upon appropriate request from VA clinicians through VHA's Prosthetics Service, for veteran patients whose pertinent medical information would be valuable to emergency medical care providers. Although VA's proposed rule stated that VA would rescind VHA Directive 2009–007, upon this final rule being effective, we will instead revise VHA Directive 2009–007 to clarify that medical alert devices and medical identification bracelets will be made available to veterans under the direct and active component standard as with all other prosthetic and rehabilitative items and services. We note that the direct and active component standard is explained more fully in the next section of this final rule that addresses comments on the proposed changes to § 17.38 and § 17.3230.

Section 17.38, Medical Benefits Package and § 17.3230, Authorized Items and Services

We received multiple comments to the proposed revisions to current § 17.38 and criteria in new proposed § 17.3230. To aid in summarizing and responding to these comments, we first provide the following background and summary of what was proposed. The medical benefits package at § 17.38 defines medical services that are available from VA to eligible veterans. Paragraph (a) of § 17.38 addresses the hospital, outpatient, and extended care services that constitute the medical benefits package, and prosthetic devices are included in the medical benefits package at § 17.38(a)(1)(viii). We proposed amending § 17.38(a)(1)(viii) to state that the medical benefits package includes prosthetic and rehabilitative items and services as authorized under proposed §§ 17.3200 through 17.3250, to reference the new proposed criteria in §§ 17.3200 through 17.3250, versus extensive and likely confusing additional revisions to § 17.38 that would apply only to prosthetic and rehabilitative items and services. Current § 17.38(b) provides that care referred to in the medical benefits package at § 17.38(a) will be provided by VA only if it is determined by appropriate healthcare professionals that the care is needed to promote, preserve, or restore the health of the individual and is in accord with generally accepted standards of medical practice. We proposed amending the introductory sentence to § 17.38(b) to exclude prosthetics and rehabilitative items and services from the requirements in § 17.38(b) (specifically, not subject to the promote, preserve, or restore standard in § 17.38(b)), and proposed a different standard in proposed § 17.3230(a) that VA would provide prosthetic and other rehabilitative devices where VA determines that such items and services serve as a direct and active component of a veteran's medical treatment and rehabilitation and do not merely support the comfort or convenience of the veteran.

In addition to the background above, we will summarize and discuss below those comments that related to proposed revisions to § 17.38 and to § 17.3230(a) as proposed in two general categories: (1) Those comments related more directly to VA's standards in determining medical necessity for prosthetic and rehabilitative items and services; and (2) those comments related more directly to VA's practices and continued provision of prosthetic and rehabilitative items and services.

Comments Related to VA's Standards in Determining Medical Necessity for Prosthetic and Rehabilitative Items and Services

We received several comments that generally opposed VA's consideration of medical necessity in its determination to provide prosthetic and rehabilitative items and services, and one comment specifically objected to the proposed rule's interpretation of 38 U.S.C. 1701(6)(F)(i)–(iii) to find that prosthetic and rehabilitative items are considered medical services to require VA to consider medical necessity. At least one comment also stated that because non-VA programs and studies have struggled with defining medical necessity, VA should not consider medical necessity in the provision of prosthetic and rehabilitative items and services, and further stated that considering medical necessity is contrary to VA's policy, mission, and public statements.

We first address those comments that generally opposed VA's consideration of medical necessity in its determination to provide prosthetic and rehabilitative items and services. We reiterate from the proposed rule that VA is required to consider medical necessity in the provision of prosthetic and rehabilitative items and services, as 38 U.S.C. 1710(a) provides that VA shall furnish, or is authorized to furnish, hospital care and medical services that the Secretary determines to be needed.

In response to another comment, we note that the term medical services is further defined in 38 U.S.C. 1701(6)(F) to include: (i) Wheelchairs, artificial limbs, trusses, and similar appliances; (ii) special clothing made necessary by the wearing of prosthetic appliances; and (iii) such other supplies or services as VA determines to be reasonable and necessary, where VA has interpreted section 1701(6)(F)(i)–(iii) to authorize the provision of prosthetic and rehabilitative items generally. To address the comment that objected to the proposed rule's interpretation of section 1701(6)(F) to find that prosthetic and rehabilitative items are considered medical services to require VA to consider medical necessity, we reiterate from the proposed rule that VA has interpreted section 1701(6)(F)(iii) to authorize the provision of other supplies and services if they are similar or related to the expressly listed items in sections 1701(6)(F)(i) and (ii) (*i.e.,* wheelchairs, artificial limbs, trusses or similar appliances, and special clothing made necessary by the wearing of prosthetic appliances) because such other supplies and services are similarly required to assist a veteran to compensate for the loss of mobility or loss of other functional abilities. 82 FR 48019. We base this interpretation on tenets of statutory construction and opinions of VA's Office of General Counsel. See 2A Norman J. Singer, Statutes and Statutory Construction § 47.17 (6th ed. 2000) (explaining that as a matter of statutory interpretation, where general words follow specific words, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words). See also

VAOPGCADV 7–2009, VAOPGCADV 9–2005, VAOPGCCONCL–8–98.

We next address the comment that asserted VA struggles with defining medical necessity and therefore should not consider it when determining whether to provide prosthetic or rehabilitative items or services, and that further asserted consideration of medical necessity is contrary to VA's practice, mission, or messaging. We reiterate from the proposed rule that durable medical equipment and prosthetic and orthotic devices are expressly listed as medical services available to eligible veterans as part of VA's medical benefits package in § 17.38(a)(1)(viii). When VA promulgated § 17.38, we explained that the promote, preserve, or restore standard in § 17.38(b) would be used to determine whether health care and services available under § 17.38(a) were medically needed for a veteran. *See* 63 FR 37300. VA's assessment of medical need for prosthetic and rehabilitative items and services is clearly stated in § 17.38(a)(1)(viii) and (b) and is longstanding VA practice.

We received other comments that did not object to VA's consideration of medical necessity per se in providing prosthetic and rehabilitative items and services, but that opposed replacement of the promote, preserve, or restore standard in current § 17.38(b) with the direct and active component standard in § 17.3230(a) as proposed. We note that a few of these comments did not indicate an understanding that the current promote, preserve, or restore standard already required VA to consider medical necessity in the provision of medical services generally, so we again clarify that it has been longstanding VA practice to use the promote, preserve, or restore standard under § 17.38(b) when determining medical necessity for care and services provided in the medical benefits package under § 17.38(a), to include prosthetic and rehabilitative items under § 17.38(a)(1)(viii). We reiterate from the proposed rule that VA has found it necessary, however, to more specifically characterize medical necessity in the context of providing prosthetic and rehabilitative items and services through establishing the more specific direct and active component standard in § 17.3230(a) as proposed. 82 FR 48019. The direct and active component standard in § 17.3230(a) as proposed is more appropriately descriptive of VA's assessment of veterans' medical need for prosthetic and rehabilitative items and services because these items and services are durable medical equipment, which is a unique category of care under § 17.38(a) that functions as an extension of the direct provision of clinical treatment from a provider to a veteran. The extended use of reusable, durable medical equipment by a veteran as part of their treatment or rehabilitation warrants additional considerations on VA's part to ensure such equipment is not merely beneficial but is also medically necessary.

Although we believe the direct and active component standard in § 17.3230(a) as proposed provides for the appropriate assessment of medical necessity in the context of prosthetic and rehabilitative items and services, we have reconsidered the exclusion of prosthetic and rehabilitative items and services from the requirements in § 17.38(b) based on public comments. Based on comments, we now find that the direct and active component test in § 17.3230(a) as proposed should supplement the promote, preserve, and restore standard as well as all other requirements in § 17.38(b). We therefore now remove the parenthetical exception for prosthetics and rehabilitative items and services from § 17.38(b) as proposed, to leave the reading of § 17.38(b) as it is in its current state with regard to the application of the promote, preserve, or restore standard to all care and services available under § 17.38(a), to include prosthetic and rehabilitative items and services under § 17.38(a)(1)(viii). To further ensure it is clear that VA considers both the promote, preserve, and restore standard under § 17.38(b) as well as the supplemental direct and active component standard in § 17.3230(a) as proposed when assessing medical need, we now revise § 17.3230(a) as proposed to clearly reference the assessment of medical need under § 17.38(b). Section 17.3230(a) will now state that VA will provide veterans with prosthetic and rehabilitative items and services if VA determines that such items and services are needed under § 17.38(b), serve as a direct and active component of the veteran's medical treatment and rehabilitation, and do not solely support the comfort or convenience of the veteran. We note that revisions to § 17.38(a)(1)(viii) as proposed indicated that prosthetic and rehabilitative items and services will be available as authorized by §§ 17.3200 through 17.3250, and we are retaining that language in this final rule to ensure it is clear that the prescription of prosthetic and rehabilitative items is subject not only to the promote, preserve, or restore standard in § 17.38(b), but also subject to the direct and active component standard in § 17.3230(a) as proposed. We additionally revise the reference to ''§§ 17.3200–.3250'' in § 17.38(a)(1)(viii) as proposed, to remove the dash and insert the word through, to indicate the range of applicable sections from §§ 17.3200 through 17.3250. To further ensure consistency between the medical necessity standards in §§ 17.38(b) and 17.3230, we are revising and moving the language in the note at the end of § 17.3230 as proposed to further clarify that § 17.3230 supplements determinations of need for items and services listed in § 17.3230(a) in addition to the requirements in § 17.38(b). The revised language in the former note at the end of § 17.3230 as proposed will now be lcoated in § 17.3230(a)(2), and we will renumber § 17.3230(a) as proposed to § 17.3230(a)(1), and renumber § 17.3230(a)(1) through (15) as proposed to § 17.3230(a)(1)(i) through (xv), respectively. We are also revising § 17.3240(a)(1) as proposed to remove the phrase that indicated items will be prescribed based on the veteran's clinical needs and replace it with a clearer reference to the clinical needs assessments in § 17.3230(a) (which are the needs assessment under both §§ 17.38(b) and 17.3230(a)). Lastly, we are removing extraneous language that alludes to a specific item or service listed in § 17.3230(a)(1) through (15) as being separately or additionally assessed for necessity, as this would be duplicative of the clarifications and revisions explained above. Specifically, we are revising § 17.3230(a)(12) and (15) as proposed to remove such extraneous language. However, we reiterate from the proposed rule that an item under § 17.3230(a) could be repaired if it is determined that the item meets the needs assessment in § 17.3230(a). 82 FR 48018, 48024. The same logic follows for § 17.3230(a)(15) with regards to fitting and training, that such fitting and training for an item will be provided as long as such item is found to meet the needs assessment under § 17.3230(a).

Because the proposed rule did not indicate that the direct and active component test in § 17.3230(a) should supplement, versus replace, the requirements in § 17.38(b), we now provide an example of VA's assessment of both the medical necessity standards under §§ 17.38(b) and 17.3230(a) as proposed and made final in this rulemaking. In this example, a provider who is treating a veteran may determine that a number of clinical approaches are medically necessary to treat a veteran's sleep apnea by assisting the veteran to

maintain a less obstructed airway while sleeping, such as lifestyle changes (losing weight or quitting smoking), or treatment for nasal allergies or other upper respiratory ailments or illnesses. Under the medical benefits package in § 17.38(a), the veteran could receive weight management and smoking cessation counseling, and could be prescribed allergy medications as needed, where all of these care and services meet the promote, preserve, or restore standard in § 17.38(b). None of these care and services would be considered prosthetic or rehabilitative items under § 17.38(a)(1)(viii), and the assessment of clinical need would be fully met under the § 17.38(b) promote, preserve, or restore standard. This veteran's provider, however, may also determine that a continuous positive airway pressure (CPAP) machine would be necessary for the veteran to maintain an unobstructed airway while sleeping. A CPAP machine is a durable piece of equipment that would be considered a prosthetic or rehabilitative item under § 17.38(a)(1)(viii). As such, the provider would assess medical need under the requirements in § 17.38(b) and could specifically find the standard under § 17.38(b)(3) to be met because the CPAP machine could be found to restore the daily functional level of the veteran's airway that has been obstructed due to illness or injury. The provider would then also assess the CPAP machine under the direct and active component standard in § 17.3230(a) as proposed and could find this standard to be met because the CPAP machine delivers air pressure through a mask to directly and actively assist a veteran to maintain an unobstructed airway while sleeping. A CPAP machine would also meet the requirement under § 17.3230(a) as proposed as not being solely for the comfort or convenience of the veteran.

We believe the considerations under § 17.3230(a) as proposed establish additional context that is necessary when assessing medical need for prosthetic and rehabilitative items and services, where the promote, preserve, or restore standard in § 17.38(b) by itself may not provide adequate context. In the example above of the veteran with sleep apnea, for instance, a durable item could be provided under § 17.38(b)(1) because it promotes health, even if it merely makes the act of sleeping seem subjectively easier for a veteran but does not directly address the medical issue of an obstructed airway while sleeping. A white noise machine is a durable item that may tend to make a veteran with sleep apnea feel that it is easier to fall or stay asleep, but a white noise machine does not address the medical issue of the veteran's obstructed airway while sleeping. Without the additional consideration of the direct and active component standard in § 17.3230(a), it could be possible for a white noise machine to be provided under the standard in § 17.38(b)(1) because it promotes health by enhancing the quality of life or daily functional level of a veteran.

The additional consideration that prosthetic and rehabilitative items and services must be a direct and active component of treatment in § 17.3230(a) as proposed helps ensure that VA only furnishes durable items that are medically necessary. This is consistent with current and longstanding VA practice that requires all prescriptions for prosthetic and rehabilitative items to include a medical justification that draws a nexus between the item and the function it will perform for that condition. As we will respond more directly in this rule in relation to the comfort and convenience language from § 17.3230(a) as proposed, this nexus between an item and its function to medically address a condition does not mean that items may not be both beneficial and necessary; but, there must be a medical need for an item, and the additional considerations in § 17.3230(a) as proposed help ensure that is the case.

Several comments further opposed elimination of the promote, preserve, or restore standard due to concern that the direct and active component standard could reduce services to veterans, eliminate most quality of life items, and reduce veterans' quality of life. As clarified above, the direct and active component standard in § 17.3230(a) as proposed will supplement and not replace VA's assessment of medical need under § 17.38(b). Although it is the case that the direct and active component standard will not support VA's provision of comfort or convenience items that are not medically required, this additional standard should not result in any reduction of medically necessary items or services currently being provided to veterans. Most items currently provided will continue to be provided so long as they are determined by VA health care providers or authorized non-VA providers to be medically necessary using both the promote, preserve, and restore standard under § 17.38(b) and the direct and active component standard in § 17.3230(a) as proposed.

For the reasons stated in the proposed rule and above, we adopt as final the direct and active component standard and other language in § 17.3230(a) as proposed with some revisions. We reiterate that removing the parenthetical exception from the proposed revision to § 17.38(b), as well as the additional revisions to § 17.3230(a) and the note at the end of § 17.3230 (to reference § 17.38(b)) will clarify that we are supplementing rather than replacing the promote, preserve, or restore standard in § 17.38(b).

Comments Related to VA Practices and Continued Provision of Prosthetic and Rehabilitative Items and Services

One comment opined that there is no reason to change the standards and criteria for providing prosthetic and rehabilitative items and services if we intend to continue current practices. We clarify that we are only changing our regulations to conform with current practice; these regulations will convey more clearly to the public how we administer these benefits and clarify our current practices for the public. In those cases where regulatory language does not accurately reflect current practice, we should update it to reflect the standard we use so that the public is informed of and understands the standards, criteria, and requirements that VA uses to provide these benefits.

Comments also raised concerns that prosthetics representatives could deny a prescribed item or service if they determine it to be more of a comfort or quality of life item and not a medically necessary item. One comment stated that prosthetics representatives may lack necessary training, which could result in denial of a physician-recommended item or service because the item is viewed as convenient rather than medically necessary. It was also recommended that we remove the language in proposed § 17.3230 that stated that items or services must not merely support the comfort or convenience of the veteran as this would ensure that veterans are not inappropriately denied medically-indicated items because someone not trained in prosthetics and rehabilitation may view a prescribed item as convenient rather than medically necessary. To address these comments, VA is not precluded from providing medically necessary prosthetic and rehabilitative items and services that are additionally beneficial to the veteran or support the comfort and convenience of the veteran. However, VA will not provide prosthetic and rehabilitative items and services merely because they support the veteran's comfort or convenience *only.* Prosthetic and rehabilitative services or items may be medically necessary, and incidentally or

directly support the comfort and convenience of the veteran. In response to this comment, we have not removed the comfort and convenience language as we believe it is important and necessary to include in the regulation as it is reflective of our current practices. However, we have removed the word merely that was in proposed § 17.3230(a) and have replaced it with the word solely in order to reflect that an item or service will not be provided exclusively for comfort or convenience. We believe this addresses any potential confusion and more accurately reflects our intent.

To more specifically address the concern raised in the comment related to the input of prosthetic representatives, we note that prosthetics representatives give deference to the prescription written by a VA health care provider or an authorized non-VA health care provider. In the instance that a prosthetic representative may question whether a prescribed item or service meets the direct and active component standard in § 17.3230(a), the prosthetics representative would discuss such concerns with the provider. As long as the item or service is prescribed as medically necessary under the standards in both §§ 17.38(b) and 17.3230(a), it will be provided if it can be procured; and it may be the case that in such instances a level of comfort and convenience is concomitantly obtained. Indeed, comfort and convenience are valid clinical considerations in many decisions about which item or service will best meet a veteran's clinical needs.

In sum, VA will continue to support the holistic care of our Veterans. The decision about what item will best meet the Veteran's needs will be determined jointly by clinicians and veterans, which will result in a prescription for an item. The clinician will continue to consider how a specific item may be optimized to meet the veteran's unique needs like other diagnosed medical conditions and preserve functional independence. For example, VA wheeled mobility clinics will continue to partner with veterans, conduct comprehensive evaluations of veterans, and consult with clinicians across disciplines to identify and prescribe the wheeled mobility device that will best meet a veteran's needs. This could be a basic powered wheelchair, one that is optimized for transportation in a given urban environment, or an all-terrain powered wheelchair that could allow the veteran to navigate natural obstacles that the veteran encounters on a daily basis. The direct and active component standard in § 17.3230(a) will not restrict VA's ability to provide this equipment.

One comment stated that the regulations do not distinguish between service-connected versus non service-connected veterans, as the former traditionally have been able to choose their provider in limited circumstances pursuant to VA policy. While we note that the policy documents referred to by the comment do distinguish between service-connected and non-service connected veterans, the policy documents do not provide an all-inclusive list of factors that should be considered when providing prosthetic or rehabilitative services, such as the veteran's clinical needs, and it was our intent that VA clinical providers would be involved in the decision on how the veteran's needs can be best met. Authorities such as 38 U.S.C. 1703 previously distinguished between these groups of veterans, but this authority was amended by the VA Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act of 2018, Public Law 115–182, and as amended, section 1703 no longer recognizes a distinction between service-connected and non service-connected care. We see no valid reason to continue to distinguish between these groups of veterans with regard to the provision of prosthetic and rehabilitative items and services, particularly as we believe there are compelling reasons to be consistent in how we determine whether VA or an authorized non-VA vendor will provide the prescribed item or service, as explained in this paragraph and in the SNPRM. See 83 FR 61139–61142.

One comment raised concerns that proposed § 17.3230(a)(2), which would provide that VA furnishes adaptive recreation equipment when such equipment would achieve the veteran's rehabilitation goals as documented in the veteran's medical record, would limit access to rehabilitative items such as sport-specific wheelchairs. The comment noted that participation in sports is part of a veteran's rehabilitation goals and overall health. We acknowledge that the needs of veterans are unique, and the veteran is involved in the decision on the appropriate item to be prescribed based on his or her unique needs and to ensure his or her clinical needs are met. We specifically note that rehabilitation goals, developed jointly by the veteran and clinician, will be considered when determining the appropriate item or service to be provided to the veteran pursuant to these regulations. As long as the sports-related item meets the medical necessity standards set forth in §§ 17.38(b) and 17.3230(a), we do not believe that any additional requirements in § 17.3230(a)(2) such as documentation of goals in a medical record will prevent provision of such items.

Another comment supported VA for including adaptive recreation equipment in the list of equipment VA will provide under these regulations, but suggested VA clarify that the medical need for such equipment may be identified within inpatient and outpatient settings. We note that there is nothing in the regulation limiting the determination of the medical need for prosthetic and rehabilitative items and services to inpatient or outpatient care or that the determination needs to be made within a certain timeframe. The determination that a prosthetic or rehabilitative item or service is medically needed can be made at any time by VA. As long as the equipment meets the medical necessity standards in §§ 17.38(b) and 17.3230(a), it will be provided regardless of whether the veteran is in an inpatient or outpatient setting. We also note that a veteran's medical needs and rehabilitation goals can change over time, and these regulations would not limit VA's ability to prescribe a new piece of equipment based on a change in the veteran's medical needs.

Another comment raised concerns that the definition of adaptive recreation equipment in § 17.3210 as proposed was too restrictive and that it could negatively impact veterans' quality of life. The comment referred to the language in the preamble that states that such equipment will not be provided merely to support a veteran's participation in an activity only for personal enjoyment. This comment explained that if a medical professional determines that such equipment is needed for medical or therapeutic reasons, prosthetics personnel can deny the appliance by determining it is for personal enjoyment. Similar to the explanation in prior discussion of this rulemaking on the issue of the comfort or convenience language in § 17.3230(a), VA is not precluded from providing adaptive recreation equipment if such equipment is additionally beneficial to the veteran or supports a veteran's participation in an activity for personal enjoyment. VA clinicians work closely with veterans to identify recreation activities and needed adaptive recreation equipment that are consistent with the veteran's individualized rehabilitation goals. While considering physical rehabilitation needs, the clinician and veteran simultaneously consider quality of life opportunities that are uniquely presented by

recreation, like personal enjoyment and fulfillment, and socialization with friends, family, and fellow veterans. However, VA will not provide adaptive recreation equipment solely because the equipment supports the veteran's participation in an activity for personal enjoyment. This equipment authorized under § 17.3230(a)(2) will be provided only if it meets the medical necessity requirements under §§ 17.38(b) and 17.3230(a).

We note that the provision of adaptive recreation equipment is one component of a comprehensive VA approach to reach out to veterans and encourage their participation in recreational and leisure activities, led by the VA Recreation Therapy Service. This service embraces a philosophy of health promotion and disease prevention facilitated by qualified clinicians to enhance physical, cognitive, emotional, social, and leisure development that support each veteran's self-directed, self-determined, and fully independent participation in their chosen life pursuits. The VA recreation therapist's role is not to focus solely on the medical diagnosis, but to improve and enrich bio-psycho-social functioning through active therapy and meaningful therapeutic activities to maintain or improve functional independence and life quality. VA also regularly conducts National Veteran Sports Programs and Special Events, in which we encourage veterans to participate and focus on their specific abilities, rather than disabilities. Additionally, VA connects veterans to the community of recreational resources via the VA Adaptive Sports Grant program to engage in activities that promote independent veteran participation in activities designed for personal enjoyment.

We do not make changes to the definition of the term adaptive recreation equipment based on the comments above, but we do revise § 17.3230(a)(2) to remove all language after the term adaptive recreation equipment, as this language is duplicative of the definition of adaptive recreation equipment in § 17.3210.

Proposed § 17.3230(a)(13) would authorize the replacement of items provided under proposed § 17.3230 if the original items have been damaged, destroyed, lost, or stolen, or if replacement is clinically indicated. We stated that proposed paragraph (a)(13) would establish that if items are serviceable and still meet the veteran's need, VA will not replace such items for the sole purpose of obtaining a newer model of the same or similar item. One comment stated that the definition of and references to replacement item should include that the item will be of similar value. We address this comment in terms of the cost of a replacement item because cost is an objective comparison to the item being replaced, versus the subjective and broader comparison of value. When considering whether to replace an item, VA considers the veteran's clinical needs and whether the replacement item would meet the medical necessity standards in §§ 17.38(b) and 17.3230(a). If the replacement item is the same as the previously prescribed and provided item, then we would expect the cost of the replacement item would be the same or very similar to the original item. The focus will be on what replacement item would be most appropriate to provide to meet the veteran's clinical needs, and the most appropriate item may not be the same item previously prescribed and consequently may not be the same cost as the item previously prescribed.

Proposed § 17.3230(a)(14) would authorize the provision of specialized clothing made necessary by the wearing of a prosthetic device, while paragraph (a)(6) would authorize VA to provide certain home medical equipment. One comment suggested that VA not purchase items, such as socks, shoes, heating pads, and scales, that can be purchased at retail stores. While many of these described items may be available for purchase at retail stores, VA will provide those items pursuant to this rulemaking as long as the provision of such items meets the medical necessity standards under §§ 17.38(b) and 17.3230(a) and the items are one of the types of items expressly identified under proposed § 17.3230. That a retail store may carry such items would not preclude VA from providing an item to a veteran if the criteria and requirements in the regulation are met, similar to VA's provision of prescription drugs that are available over the counter under § 17.38(a)(1)(iii). The provision of such items would be within VA's authority. We further note that eligibility for the provision of specialized clothing made necessary by the wearing of a prosthetic device is not the same as the clothing allowance provided under 38 CFR 3.810 and authorized by 38 U.S.C. 1162, which is intended to provide a clothing allowance to veterans with certain service-connected disabilities.

Section 17.3240 Furnishing Authorized Items and Services

We proposed in § 17.3240(a) that VA would determine whether VA or a VA-authorized vendor will furnish authorized items and services under § 17.3230 to veterans eligible for such items and services under § 17.3210. As stated in the preamble of the proposed rule, the intent of the language in § 17.3240(a) as proposed was to establish that when VA has the capacity or inventory, VA directly provides items and services to veterans, but that VA also may use, on a case-by-case basis, VA-authorized vendors to provide greater access, lower cost, and/or a wider range of items and services. The intent of § 17.3240(a) as proposed was to clarify in regulation that whether VA or a VA-authorized vendor provides a prosthetic item is an administrative business decision that is made solely by VA, to eliminate any possible confusion as to whether a veteran has a right to request items or services generally, or to request specific items or services from a provider other than VA, and to clarify for the benefit of VA-authorized vendors that VA retains this discretion as part of its duty to administer this program in a legally sufficient, fiscally responsible manner.

We received over 280 comments concerning proposed § 17.3240, and the vast majority of these comments (228) addressed the same issues in nearly identical language. The main arguments in these comments included the following: VA would have sole discretion in determining how prosthetic and orthotic care is delivered to veterans; this rulemaking would eliminate veterans' choice of provider; it would contradict long-standing practice and policy of VA regarding a veteran's choice of provider (particularly relating to prosthetic limbs); it would disregard the history of cooperation between VA and contracted providers as well as veterans' clinical needs; and it would directly conflict with public statements made by VA regarding veterans' choice in health care. It was also argued that this decision on how to provide prosthetic and orthotic care to veterans is not an administrative decision, but rather a clinical one. We note that these concerns were primarily raised in reference to the provision of prosthetic limbs (also referred to as artificial limbs).

In the SNPRM published on November 28, 2018, we clarified and explained our current practices for the general provision of prosthetic and rehabilitative items and services, and specifically, the provision of prosthetic limbs. See 83 FR 61137. In the SNPRM, we also addressed many of the concerns discussed above regarding the comments to the proposed rule. We also note that the SNPRM addressed other concerns raised in response to the proposed rule. These other concerns

that the SNPRM addressed included that this proposed rule would be inconsistent with the Veterans Access, Choice, and Accountability Act of 2014, Public Law 113–146 (Choice Act), with VA policy and with current practices; that it would alter current practices; that it may implicate other community care authorities (*i.e.,* 38 U.S.C. 1703 and 8153); and that we did not cite to or reference the authority for § 17.3240.

In response to public comments on the proposed rule, the SNPRM revised § 17.3240(a) as proposed to state that VA providers will prescribe items and services based on the veteran's clinical needs and will do so in consultation with the veteran, which we believed was responsive to the concerns related to clinical decision making and retaining veteran input clarified that this is current VA practice. See 83 FR 61141. The SNPRM also revised § 17.3240(a) as proposed to state that once the prescribed item or service is determined to be authorized under § 17.3230, VA will determine whether VA or a VA-authorized vendor will furnish authorized items and services under § 17.3230 to veterans eligible for such items and services under § 17.3220, and further that the determination on whether VA or a VA-authorized vendor will furnish the authorized item or service under § 17.3230 will be based on, but not limited to, such factors as the veteran's clinical needs, VA capacity and availability, geographic availability, and cost. We believed these additional revisions made in the SNPRM to § 17.3240(a) as originally proposed further supported and clarified current VA practice concerning how VA makes the administrative decision regarding who furnishes a prosthetic item to a veteran (*i.e.,* VA or a VA-authorized vendor), for the benefit of both veterans and VA-authorized vendors. See 83 FR 61141.

In response to the SNPRM, we received 8 comments, many of which raised the same concerns previously raised in response to the language in § 17.3240(a) as originally proposed. In response to these same concerns as raised in comments to § 17.3240(a) as originally proposed, we reiterate from above that the revisions made in the SNPRM clarified that current VA practice does consider clinical need and consider veteran input, but also that VA retains control over the administrative decision of whether to provide the prosthetic item directly to the veteran or have it provided by a VA-authorized vendor. See 83 FR 61139–61143. We address below other comments we received to the SNPRM.

In response to the SNPRM, one comment commended VA for the emphasis on clinical consultation between the veteran and VA providers in § 17.3240 and the supporting explanation provided within the SNPRM. One comment expressed an expectation that in applying § 17.3240, a veteran's prosthetic needs will outweigh any concern with nationwide consistency when items are clinically recommended. We acknowledge that prosthetic and rehabilitative items and services will be prescribed based on a determination that such item or service is medically necessary under the direct and active component standard, and that medical need will outweigh other concerns such as nationwide consistency. This prioritization of medical need is consistent with current practice.

In the SNPRM, we did not specifically address the concern raised in the 228 comments that this rulemaking would disregard the history of cooperation between VA and contracted providers. Related to this set of comments, one comment stated that through these regulations, VA will restrict a veteran's ability to receive care from non-VA contractors. We now state that this rulemaking does not disregard this history of cooperation, as we intend to continue to contract and work with non-VA providers to provide the most appropriate and high-quality care, and we acknowledge that VA alone cannot meet every veteran's prosthetic and rehabilitative needs. VA has over 600 contracts with non-VA providers that are utilized to meet the clinical needs of veterans, and we intend to continue to utilize such contracts. As explained in the SNPRM, veterans will continue to receive care from authorized non-VA providers, and this determination is based upon the clinical needs of the veteran, as well as additional considerations (*e.g.,* VA capacity and availability, geographic availability, cost) which will vary on a case by case basis. See 83 FR 61137–61142. These determinations will be made for routine, non-urgent, and non-emergent needs for durable medical equipment and medical devices. This will ensure that veterans' needs are met with the most appropriate and highest quality items and services in a consistent manner throughout VA and ensure that VA complies with Federal acquisition requirements. Id. As noted in the SNPRM revision to § 17.3240(a)(2), we consider veterans' clinical needs when determining whether to provide artificial limbs and all other items and services under § 17.3230(b) internally or via authorized community vendors.

Several comments raised concerns that § 17.3240 is inconsistent with the Choice Act. In the SNPRM, we addressed this concern, and incorporate in this final rule our related response from the SNPRM. See 83 FR 61139–61140. We further note that, effective June 6, 2019, VA was no longer authorized to furnish care and services under section 101 of the Choice Act. Consequently, we consider these comments to be moot.

One comment specifically stated that § 17.3240(b) should not prevent a provider authorized under the Choice Act to provide care to a veteran from providing all items and services related to the care being furnished. Similarly, another comment opined that once care is authorized in the community, all care should be authorized without additional authorization being needed. VA treated prescriptions from authorized community providers under the Veterans Choice Program, and treats prescriptions under the Veterans Community Care Program, the same way that a prescription from an internal VA provider would be managed. As explained in the SNPRM, if VA authorized a community provider to furnish care to a veteran pursuant to the Choice Act and it was determined that a prosthetic or rehabilitative item or service is needed, VA would review the prescribed item or service to determine whether the prescribed item is within the scope of the authorized community care; this requirement applies as well to the Veterans Community Care Program. As long as the prescribed item or service meets the medical necessity standards in §§ 17.38(b) and 17.3230(a) and is otherwise authorized pursuant to §§ 17.3230 through 17.3250, then VA will provide the item to the veteran either directly or through a VA-authorized vendor. If the prescription is lacking sufficient justification, VA will attempt to contact the prescribing clinician and may consult with internal VA clinicians with subject matter expertise if necessary. If the prescribing clinician or a consulted VA clinician is able to provide the needed justification, then VA will provide the item to the veteran either directly or through a VA-authorized vendor. If the prescribing provider does not respond or otherwise provide the necessary justification, then VA is not authorized to purchase the item for the veteran. In such an instance, VA will ensure that the veteran is seen by a provider who can determine whether the initially prescribed item or another item or service is needed. We further note that

in VA's regulations implementing the Veterans Community Care Program, VA stated it would pay for prescriptions written by eligible entities or providers for covered veterans that have an immediate need for durable medical equipment and medical devices that are required for urgent or emergent conditions, and that VA would fill prescriptions written by such entities and providers for covered veterans for durable medical equipment and medical devices that are not required for urgent or emergent conditions. See 38 CFR 17.4025(b)(3) and (4). To ensure consistency with these community care regulations, we now revise § 17.3240(a)(1) to similarly state that VA providers or eligible entities and providers as defined in 38 CFR 17.4005 will prescribe items and services based on the veteran's clinical needs and will do so in consultation with the veteran. We further revise § 17.3240(a)(2) and (3) to reflect that once an item or service is authorized under paragraph (a)(1), VA will either fill a prescription directly or will pay for such prescriptions to be furnished through a VA-authorized vendor. Lastly, to ensure these regulations are consistent with VA's community care regulations, we revise § 17.3240(b) to include mention of emergency care available under 38 CFR 17.4020(c) and urgent care under 38 CFR 17.4600, and revise § 17.3220(b) to also expressly include eligible entities and providers as defined in 38 CFR 17.4005. We believe these provisions address the issues raised by this comment. Incorporating the provisions promulgated separately (RIN 2900–AQ46, Veterans Community Care Program, and RIN 2900–AQ47, Urgent Care) and already subject to public comment will ensure that VA's programs are consistently operated.

The revisions to §§ 17.3220 and 17.3240 as proposed and described above we believe clarify that VA would determine whether the item or service could be provided, and that VA would separately determine whether it is furnished by VA or a VA-authorized vendor. If a VA provider prescribed an item or service, and VA authorized and contracted with a community prosthetist for the item or service, that prosthetist would only provide the prescribed item or service. If a community prosthetist suggests additional or different items or services those items or services must be further reviewed and authorized by VA, and VA would additionally determine whether it will furnish the item directly or through a VA-authorized vendor. Similarly, if a an eligible entity or provider under 38 CFR 17.4005 prescribes items or services, because VA will have entered into a contract, agreement, or other arrangement for care from such a provider, any prescribed items or services would be reviewed and authorized by VA, and VA would then determine whether it will furnish the items or services directly or through a VA-authorized vendor. This is consistent with Federal and VA acquisition requirements, the Veterans Community Care Program, and our current business practices to require community providers to complete a secondary authorization request or a request for service form for additional or continued care to include all prosthetic item and service requests (except in the case of items or services needed in emergent or urgent circumstances). Because we believe that this requirement for VA-authorized vendors to receive authorization from VA, prior to such vendors furnishing items or services to veterans, is clear within the terms of the contracts, agreements, or other arrangements for care VA forms with such vendors, we further amend § 17.3240(b) as proposed to remove the last sentence that states prior authorization must be obtained from VA by contacting any VA medical facility. We believe the revisions to §§ 17.3220 and 17.3240 described above assist to clarify that in all cases, VA either itself furnishes items or services or provides them through a VA-authorized vendor as long as VA finds that the prescription meets the medical necessity standards in §§ 17.38(b) and 17.3230(a) and otherwise meets the requirements set forth in § 17.3200 through 17.3250.

Comments to both the proposed rule and SNPRM opposed VA retaining sole authority in § 17.3240 to determine whether VA or an authorized VA vendor will provide the authorized item or service under these regulations, and that veterans should maintain this right. As we explained in the SNPRM, the veteran will be involved in the decision of what item or service will be prescribed in order to meet their needs, but VA retains the authority over the determination of how the item or service will be provided. This is because VA needs to ensure that veterans' needs are met with the most appropriate and highest quality items and services in a consistent manner throughout VA, that VA does so in a manner that complies with Federal and VA acquisition requirements, and that VA is also being fiscally responsible in the provision of these items and services. See 83 FR 61138–61142. As previously explained, VA has already regulated these general conditions in § 17.4025(b)(3) and (4) as part of the Veterans Community Care Program.

One comment stated that § 17.3240 could result in a prosthetics representative hundreds of miles away making a decision on how the item or service is provided without knowing what is best for the veteran. As explained in the SNPRM, the decision regarding what item or service will be provided is a clinical decision, and the decision of how that item or service is provided is a separate decision that is based on clinical and administrative factors. 83 FR 61137, 61138–61142. Both decisions take into account the best interests of the veteran, and VA clarified the clinical and administrative factors it considers when determining how to furnish an item in proposed § 17.3240(a)(2) as revised by the SNPRM. 83 FR 61137, 61141. As long as the prescribed item or service is authorized pursuant to these regulations and meets the medical necessity standards in §§ 17.38(b) and 17.3230(a), the VA prosthetics representative will honor the prescription and procure the prescribed item or service. 83 FR 61137, 61138. This rule will not permit a VA decision of how an item or service is furnished without considering what is best for a veteran, and we do not make changes based on this comment.

One comment suggested VA revise the regulation as proposed to codify VA's consideration of a non-VA provider's input in determining what to authorize. We reiterate from the discussion above that VA clinicians do consider a non-VA provider's input when VA reviews prescriptions from non-VA providers, and that the revision of § 17.3240 as proposed to specifically reference non-VA eligible entities and providers makes this clear without further revisions to the regulations as proposed.

One comment argued that under these regulations, a veteran has no role in the decision of who they see or who provides the prescribed item. As we explained in the SNPRM, the veteran, in consultation with his or her clinician, is directly involved in the decision of what item or service is prescribed. See 83 FR 61137–61139. In the SNPRM, we modified the language of proposed § 17.3240 to incorporate the veteran's input in this decision, and now adopt that language as final in this rulemaking. VA retains the authority to make the determination of how the item or service is provided in order to ensure that veterans' clinical needs are met with the most appropriate and highest quality items and services in a consistent manner throughout VA, and that we comply with Federal and VA

acquisition requirements in providing such items and services. See 83 FR 61138. We further note that in the provision of artificial or prosthetic limbs, if VA decides that the veteran should receive the item or service from a community prosthetist, the veteran, in consultation with his or her VA clinician or amputee clinic (or eligible entities and providers as defined in 38 CFR 17.4005), would in most cases be able to select a vendor that has an existing agreement with VA and is able to meet the veteran's clinical needs.

At least two comments opined that non-VA providers should be utilized to prescribe prosthetic and rehabilitative items and services as VA does not have the necessary expertise to meet the needs and requirements of veterans to ensure they receive appropriate care. Other comments stated that non-VA providers should be utilized to ensure appropriate, available, quality, timely, and convenient care. Another comment opined that decreased access to non-VA providers would result in sub-optimal care, leading to unnecessary pain, less mobility, depression, and unemployment among veterans. Comments also noted that veterans will have to travel long distances to VA facilities if not given a choice to utilize non-VA providers, or claimed VA's historical issues with time constraints, availability, and administrative deficiencies presented obstacles to justify use of non-VA providers. Similar to our response above, we intend to continue to contract and work with non-VA providers to enable VA to provide the needed items and services in a timely, appropriate, convenient, or quality manner in specific cases. As we explained in the proposed rule, VA may use, on a case-by-case basis, VA-authorized vendors to provide greater access, lower cost, and/or a wider range of items and services. 82 FR 48025. In the SNPRM, we further explained that the determination of whether VA or a VA-authorized vendor will furnish authorized items or services will be based on, but not limited to, such factors as the veteran's clinical needs, VA capacity and availability, geographic availability, and cost. 83 FR 61141–61143. We clarify here that these determinations are only about the furnishing of items or services (such as fitting a prosthetic) and not the clinical care that establishes the medical necessity of such items and services. The eligibility for receipt of that clinical care in the community by covered veterans is controlled by the Veterans Community Care Program established in regulation at 38 CFR 17.4000 through 17.4040. We enter into contracts, agreements, and other arrangements with non-VA providers for both clinical care and furnishing items and services and will continue to do so on a case-by-case basis and as clinically needed, to ensure that veterans' clinicals needs are met in an appropriate, timely, convenient, and high-quality manner.

We note that VA provides high-quality and timely in-house care in the area of artificial limbs. VA has modernized the way that veterans access and receive amputation care services. Currently VA offers same-day service to veterans at all of the 145 sites that offer orthotic and prosthetic services. Veterans may also schedule their amputation care services directly with the amputee clinics, rather than through a referral from another clinical service, facilitating more timely provision of care. This ultimately results in the care plan for amputee veterans being created on the day that the veteran contacts VA. We also note VA has engaged in several activities to ensure that veterans receive the best prosthetic care possible from VA. Since 2009, through the Extremity Trauma and Amputation Center of Excellence (EACE), we have collaborated with the Department of Defense (DoD) to conduct research and foster innovation to improve prosthetics for wounded servicemembers and veterans. EACE allows VA and DoD to collaborate and study extremity trauma care to ensure that prosthetics are made more comfortable and better fitting. Since 2008, we also have implemented the Amputation System of Care (ASoC) within VA to enhance quality and consistency of care provided to veterans with limb loss. ASoC is designed to provide the latest practices in medical care, prosthetic technology, and rehabilitation management to support veterans in reaching the highest level of functional independence. We note that ASoC is similar to DoD's amputation care program, which ensures consistency during the transition from DoD to VA health care. In addition to these systems, we also have prosthetic and orthotic laboratories across VA. Prosthetic and orthotic laboratories have artificial limb fabrication and repair equipment, and allow for on-site evaluation, fitting, maintenance, and long-term care of prosthetic and orthotic needs. As of the publication of this final rule, VA currently has 84 such laboratories across the country. This allows veterans to receive on-site and specialized care at their local facilities in a timely manner.

Similarly, another comment opined that non-VA providers augment VA care by providing cutting-edge technology and advanced labs. VA often leads in providing such technology when clinically appropriate for artificial limbs and any other class of device that may clinically benefit veterans, including breakthrough devices newly cleared by the United States Food and Drug Administration to be marketed. VA is able to provide items that may be unavailable from the private sector due to the cost of a given device and limitations of private insurance coverage. With regard to artificial limbs and components, VA is a leader in clinical research. As mentioned above, we also have prosthetic and orthotic labs that allow us to provide timely and appropriate care to veterans. Additionally, through EACE, we also continue research to find innovative ways to meet the prosthetic needs of veterans.

One comment opined that VA is unable to handle combat amputees and is only able to handle amputees due to vascular issues. We acknowledge that the vast majority of the amputees we treat are those who had an amputation due to disease processes. However, this is reflective of the veteran amputee population as only a small percentage of the veteran population with amputations has an amputation of traumatic etiology. We do provide amputee care to both populations. Webster JB, Poorman CE, Cifu DX. *Department of Veterans Affairs Amputation System of Care: 5 years of accomplishments and outcomes.* J Rehabil Res Dev. 2014;51(4):vii–xvi. VA collaborates with DoD via sharing agreements, joint education programs, and other initiatives, specifically to provide the care for newly-separated reserve and active duty servicemembers, as well as veteran combat amputees. A VA Office of Inspector General report found that within 5 years of military separation, 99 percent of servicemembers with combat-related amputations transitioned their care to VA. *Health care Inspection: Prosthetic limb care in VA facilities,* Report No. 11–02138–116. Washington, DC, March 8, 2012.

We note that VA has unique experience in providing care to amputee veterans. For example, we have seen over 80,000 veterans with amputations for amputee services since 2013. Between 2008 and 2013, VA performed an average of 7,669 new amputation procedures annually. See Webster JB, *et al. Department of Veterans Affairs Amputation System of Care: 5 years of accomplishments and outcomes,* cited above. In fiscal year 2019 VA saw 96,518 veterans with amputations, with

46,214 of these veterans having at least one major limb amputation (*i.e.,* amputation at or proximal to the wrist or ankle). Of those 96,518 veterans, 39,291 of them were service-connected for an amputation-related disability while 2,375 veterans were service-connected for a combat-related amputation disability. Due to the large number of veterans with amputations that we see for care within our system, we have unique expertise that allows us to provide specialized care to meet these veterans' clinical needs.

A related comment noted that § 17.3240 as proposed does not address the unique clinical needs of veterans, in particular amputees. As explained in the SNPRM, we are trying to ensure consistency with the provision of all prosthetic and rehabilitative items and services across VA, and therefore do not expressly or explicitly distinguish between veterans based on their clinical needs in the regulations. However, the proposed rules were drafted in a manner to allow clinicians to determine, based on each veteran's unique clinical needs, those items or services to be provided and how such items or services will be provided.

At least one comment stated that choice of provider is an important quality assurance mechanism. The comment noted that veterans can determine quality versus VA making that determination. One comment additionally noted that the fact that VA contracts with non-VA providers indicates that non-VA providers meet or exceed a required level of quality. We reiterate from earlier in this rulemaking that revisions to § 17.3240(a) as proposed will account for consultation with a veteran when VA or non-VA providers prescribe items or services for veterans, although this does not necessarily address the issue of a veteran's choice of provider. We note that in terms of VA providers, VA can address issues of provider choice with veterans internally without any changes to these regulations. In terms of non-VA providers (*i.e.,* eligible entities and providers as defined in 38 CFR 17.4005, per revised § 17.3240(a)(1)), such providers are available to veterans to choose from under VA community care regulations at 38 CFR 17.4030, to the extent that community providers meet the criteria of § 17.4030 and to the extent the veteran is a covered veteran and meets one or more of the eligibility criteria in § 17.4010. Particularly, we note that § 17.4030(c)(2) requires VA to assess the qualifications of the community provider to furnish care or services, such that a contractual relationship between a community provider and VA does not equate with an assumption on VA's part of the quality of the provider; VA must still determine whether the community provider would be able to provide the services that would meet the veteran's unique clinical needs. Thus, even though a veteran may want to choose a certain community provider because they have a relationship with that community provider or for other reasons, it does not mean that the community provider has the specific expertise needed in all instances. VA retains ultimate authority to ensure that the veteran's clinical needs can be met in an appropriate and high-quality manner.

Another comment opined that if VA does not allow veterans to choose their provider, VA will mass produce prosthetics, and in particular will do so using the computer-aided design and manufacturing (CAD–M) production method. As a result, this comment explained that veterans would receive uncomfortable prosthetics that do not work well. We note that VA does not mass produce artificial limbs, and our providers work to ensure that the artificial limbs fit each veteran properly. VA also has no such plan to mass produce artificial limbs or components using any known production method. VA fabricates customized artificial limbs based on the individualized needs of each veteran and that veteran's personal goals. Most VA prosthetists make the artificial limb by hand and make a plaster bandage of the limb shape. We do not generally make the limb by CAD–M.

Another comment asked that VA clarify in the final rule the mechanisms it will use to determine and ensure that the clinical needs of veterans drive the decision-making of the agency in determining whether VA will directly provide the prescribed item or service or whether VA will use an authorized vendor. As a general rule, VA internal agency processes are not reflected in VA regulations. We will develop policies that implement the rule to ensure that clinicians and prosthetics representatives make this determination based on the veteran's clinical needs, and we do not make changes based on this comment.

A comment also raised a concern that VA may consider cost savings ahead of the provision of optimal, timely, efficient care, which would harm veterans. This comment requested that we clarify in this final rule that when cost is factored into the determination of who will provide the authorized item or service, the veteran will receive the prescribed item of the same quality, caliber, and effectiveness regardless of who furnishes it. This comment also urged VA to afford a veteran's preferences greater weight in instances in which cost is the sole administrative factor considered and the veteran's preferences do not align with VA's determination. We agree with these comments and believe that the amendments to § 17.3240 as proposed in the SNPRM sufficiently prioritize the clinical needs of each veteran over other factors, including cost. We clarify that the clinical needs of the veteran are critical to prescribing the correct item. Generally, VA will provide the exact item described in the prescription. If the item must be procured from a VA-authorized vendor, VA complies with Federal acquisition regulations and VA acquisition regulations, which require VA to enter into and utilize national and regional contracts when appropriate. In the instance that the fabrication of an item like an artificial limb requires a skilled clinician to work with the veteran on an ongoing basis, then we noted in § 17.3240(a)(2) as proposed in the SNPRM that VA will consider the veteran's clinical needs and other factors in addition to cost.

Additionally, a comment requested that as VA develops and implements the VA MISSION Act of 2018, it does so in a meaningful way that is designed to limit disruption or delay in the delivery of care that does not impose undue financial and administrative burdens on VA authorized vendors. As we explained in the SNPRM, the VA MISSION Act of 2018 was enacted on June 6, 2018, and section 101 of this Act revised section 1703 of title 38, U.S.C., when VA's implementing regulations became effective June 6, 2019. As we have previously discussed, these regulations expressly address how VA will pay for or fill prescriptions written by eligible entities or providers for covered veterans for durable medical equipment and devices at 38 CFR 17.4025(b)(3) and (4); similar regulations also apply to the urgent care benefit regulated by VA at 38 CFR 17.4600(e)(3). We do not believe that VA-authorized vendors will experience any undue financial or administrative burdens as a result of VA's implementation of the new Veterans Community Care Program or the urgent care benefit, but VA will continue to work to ensure that its processes do not cause undue disruption or delay in the delivery of care. As previously stated, we have also revised this final rule to account for the regulations implementing the changes made by

section 101 of the VA MISSION Act of 2018.

Section 17.3250 Veteran Responsibilities

We proposed that § 17.3250 would establish responsibilities of veterans who are provided prosthetic and rehabilitative items and services. Proposed § 17.3250(a) would establish that veterans must use items provided under proposed § 17.3230(a) in the manner for which they are prescribed and consistent with the manufacturer's instructions and any training provided. This would ensure, to the extent practicable, veteran safety in using the item as well as the longevity of the item.

In proposed § 17.3250(b) we stated that, except for emergency care under 38 CFR 17.120 through 17.132 or 38 CFR 17.1000 through 17.1008, veterans must obtain prior authorization from VA if they want VA to reimburse a VA-authorized vendor for such items and services provided under § 17.3230. This would reinforce general VA oversight requirements already proposed in these regulations to ensure the highest quality and most appropriate item or service is provided and would distinctly provide notice to veterans and vendors that VA will not be responsible for the cost of items and services provided to veterans who are not preauthorized by VA or that are not otherwise covered as emergency care.

One comment stated that proposed § 17.3250(b) was too restrictive, as veterans should not be required to obtain pre-approval on an item or service obtained from a VA-authorized vendor as this could cause delays, lead to lapses in care, and be detrimental to treatment. This comment and others also raised similar concerns about pre-approvals for repairs or replacement services and opposed elimination of § 17.122 and the related revision of § 17.120. As previously mentioned above, VA may authorize a veteran to receive an item or service in the community for numerous reasons. If an item or service has been prescribed and VA has authorized a vendor to provide that item or service, no further approval is needed unless the vendor determines that a different item or service is necessary. This would require further VA approval as a new prescription would be needed. This would be consistent with our practices and with Federal and VA acquisition regulations, as VA has to authorize items and services prior to their being provided. We do not find that VA's review and approval of prescriptions or review of different requested items or services creates undue delay, lapses in care, or is detrimental to a veteran's treatment. Absent emergent cases, VA's review and approval of prescriptions from non-VA providers, or requests for items or services from VA-authorized vendors that differ from what VA providers prescribed, is necessary to consider the unique needs of each veteran. We note that in emergent cases, VA could reimburse a veteran for emergency care pursuant to 38 U.S.C. 1725 or 1728 and 38 CFR 17.120 through 17.132, or 38 CFR 17.1000 through 17.1008. As previously noted, §§ 17.4025(b)(3) and 17.4600(e)(3) also authorize payment for prescriptions for durable medical equipment and medical devices that are required for urgent or emergent conditions. We find that, although these other authorities have their own criteria, they would also address situations in which a veteran needed an item or service due to an emergency.

Similarly, repairs and replacements by a vendor must also have prior authorization from VA before such items and services can be provided. When VA contracts for items and services, a scope of work is generated, which specifically identifies the items and services for which VA is contracting. Prior to performing work for which a vendor can be reimbursed, VA must comply with the Federal Acquisition Regulation and create a purchase order or establish a contract for such work. As a result, VA cannot provide a blanket authorization for a vendor to provide any repairs and replacements in addition to the item or service prescribed. A new authorization for a vendor to provide repairs or replacements would be required. To the extent that there is an emergent or urgent situation, prior authorization would not be required under one of the authorities described above. We believe that these authorities would address the situation in which a veteran needed a repair or replacement due to an emergency or urgent situation, and we would be able to pay or reimburse for that care consistent with those authorities. Thus, VA has determined that § 17.122 is unnecessary, although we clarify in this rulemaking that we will remove § 17.122 but also mark it reserved for future use of the section number as needed. VA could also obviate the need for veterans to obtain emergency repairs from vendors by providing spare items or devices for prosthetic and rehabilitative items under § 17.3230, as clinically appropriate.

One comment stated that moving emergency repairs from under § 17.120 to § 17.3250 would cause confusion, and that if this change is made, outreach and education to veterans on this change should be provided. VA believes that consolidating all information on the provision of prosthetic and rehabilitative items and services within the scope of this rulemaking under one set of regulations, at §§ 17.3200 through 17.3250, will provide a centralized location for veterans to look for information on the provision of these items and services. As a result, we believe this will lead to less confusion. We will be providing information to veterans once this rulemaking becomes final to ensure that veterans are educated and informed on how these items and services including emergency repairs will be provided.

We make no changes to the regulations based on these comments.

Elimination of the Prosthetics Service Card

We noted in discussion of the proposed rule that VA intended to stop use of the prosthetics service card (VA Form 10–2501) when the final rule is published. 82 FR 48026. We stated that the prosthetics service card is often not used for its intended purpose, is not universally utilized by veterans and VA vendors, and would not be necessary after publication of the final rule.

One comment opposed elimination of the prosthetics service card as it would result in veterans not being allowed to have immediate non-emergent repairs completed without prior approval by VA. This comment raised concerns that VA would not be able to provide timely pre-approval and that it is unclear whether an estimate for pre-approval would be needed or whether a list of VA authorized vendors would be provided. The comment also expressed concern about this adding another level of bureaucracy before an item can be repaired. As we explained in the preamble of the proposed rule, prosthetics service cards were intended to be used in emergency situations. However, these cards have not been widely used or consistently used for this purpose. As we noted, many veterans have lost these cards or have failed to provide them to third party vendors; many vendors still contact VA for authorization prior to making repairs; and these cards merely provide notice that VA will reimburse repairs up to a certain amount. We have found that third party vendors still submit invoices and documentation to VA for reimbursement for repairs. As a result, we are eliminating use of the prosthetics service card. Non-emergency repairs will be authorized pursuant to §§ 17.3230 and 17.3240. As we noted above, pre-approval is required to

comply with Federal and VA acquisition regulations. Additionally, as explained in § 17.3240(b), prior authorization is not required for emergency care under 38 CFR 17.120 through 17.132, 38 CFR 17.1000 through 17.1008, and 38 CFR 17.4020(c), or urgent care under 38 CFR 17.4600.

We make no changes to the regulation based on this comment.

Comments Received on Miscellaneous Issues

Several comments generally opposed the changes. Some of these comments, which included issues with VA leadership, are beyond the scope of these regulations, and we are not making any edits based on these comments. One comment opined that the drafter of the comment should be involved in the development of VA handbooks, directives, and other policies that will implement these regulations. We note that this comment is outside the scope of these regulations, and we are not making any edits based on this comment. In response to the SNPRM, one comment raised several other issues, including implementation of the VA MISSION Act of 2018, the recommendation that VA consider how to incentivize more community-based physical therapists and physical therapist assistants to work with VA, and that Veterans Integrated Service Networks should include a therapist on the leadership team to provide therapy-services relations guidance and expertise. These are also outside the scope of these regulations, and we are not making any edits based on these comments.

One comment expressed concerns with veterans' ability to receive cochlear implantation through these regulations. While we do reference implants in this regulation, hearing aids and other hearing technology, including cochlear implants, are outside the scope of these regulations as they are covered by a separate regulation, 38 CFR 17.149. Additionally, this comment suggested that VA provide training and updates on current cochlear implant candidacy practices and outcomes to align with best practices. This is also outside the scope of these regulations, but we have provided this comment to the appropriate VA program office to consider.

One comment suggested that the clothing allowance should be abolished or awarded for artificial limbs only. We note that clothing allowance is provided pursuant to separate authorities, 38 U.S.C. 1162 and 38 CFR 3.810, as explained in proposed § 17.3200, and thus is not covered by this rulemaking. This comment is beyond the scope of these regulations, and we are not making any edits based on this comment.

One comment opined that the proposed rule may have violated the Administrative Procedure Act (APA) due to ambiguities in the discussion of the proposed rule concerning the intent of proposed § 17.3240, no explanation or citation for the discretionary authority for proposed § 17.3240 or on how VA would exercise this authority, the lack of discussion in the proposed rule regarding existing law and policy and how that will change under § 17.3240, and the failure to address non-VA care authorities or prosthetics procurement authority in the proposed rulemaking. We note that these issues were addressed in the SNPRM, as we explained the intent of proposed § 17.3240; described our authority for that section and our exercising of that authority; and discussed current laws (including non-VA care authorities such as VA MISSION Act of 2018 and Choice Act) as well as VHA policies concerning the provision of prosthetic and rehabilitative items and services and how these regulations are impacted by the laws and how they will impact the referenced policies. See 83 FR 61139–61143. Elements of VA's Veterans Community Care Program that affect the prescription of prosthetic items and services were subject to notice and comment rulemaking (see RIN 2900–AQ46 and RIN 2900–AQ47), and elements of those rules are incorporated here for consistency. We are not making any edits based on this comment.

Non-Substantive Revisions That Are Not Based on Comments

We are making certain revisions to provisions from the proposed rule that are not based on comments, and that are non-substantive in nature.

We add a section list, immediately following the undesignated center heading that reads Prosthetic And Rehability Items and Services, to identify each of the §§ 17.3200 through 17.3250 with their corresponding section header.

We revise § 17.3200(a) as proposed to add the phrase ''[t]his section and §§ 17.3210'' through 17.3230 are applicable as proposed, to better distinguish reference to § 17.3200.

We revise § 17.3200(b) as proposed to add the phrase ''[t]his section and §§ 17.3210'' through 17.3230 are applicable as proposed, to better distinguish reference to § 17.3200. We additionally revise § 17.3200(b) as proposed to add the phrase ''to be provided'' after the first use of the term ''authorized'', so that the first sentence of § 17.3200(b) now reads ''[s]ections 17.3200 through 17.3250 apply only to items and services listed in § 17.3230(a) and authorized to be provided as medical services under 38 U.S.C. 1701(6)(F) and 38 U.S.C. 1710(a).'' We lastly revise § 17.3200(b) to add more specific reference to the accompanying table as proposed, to identify the table as table 1, to add to the table a corresponding title to read ''Table 1 to Paragraph (b),'' and in table 1 to correct the ''*et seq.*'' citation format to include, instead, a citation through the end of the applicable section numbers for the automobile adaptive equipment and home improvement and structural alterations regulatory citations.

We revise § 17.3220(a) as proposed to remove, from the reference to § 17.37, the dash between § 17.37(a) and (c), and insert the word ''through'' in its place to better distinguish the range of applicable paragraphs. We revise § 17.3220(b) as proposed to correct the citation to § 17.4005 with a section symbol versus reference to ''38 CFR.''

We revise § 17.3240(a)(1) as proposed to correct the citation to § 17.4005 with a section symbol versus reference to ''38 CFR.'' We revise § 17.3240(a)(2) as proposed to correct the reference to paragraph (a)(1) of § 17.3240. We revise § 17.3240(a)(3) as proposed to correct the reference to paragraph (a)(2) of § 17.3240. We revise § 17.3240(b) as proposed to correct citations to §§ 17.120, 17.1000, 17.4020(c), and 17.4600 with section symbols versus reference to ''38 CFR,'' and to correct the ''*et seq.*'' citation format to include, instead, a citation through the end of the applicable section numbers for §§ 17.120 through 17.132 and 17.1000 through 17.1008.

We revise § 17.3250(a) as proposed to add a reference to § 17.3240, as § 17.3240 also relates to the provision of items and services set forth in these regulations. We also revise § 17.3250 (a) as proposed to replace the phrase ''in the manner for which they are prescribed'' with the phrase ''as they are prescribed'', as we believe this language is more easily understood.

We revise § 17.3250(b) to correct citations to §§ 17.120, 17.1000, 17.4020(c), and 17.4600 with section symbols versus reference to ''38 CFR,'' and to correct the ''*et seq.*'' citation format to include, instead, a citation through the end of the applicable section numbers for §§ 17.120 through 17.132 and 17.1000 through 17.1008. We additionally revise § 17.3250(b) to remove from the last sentence the phrase ''that otherwise are'', as this language is extraneous and does not add

to the provisions in § 17.3250(b). We additionally revise the last sentence of § 17.3250(b) to reference emergency care under 38 CFR 17.4020(c) and urgent care under 38 CFR 17.4600, to be consistent with the first sentence of § 17.3250(b) and be consistent with § 17.3240(b) as revised.

External Communications Discussed in SNPRM

In the SNPRM, we described communications VA had with external parties after the comment period for the proposed rule had closed. See 83 FR 61142. We briefly described a roundtable that was held on July 25, 2018, which VA attended. We noted that the concerns that were raised at the roundtable that related to the proposed rule at RIN 2900–AP46 were similar to those raised during the public comment period for that proposed rule. In the SNPRM, we stated that we addressed these concerns within the SNPRM. 83 FR 61142. In response to the SNPRM, at least one comment noted that we did not address issues raised concerning the proposed rule and medical alert devices and medical identification bracelets that were discussed at the roundtable. We acknowledge and clarify now that we misstated when we explained that we addressed in the SNPRM all the concerns of the roundtable. While we addressed, in the SNPRM, some of the concerns that were raised during the roundtable, we did not address all of the concerns, such as medical alert devices and medical identification bracelets. However, we note that in this final rulemaking, we have addressed the remaining concerns that were raised during the roundtable. We are not making any edits based on this comment.

We lastly note that we make one technical and nonsubstantive revision to § 17.38(b) as proposed, to indicate that the term ''healthcare'' as proposed will be printed as two words to read ''health care'', as is consistent with a majority of VA's other medical regulations. We also make one technical and nonsubstantive revision to § 17.3220(a) as proposed to clarify that veteran eligibility may occur if a veteran is exempt from enrollment under § 17.37(a) through (c), and not under § 17.37 more generally.

Based on the rationale set forth in the proposed rule, the SNPRM, and in this document, VA is adopting the provisions of the proposed rule as a final rule with changes as noted above.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. See also 5 CFR 1320.8(b)(2)(vi).

This final rule contains no new and/or revised provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). However, as stated in the proposed rule, we noted that after the final rule is published, VA would request to rescind several VHA handbooks and several VA forms, to include VA Form 10–2520, which is an approved collection under OMB Control Number 2900–0188. We proposed to rescind this form, which is an invoice used by vendors to submit to VA requests for payment for repairs performed pursuant to the prosthetic service cards. Prosthetic service cards have not been widely or consistently used by veterans or vendors, these cards have typically been lost, and third-party vendors still submit separate invoices for reimbursement. We reiterate from earlier in this rule that although we received one comment in opposition to rescinding this form, we will not keep this form because we find that many vendors do not use it as an assurance of pre-approval for emergency repairs. Instead, VA-authorized vendors still contact VA for authorization prior to making repairs and still submit invoices and documentation to VA for reimbursement of repairs, thereby negating the concept that this form functions as an emergency approval for repairs. Therefore, upon publication of this final rule, VA will request to rescind this form through VA's Paperwork Reduction Act Clearance Officer.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. There will be no material changes to the types of items and services available to veterans or veteran eligibility for such items and services. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866, 13563, and 13771

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

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

This final rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Unfunded Mandates

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

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits; 64.013, Veterans Prosthetic Appliances; 64.029—Purchase Care Program; 64.041—VHA Outpatient Specialty Care.

Congressional Review Act

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

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs—health, Grant programs—

veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Brooks D. Tucker, Assistant Secretary for Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, Department of Veterans Affairs, approved this document on October 1, 2020, for publication.

Luvenia Potts,

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

For the reasons stated in the preamble, we amend 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended by adding entries for §§ 17.3200 through 17.3250 in numerical order to read in part as follows:

Authority: 38 U.S.C. 501, and as noted in specific sections.

* * * * *

Section 17.3200 also issued under 38 U.S.C. 1162, 1701, 1707, 1710, 1714, 1717, 3901.
Section 17.3210 also issued under 38 U.S.C. 1701, 1710.
Section 17.3220 also issued under 38 U.S.C. 1701(6)(F), 1710.
Section 17.3230 also issued under 38 U.S.C. 1701(6)(F), 1710, 1714(a).
Section 17.3250 also issued under 38 U.S.C. 1701, 1710, 1725, 1728.

* * * * *

■ 2. Amend § 17.38, revise paragraph (a)(1)(viii) and in paragraph (b) introductory text, remove the word ''healthcare'' and add in its place the phrase ''health care'' to read as follows:

§ 17.38 Medical Benefits Package.

(a) * * *

(1) * * *

(viii) Prosthetic and rehabilitative items and services as authorized under §§ 17.3200 through 17.3250, and eyeglasses and hearing aids as authorized under § 17.149.

* * * * *

§ 17.120 [Amended]

■ 3. Amend § 17.120 introductory text by removing ''(except prosthetic appliances, similar devices, and repairs)''.

§ 17.122 [Removed and Reserved]

■ 4. Remove and reserve § 17.122.

■ 5. Revise the undesignated center heading that precedes § 17.148 to read as follows:

Sensory and Other Rehabilitative Aids

§§ 17.150 and 17.153 [Removed and Reserved]

■ 6. Remove and reserve §§ 17.150 and 17.153.

■ 7. Add an undesignated center heading and §§ 17.3200 through 17.3250 to read as follows:

Prosthetic and Rehabilitative Items and Services

Sec.

17.3200 Purpose and scope.
17.3210 Definitions.
17.3220 Eligibility.
17.3230 Authorized items and services.
17.3240 Furnishing authorized items and services.
17.3250 Veteran responsibilities.

§ 17.3200 Purpose and scope.

(a) *Purpose.* The purpose of this section and §§ 17.3210 through 17.3250 is to establish eligibility and other criteria for the provision to veterans of the prosthetic and rehabilitative items and services, listed in § 17.3230, authorized as medical services under 38 U.S.C. 1701(6)(F) and 38 U.S.C. 1710(a).

(b) *Scope.* This section and §§ 17.3210 through 17.3250 apply only to items and services listed in § 17.3230(a) and authorized to be provided as medical services under 38 U.S.C. 1701(6)(F) and 38 U.S.C. 1710(a). The provision of the items or services and payments in table 1 to this paragraph (b) are authorized in whole or in part by separate statutes and controlled by other implementing regulations:

TABLE 1 TO PARAGRAPH (B)

Item or service	Statute	Regulation(s)
Clothing allowance	38 U.S.C. 1162	38 CFR 3.810
Service and guide dog benefits	38 U.S.C. 1714(b) & (c)	38 CFR 17.148
Sensori-neural aids	38 U.S.C. 1707(b)	38 CFR 17.149
Patient lifts and other rehabilitative devices	38 U.S.C. 1717(b)	38 CFR 17.151
Devices for deaf veterans	38 U.S.C. 1717(c)	38 CFR 17.152
Equipment for blind veterans	38 U.S.C. 1714(b)	38 CFR 17.154
Automobile adaptive equipment	38 U.S.C. 3901 *et seq.*	38 CFR 17.155 through 17.159
Home improvements and structural alterations	38 U.S.C. 1717(a)(2)	38 CFR 17.3100 through 17.3130

§ 17.3210 Definitions.

For the purposes of §§ 17.3200 through 17.3250:

Activities of daily living (ADL) means specific personal care activities that are required for basic daily maintenance and sustenance, to include eating, toileting, bathing, grooming, dressing and undressing, and mobility.

Adaptive household item means a durable household item that has been adapted to compensate for, or that by design compensates for, loss of physical, sensory, or cognitive function and is necessary to complete one or more ADLs in the home or other residential setting. Adaptive household items include but are not limited to adaptive eating utensils, shower stools or chairs, hooks to assist in buttoning clothing, or shoe horns. This definition does not include household furniture or furnishings, improvements or structural alterations, or household appliances, unless a household appliance is necessary to complete an ADL in the home or other residential setting. VA will not furnish such items or services in such a manner as to relieve any other person or entity of a contractual obligation to furnish these items or services to the veteran.

Adaptive recreation equipment means an item that is designed to compensate for, or that by design compensates for, loss of physical, sensory, or cognitive function and is necessary for the veteran to actively and regularly participate in a sport, recreation, or leisure activity to

achieve the veteran's rehabilitation goals as documented in the veteran's medical record.

Cognitive device means an item that compensates for a cognitive impairment and that is used to maintain or improve a veteran's functional capabilities, including but not limited to technological equipment such as tablets and smart phones, and associated technological equipment, applications or software that can assist veterans in maintaining daily scheduling of important tasks or navigating their surroundings (*e.g.,* global positioning system, or GPS).

Communication device means an item that compensates for a communication deficiency and allows participation in daily communication activities, including but not limited to picture or symbol communication boards and an electro larynx.

Durable means capable of, and intended for, repeat use.

Home exercise equipment means an item used in a home or residential setting that compensates for a loss of physical, sensory, or cognitive function and that is necessary for the veteran to actively and regularly participate in aerobic, fitness, strength, or flexibility activities to achieve the veteran's rehabilitation goals as documented in the veteran's medical record, when there is no other means for the veteran to exercise to achieve the veteran's rehabilitation goals. Such equipment includes but is not limited to an upper body ergometer and a functional electrical stimulation cycle.

Home medical equipment means an item that is a movable and durable medical device that is used in a home or residential setting to treat or support treatment of specific medical conditions. Such equipment includes but is not limited to hospital beds, portable patient lifts, portable ramps, ventilators, home dialysis equipment, and infusion, feeding, or wound therapy pumps. This definition does not include household furniture or furnishings, improvements or structural alterations, or household appliances. VA will not furnish home medical equipment in such a manner as to relieve any other person or entity of a contractual obligation to furnish these items or services to the veteran.

Home respiratory equipment means an item used to provide oxygen therapy or to support or enhance respiratory function, including but not limited to compressed oxygen, oxygen concentrators, and continuous positive airway pressure machines.

Household appliance means an item used in the home for performance of domestic chores or other domestic tasks, including but not limited to a refrigerator, stove, washing machine, and vacuum cleaner.

Household furniture or furnishing means an item commonly used to make a home habitable or otherwise used to ornament a home, including but not limited to tables, chairs, desks, lamps, cabinets, non-hospital beds, curtains, and carpet(s).

Implant means any biological or non-biological material that:

(1) Is manufactured or processed to be placed into a surgically or naturally formed cavity on the human body;

(2) Is covered with tissue, has the potential to be covered with tissue, or is permanently embedded in tissue;

(3) Does not dissolve or dissipate within the body; and

(4) Is not a living organ, embryonic tissue, blood, or blood product.

Improvements or structural alterations means a modification to a home or to an existing feature or fixture of a home, including repairs to or replacement of previously improved or altered features or fixtures.

Mobility aid means an item that compensates for a mobility impairment and that is used to maintain or improve a veteran's functional capabilities to be mobile. Mobility aids include but are not limited to manual and motorized wheelchairs, canes, walkers, and equipment to assist a veteran to reach for or grasp items. This definition does not include a service or guide dog.

Orthotic device means an item fitted externally to the body that is used to support, align, prevent, or correct deformities or to improve the function of movable parts of the body. Orthotic devices include but are not limited to leg braces, upper extremity splints and braces, and functional stimulation devices.

Primary residence means the personal domicile or residential setting in which the veteran resides the majority of the year.

Prosthetic device means an item that replaces a missing or defective body part. Prosthetic devices include but are not limited to artificial limbs and artificial eyes.

Replacement item means an item that is similar or identical to an item provided under § 17.3230(a), and that takes the place of such an item.

VA-authorized vendor means a vendor that has been authorized by VA to provide items and services under § 17.3230.

§ 17.3220 Eligibility.

A veteran is eligible to receive items and services described in § 17.3230 if:

(a) The veteran is enrolled under § 17.36 or exempt from enrollment under § 17.37(a) through (c); and

(b) The veteran is otherwise receiving care or services under chapter 17 of title 38 U.S.C. If a VA provider or an eligible entity or provider as defined in § 17.4005 prescribes an item or service for the veteran, the veteran is considered to otherwise be receiving care or services under chapter 17 of title 38 U.S.C.

§ 17.3230 Authorized items and services.

(a)(1) VA will provide veterans eligible under § 17.3220 with the following items and services if VA determines that such items and services are needed under § 17.38(b), serve as a direct and active component of the veteran's medical treatment and rehabilitation, and do not solely support the comfort or convenience of the veteran:

(i) Adaptive household items.

(ii) Adaptive recreation equipment.

(iii) Cognitive devices.

(iv) Communication devices.

(v) Home exercise equipment, where such equipment will only be provided for one location, the veteran's primary residence, unless it is clinically determined that the equipment should be provided at the veteran's non-primary residence instead of the veteran's primary residence. Prior to any installation of home exercise equipment, the owner of the residence must agree to the installation. Such equipment will only be provided to achieve the veteran's rehabilitation goals as documented in the veteran's medical record.

(vi) Home medical equipment, and if required, installation that does not amount to an improvement or structural alteration to a veteran's residence. Such equipment will only be provided for one location, the veteran's primary residence, unless it is clinically determined that the equipment should be provided at the veteran's non-primary residence instead of the veteran's primary residence. Prior to any installation of home medical equipment, the owner of the residence must agree to the installation.

(vii) Home respiratory equipment.

(viii) Implants.

(ix) Mobility aids.

(x) Orthotic devices.

(xi) Prosthetic devices.

(xii) Repairs to items provided under paragraph (a) of this section, even if the item was not initially prescribed by VA, unless VA determines to replace the item for cost or clinical reasons.

(xiii) Replacement items, if items provided under this section have been

damaged, destroyed, lost, or stolen, or if replacement is clinically indicated, subject to the following: Items that are serviceable, and that still meet the veteran's need, will not be replaced for the sole purpose of obtaining a newer model of the same or similar item.

(xiv) Specialized clothing made necessary by the wearing of a prosthetic device.

(xv) Training with and fitting of prescribed items.

(2) Paragraph (a)(1) of this section supplements the requirement in § 17.38(b) for a determination of need but only with respect to the provision of items and services listed in paragraph (a)(1) of this section. The exclusions under § 17.38(c) will apply to the items and services provided under this section. While VA will generally provide only one item under this section, the provision of spare items may be authorized based on a clinical determination of need using the criteria set forth in this section.

(b) Unless an item provided under § 17.3230(a) is loaned to the veteran based on a clinical determination that a loan is more beneficial for the veteran, such items become the property of the veteran once the veteran takes possession of those items. If the determination is that the item will be loaned to a veteran, the veteran must agree to the terms of the loan in order to receive the item.

§ 17.3240 Furnishing authorized items and services.

(a)(1) VA providers, or eligible entities and providers as defined in § 17.4005, will prescribe items and services in accordance with § 17.3230(a) and will do so in consultation with the veteran.

(2) Once the item or service is prescribed under paragraph (a)(1) of this section, VA will either fill such prescriptions directly or will pay for such prescriptions to be furnished through a VA-authorized vendor.

(3) The determination under paragraph (a)(2) of this section of whether a prescription will be filled by VA directly or will be furnished by a VA-authorized vendor will be based on, but not limited to, such factors as the veteran's clinical needs, VA capacity and availability, geographic availability, and cost.

(b) Except for emergency care under §§ 17.120 through 17.132, §§ 17.1000 through 17.1008, or § 17.4020(c), or urgent care under § 17.4600, prior authorization of items and services under § 17.3230 is required for VA to reimburse VA-authorized vendors for furnishing such items or services to veterans.

§ 17.3250 Veteran responsibilities.

(a) Veterans must use items provided under §§ 17.3230 and 17.3240 as they are prescribed, and consistent with the manufacturer's instructions and any training provided. Failure to do so may result in the item not being replaced under § 17.3230(a)(13).

(b) Except for emergency care under §§ 17.120 through 17.132, §§ 17.1000 through 17.1008, or § 17.4020(c), or urgent care under § 17.4600, veterans obtaining items and services provided under § 17.3230 must obtain prior authorization from VA in order to obtain VA reimbursement for such items and services obtained from a VA-authorized vendor. VA will not be responsible for the cost of items and services provided that are not preauthorized by VA or not covered as emergency care under §§ 17.120 through 17.132, §§ 17.1000 through 17.1008, or § 17.4020(c), or urgent care under § 17.4600.

[FR Doc. 2020–27014 Filed 12–23–20; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2019–0282; FRL–10014–50–OAR and FRL–10019–02–OAR]

RIN 2060–AM75

Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is correcting a final rule that appeared in the **Federal Register** on November 19, 2020, and will become effective on January 19, 2021. The EPA finalized the amendments to the General Provisions that apply to National Emission Standards for Hazardous Air Pollutants (NESHAP). This action corrects inadvertent typographical errors and redundant text in the **Federal Register**. The corrections described in this action do not affect the substantive requirements of the final rule implementing the plain language reading of the ''major source'' and ''area source'' definitions of section 112 of the Clean Air Act.

DATES: This final rule is effective on January 19, 2021.

FOR FURTHER INFORMATION CONTACT: For questions about this final action, contact Elineth Torres, Sector Policies and Programs Division (D205–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–4347; fax number: (919) 541–4991; and email address: *torres.elineth@epa.gov*.

SUPPLEMENTARY INFORMATION: The EPA is making the following corrections to the final rule, Reclassification of Major Sources as Area Sources Under Section 112 of the Clean Air Act (also refered as final Major MACT to Area or MM2A rule) as published in the **Federal Register** on November 19, 2020 (85 FR 73854).

The EPA is correcting inadvertent typographical errors and redundant text included in the regulatory text of six NESHAP subparts amended by the final MM2A rule. As described in the preamble to the final MM2A rule, the EPA finalized amendments to the NESHAP General Provision applicability tables for most of the NESHAP subparts to account for the final amendments to the General Provisions included in the final MM2A rule.

With this action, the EPA is correcting the following errors in FR Document Number (FR Doc) 2020–22044 in the issue of November 19, 2020. These corrections do not change the requirements finalized in the MM2A rule.

- At 85 FR 73894, second column, 40 CFR part 63, subpart EE. The final MM2A rule instruction 37 amended Table 1 to subpart EE by revising the entry for 40 CFR 63.9(b)(2), however, there is no such entry on Table 1 to subpart EE. In this action, instruction 37 is corrected to read ''adding in numerical order entries for §§ 63.1(c)(6) and 63.9(k) . . .'' and amendatory text is corrected by removing the entry for 40 CFR 63.9(b)(2) from Table 1 to Subpart EE of Part 63—Applicability of General Provisions to Subpart EE.
- At 85 FR 73897, third column, 40 CFR part 63, subpart DDD. The final MM2A rule instruction 51 amended Table 1 to subpart DDD to add an entry for 40 CFR 63.1(c)(6), however this addition is unnecessary as Table 1 to subpart DDD has another entry including that provision. In this action, instruction 51 is corrected to read ''. . . by adding in numerical order an entry for § 63.9(k) . . .'' and the amendatory text is corrected by removing the entry for 40 CFR 63.1(c)(6) from Table 1 to Subpart DDD of Part 63—Applicability of General Provisions (40 CFR part 63, subpart A) to Subpart DDD of Part 63.
- At 85 FR 73899, first column, 40 CFR part 63, subpart NNN. The final

MM2A rule instruction 60 amended Table 1 to subpart NNN to add an entry for 40 CFR 63.1(c)(6), however this addition is unnecessary as Table 1 to subpart NNN has another entry including that provision. In this action, instruction 60 is corrected to read ''. . . by adding in numerical order an entry for § 63.9(k) . . .'' and the amendatory text is corrected by removing the entry for 40 CFR 63.1(c)(6) from Table 1 to Subpart NNN of Part 63—Applicability of General Provisions (40 CFR part 63, subpart A) to Subpart NNN.

- At 85 FR 73912, third column, 40 CFR part 63, subpart AAAAA. The final MM2A rule instruction 118 reads as if amendments were for Table 8 to subpart AAAAA when they were for Table 9 to subpart AAAAA. In this action, instruction 118 is corrected to read ''Amend table 9 to subpart AAAAA of part 63 . . .''. The table header in the amendatory text is also corrected to read ''Table 9 to Subpart AAAAA of Part 63—Applicability of General Provisions to Subpart AAAAA.''
- At 85 FR 73913, first column, 40 CFR part 63, subpart DDDDD. The final MM2A rule instruction 121 correctly referenced the amendments to 40 CFR 63.7545, however, the corresponding section header in the amendatory text read ''§ 63.7189 What notifications must I submit and when?'' instead. In this action, the section header in the amendatory text is corrected to read ''§ 63.7545 What notifications must I submit and when?''
- At 85 FR 73914, first column, 40 CFR part 63, subpart IIIII. The final MM2A rule instruction 128 correctly referenced the amendments to 40 CFR 63.8252, however, the corresponding regulatory text section header read ''§ 63.825 What notifications must I submit and when?'' instead. Additionally, the amendatory text at 85 FR 73914, second column for 40 CFR 63.8252(b) incorrectly referenced ''120 calendar days after December 19, 2003'' which should have remained April 19, 2004, as in the original regulatory text. In this action, the regulatory text section header is corrected to read ''§ 63.8252 What notifications must I submit and when?''; and the amendatory text to paragraph (b) is corrected to read ''(b) As specified in § 63.9(b)(2), if you start up your affected source before December 19, 2003, you must submit an Initial Notification no later than April 19, 2004, or no later than 120 days after the source becomes subject to this subpart, whichever is later.''

Section 553 of the Administrative Procedure Act, 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for making this rule final without prior proposal and opportunity for comment because, as explained here and in each bullet above, the changes to the rule are minor technical corrections, are noncontroversial in nature, and do not substantively change the requirements of the MM2A final rule. Rather, the changes correct inadvertent typographical errors and redundant text. Additionally, the corrections to the regulatory text match the revisions described in the preamble to the final MM2A rule. Thus, notice and opportunity for public comment are unnecessary. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

Federal Register Correction

In FR doc 2020–22044 at 85 FR 73854 in the issue of November 19, 2020, the following corrections are made:

■ 1. On page 73894, in the second column, amendatory instruction 37 is corrected to read: ''37. Amend table 1 to subpart EE of part 63 by adding in numerical order entries for §§ 63.1(c)(6) and 63.9(k) to read as follows:''.

■ 2. On page 73897, in the third column, amendatory instruction 51 is corrected to read: ''51. Amend table 1 to subpart DDD of part 63 by adding in numerical order an entry for § 63.9(k) to read as follows:''.

■ 3. On page 73899, first column, amendatory instruction 60 is corrected to read: ''60. Amend table 1 to subpart NNN of part 63 by adding in numerical order an entry for § 63.9(k) to read as follows:''.

■ 4. On page 73912, third column, amendatory instruction 118 and the table heading are corrected to read: ''118. Amend table 9 to subpart AAAAA of part 63 by adding in numerical order entries for §§ 63.1(c)(6) and 63.9(k) to read as follows:''

TABLE 9 TO SUBPART AAAAA OF PART 63–APPLICABILITY OF GENERAL PROVISIONS TO SUBPART AAAAA

* * * * *

§ 63.7545 What notifications must I submit and when?

■ 5. On page 73913, second column, the section heading for § 63.7545 is corrected to read as set forth above.

■ 6. On page 73914, second column, in section § 63.8252 the section heading and paragraph (b) are corrected to read as follows:

§ 63.8252 What notifications must I submit and when?

* * * * *

(b) As specified in § 63.9(b)(2), if you start up your affected source before December 19, 2003, you must submit an Initial Notification no later than April 19, 2004, or no later than 120 days after the source becomes subject to this subpart, whichever is later.

* * * * *

Dated: December 17, 2020.

Anne Austin,

Principal Deputy Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2020–28384 Filed 12–23–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2020–0005; Internal Agency Docket No. FEMA–8659]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur. Information identifying the current participation status of a community can be obtained from FEMA's CSB available at *www.fema.gov/flood-insurance/work-with-nfip/community-status-book*. Please note that per Revisions to Publication Requirements for Community Eligibility Status Information Under the National Flood Insurance Program, notices like this one for scheduled suspension will no longer be published in the **Federal Register** as of June 2021 but will be available at *www.fema.gov*. Individuals without

internet access will be able to contact their local floodplain management official and/or State NFIP Coordinating Office directly for assistance.

DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 674–1087. Details regarding updated publication requirements of community eligibility status information under the NFIP can be found on the CSB section at *www.fema.gov*.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives, new and substantially improved construction, and development in general from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with NFIP regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date listed in the third column. As of that date, flood insurance will no longer be available in the community. FEMA recognizes communities may adopt and submit the required documentation after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. Their current NFIP participation status can be verified at anytime on the CSB section at *fema.gov*.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the published FIRM is indicated in the fourth column of the table. No direct federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region V				
Michigan:				
Clinton, Charter Township of, Macomb County.	260121	February 9, 1973, Emerg; August 1, 1979, Reg; Dec. 30, 2020, Susp.	Dec. 30, 2020 ...	Dec. 30, 2020.
Harrison, Township of, Macomb County	260123	December 8, 1972, Emerg; May 5, 1981, Reg; December 30, 2020, Susp.	.....do *	Do.
New Baltimore, City of, Macomb and Saint Clair Counties.	260125	January 12, 1973, Emerg; September 1, 1978, Reg; December 30, 2020, Susp.	.....do	Do.
Wisconsin:				

State and location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Pierce County, Unincorporated Areas ...	555571	December 31, 1970, Emerg; July 14, 1972, Reg; December 30, 2020, Susp.	.....do	Do.
Spring Valley, Village of, Pierce and Saint Croix Counties.	550331	July 2, 1975, Emerg; March 15, 1984, Reg; December 30, 2020, Susp.	.....do	Do.
Region VI				
Texas:				
Angleton, City of, Brazoria County	480064	September 17, 1973, Emerg; June 10, 1977, Reg; December 30, 2020, Susp.	.....do	Do.
Brazoria, City of, Brazoria County	480066	July 27, 1973, Emerg; December 15, 1983, Reg; December 30, 2020, Susp.	.....do	Do.
Clute, City of, Brazoria County	480068	October 1, 1971, Emerg; December 7, 1976, Reg; December 30, 2020, Susp.	.....do	Do.
Freeport, City of, Brazoria County	485467	June 19, 1970, Emerg; November 13, 1970, Reg; December 30, 2020, Susp.	.....do	Do.
Jones Creek, Village of, Brazoria County.	480072	August 9, 1973, Emerg; June 5, 1985, Reg; December 30, 2020, Susp.	.....do	Do.
Manvel, City of, Brazoria County	480076	November 20, 1975, Emerg; December 1, 1981, Reg; December 30, 2020, Susp.	.....do	Do.
West Columbia, City of, Brazoria County.	480081	July 18, 1973, Emerg; December 15, 1983, Reg; December 30, 2020, Susp.	.....do	Do.
Region VII				
Iowa:				
Aurora, City of, Buchanan County	190698	June 17, 2008, Emerg; July 16, 2008, Reg; December 30, 2020, Susp.	.....do	Do.
Brandon, City of, Buchanan County	190328	September 15, 1993, Emerg; April 1, 1997, Reg; December 30, 2020, Susp.	.....do	Do.
Buchanan County, Unincorporated Areas.	190848	December 17, 1990, Emerg; September 1, 1991, Reg; December 30, 2020, Susp.	.....do	Do.
Fairbank, City of, Buchanan and Fayette Counties.	190329	September 21, 1976, Emerg; August 19, 1986, Reg; December 30, 2020, Susp.	.....do	Do.
Hazleton, City of, Buchanan County	190330	July 8, 2004, Emerg; July 16, 2008, Reg; December 30, 2020, Susp.	.....do	Do.
Independence, City of, Buchanan County.	190031	September 24, 1971, Emerg; May 16, 1977, Reg; December 30, 2020, Susp.	.....do	Do.
Jesup, City of, Buchanan County	190599	N/A, Emerg; February 9, 2011, Reg; December 30, 2020, Susp.	.....do	Do.
Lamont, City of, Buchanan County	190331	August 13, 2002, Emerg; July 16, 2008, Reg; December 30, 2020, Susp.	.....do	Do.
Quasqueton, City of, Buchanan County	190332	May 6, 1977, Emerg; July 2, 1987, Reg; December 30, 2020, Susp.	.....do	Do.
Region VIII				
South Dakota:				
Clay County, Unincorporated Areas	460259	May 16, 1986, Emerg; April 1, 1987, Reg; December 30, 2020, Susp.	.....do	Do.
Wakonda, Town of, Clay County	460232	N/A, Emerg; April 8, 2010, Reg; December 30, 2020, Susp.	.....do	Do.

* .....do = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Katherine B. Fox,

Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration—FEMA Resilience, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2020–28478 Filed 12–23–20; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 63

[WC Docket No. 17–84; DA 20–1241; FRS 17274]

Accelerating Wireline Broadband Deployment by Removing Barriers to Infrastructure Investment

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Wireline Competition Bureau of Federal Communications Commission (Commission) makes two ministerial updates to the Commission's rules revising a now inaccurate cross-reference to the definition of copper retirement in changing it from now-repealed), and an inaccurate cross-reference to the definition of ''technology transition'' in section changing it from

DATES: Effective January 27, 2021.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Wireline Competition Bureau, Competition Policy Division, Michele Levy Berlove, at (202) 418–1477, *michele.berlove@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Wireline Competition Bureau's Order in WC Docket No. 17–84, adopted October 20, 2020 and released October 20, 2020. The full text of this document is available on the Commission's website at *https://docs.fcc.gov/public/attachments/DA-20-1241A1.docx.* To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4).

The Commission will not send a copy of this Order on Reconsideration and Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A), because the adopted rules are rules of particular applicability. The final rules associated with the Order are ministerial clarifications of inaccurate cross-references of the Commission's rules.

Synopsis

I. Introduction

1. Next-generation networks hold the promise of new and improved service offerings for American consumers, and encouraging the deployment of these facilities as broadly as possible has long been a priority of the Commission. The COVID–19 pandemic has served to underscore the importance of ensuring that people throughout the country can reap the benefits of these next-generation networks, which provide increased access to economic opportunity, healthcare, education, civic engagement, and connections with family and friends. Removing unnecessary regulatory barriers faced by carriers seeking to transition legacy networks and services to modern broadband infrastructure is therefore a key component of the Commission's work to improve access to advanced communications services and to close the digital divide.

2. In this Order, the Wireline Competition Bureau adopts non-substantive ministerial updates to codified rules required by actions the Commission took in the 2017 *Wireline Infrastructure First Report and Order* (82 FR 61453, Dec. 28, 2017), by revising and correcting two now-inaccurate cross-references in the rules.

II. Order

3. In this Order, the Wireline Competition Bureau makes two ministerial updates to codified rules required by Commission actions taken in the 2017 *Wireline Infrastructure First Report and Order.* We revise a now-inaccurate cross-reference to the definition of copper retirement in § 63.60(i) of the rules, changing it from now-repealed § 51.332(a) to § 51.325(a)(3), and an inaccurate cross-reference to the definition of ''technology transition'' in § 63.602(a)(2), changing it from § 63.60(h) to § 63.60(i). We find that there is good cause for adopting this amendment here because an inaccurate cross-reference may confuse applicants seeking to determine whether a copper retirement, as defined by the rules, is excluded from consideration as a ''technology transition'' in accordance with § 63.60(i). The inaccurate cross-references occurred inadvertently as a result of a series of overlapping changes to these rules over a three year period when previous rules had not yet become effective at the time the new rules were adopted.

4. Section 553 of the Administrative Procedure Act permits the Commission to amend its rules without undergoing notice and comment where it finds good cause that doing so is ''impracticable, unnecessary, or contrary to the public interest.'' The Commission has previously determined that notice and comment is not necessary for ''rule amendments to ensure consistency in terminology and cross references across various rules or to correct inadvertent failures to make conforming changes when prior rule amendments occurred.'' Consistent with these previous decisions, in this instance the Wireline Competition Bureau finds that notice and comment is unnecessary for adopting ministerial revisions to §§ 63.60(i) and 63.602(a)(2) to ensure that the cross-references to the definitions of copper retirement and technology transition are consistent with the recent amendments to the Commission's rules.

5. This action is taken pursuant to the authority delegated by §§ 0.91 and 0.291 of the Commission's rules, 47 CFR 0.91 and 0.291.

III. Procedural Matters

6. This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

7. *Contact Person.* For further information about this proceeding, please contact Michele Levy Berlove, Competition Policy Division, Wireline Competition Bureau, at (202) 418–1477.

IV. Ordering Clauses

8. Accordingly, *it is ordered* that, pursuant to sections 1–4 and 214 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154 and 214, this Order *is adopted.*

9. *It is further ordered* that part 63 of the Commission's rules *is amended* as set forth in the Final Rules.

10. *It is further ordered* that this Order *shall be* effective 30 days after publication in the **Federal Register**.

List of Subjects in 47 CFR Part 63

Cable television, Communications common carriers, Radio, Reporting and recordkeeping requirements, Telegraph, Telephone.

Federal Communications Commission.

Daniel Kahn,

Associate Chief, Wireline Competition Bureau.

Final Rules

For the reasons set forth above, part 63 of title 47 of the Code of Federal Regulations is amended as follows:

PART 63—EXTENSION OF LINES, NEW LINES, AND DISCONTINUANCE, REDUCTION, OUTAGE AND IMPAIRMENT OF SERVICE BY COMMON CARRIERS; AND GRANTS OF RECOGNIZED PRIVATE OPERATING AGENCY STATUS

■ 1. The authority for part 63 continues to read as follows:

Authority: 47 U.S.C. 151, 154(i), 154(j), 160, 201–205, 214, 218, 403, 571, unless otherwise noted.

■ 2. Amend § 63.60 by revising paragraph (i) to read as follows:

§ 63.60 Definitions.

* * * * *

(i) The term ''technology transition'' means any change in service that would result in the replacement of a wireline TDM-based voice service with a service using a different technology or medium for transmission to the end user, whether internet Protocol (IP), wireless, or another type; except that retirement of copper, as defined in § 51.325(a)(3) of this chapter, that does not result in a discontinuance, reduction, or impairment of service requiring Commission authorization pursuant to this part shall not constitute a ''technology transition'' for purposes of this part.

■ 3. Amend § 63.602 by revising paragraph (a)(2) to read as follows:

§ 63.602 Additional contents of applications to discontinue, reduce, or impair an existing retail service as part of a technology transition.

(a) * * *

(2) A statement identifying the application as involving a technology transition, as defined in § 63.60(i);

* * * * *

[FR Doc. 2020–26936 Filed 12–23–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MB Docket No. 20–334; RM–11864; DA 20–1435; FRS 17288]

Television Broadcasting Services; Portland, Oregon

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Media Bureau, Video Division (Bureau) has before it a Notice of Proposed Rulemaking issued in response to a petition for rulemaking filed by Sander Operating Co. III LLC (Sander), licensee of KGW, channel 8, Portland, Oregon, requesting the substitution of channel 26 for channel 8 at Portland in the DTV Table of Allotments. The Bureau had instituted a freeze on the acceptance of rulemaking petitions by full power television stations requesting channel substitutions in May 2011 and waived the freeze to consider Sander's proposal to substitute channel 26 at Portland. TEGNA, Inc., filed comments in support of the petition reaffirming its commitment to applying for channel 26. The Bureau believes the public interest would be served by the substitution and will permit the station to better serve its viewers, who have experienced reception problems with VHF channel 8.

DATES: Effective December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, Media Bureau, at *Joyce.Bernstein@fcc.gov*.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order,* MB Docket No. 20–334; RM–11864; DA 20–1435, adopted and released on December 2, 2020. The full text of this document is available for download at *https://www.fcc.gov/edocs*. To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law. 104–13. In addition, therefore, it does not contain any proposed information collection burden ''for small business concerns with fewer than 25 employees,'' pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.

Federal Communications Commission.

Thomas Horan,

Chief of Staff, Media Bureau.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICE

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622 [Amended]

■ 2. Section 73.622 is amended in paragraph (i), in the Post-Transition Table of DTV Allotments under Oregon, by removing channel 8 and adding channel 26 in numerical order at Portland.

[FR Doc. 2020–27218 Filed 12–23–20; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF VETERANS AFFAIRS

48 CFR Part 825

RIN 2900–AQ79

VA Acquisition Regulation: Foreign Acquisition

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending and updating its VA Acquisition Regulation (VAAR) in phased increments to revise or remove any policy superseded by changes in the Federal Acquisition Regulation (FAR), to remove any procedural guidance internal to VA into the VA Acquisition Manual (VAAM), and to incorporate any new agency specific regulations or policies. These changes seek to streamline and align the VAAR with the FAR and remove outdated and duplicative requirements and reduce burden on contractors. The VAAM incorporates portions of the removed VAAR as well as other internal agency acquisition policy. VA will rewrite certain parts of the VAAR and VAAM, and as VAAR parts are rewritten, will publish them in the **Federal Register**. In particular, this rulemaking removes VAAR coverage concerning Foreign Acquisition.

DATES: This rule is effective on January 27, 2021.

FOR FURTHER INFORMATION CONTACT: Mr. Bogdan Vaga, Senior Procurement Analyst, Procurement Policy and Warrant Management Services, 003A2A, 425 I Street NW, Washington, DC 20001, (202) 894–0686. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On June 9, 2020, VA published a proposed rule in the **Federal Register** (85 FR 35238) which announced VA's intent to amend regulations for VAAR Case RIN 2900–AQ79—VA Acquisition Regulation: Foreign Acquisition. VA provided a 60-day comment period for the public to respond to the proposed rule and submit comments. The comment period for the proposed rule ended on August 10, 2020 and VA received comments from seven respondents. This rule adopts as a final rule the proposed rule published in the **Federal Register** on June 9, 2020, with the exception of minor formatting edits.

As stated previously, VA received comments from seven respondents. A summary of the comments and the issues raised are provided as follows:

One commenter expressed support for the Buy American Act and concern regarding future procurements from China. VA is fully committed to complying with the Buy American Act as set forth in the Federal Acquisition Regulation.

Multiple respondents expressed concern about the Los Angeles Metropolitan Transportation Authority awarding a contract to a Chinese firm to build railcars for their public transportation system. VA appreciates these comments. However, the VA does not have any authority with the Los Angeles Metropolitan Transportation Authority and has no influence regarding this organization's procurement decisions. As the comment does not specifically address issues with the proposed rule, VA is making no revisions as a result of these comments.

Multiple respondents expressed concern that VA was attempting to eliminate the requirement to comply with the Buy American Act via the removal of Part 825 which results from this rulemaking. VA is fully committed to complying with and implementing all Buy American Statutes. The updating of the VAAR to remove coverage at 825 does not in any way create loopholes to circumvent the FAR or the Buy American Statutes. As a Federal agency, VA must comply with all federal regulations, statutes, rules, etc.

Another commenter expressed consternation regarding a school in Los Angeles that would be encroaching on VA property if it were to expand beyond its existing boundaries. In regard to the concern expressed about the expansion of the ''Brentwood school'' and its possible encroachment on VA property, this rulemaking has no impact on this situation, and this is beyond the purview of this regulation. As the comment does not specifically address issues with the proposed rule applicable to VA procurements, VA is making no revisions as a result of the comment.

Executive Orders 12866, 13563 and 13771

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

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

This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). The rule primarily affects the use of authorities that VA contracting officers are already authorized by statute to utilize when required and in accordance with existing agency regulation, policies and procedures. This rule appropriately clarifies and revises the use of such authorities and when certain justification and approval requirements apply. The authorities were previously codified in the VAAR either in this part or in other parts, to include those affecting small business programs, and they affected both large and small entities alike. With this rule, VA ensures content to supplement the FAR for VA's unique service-disabled veteran-owned small business and veteran-owned small business program is properly implemented in this part.

The overall impact of the rule is of benefit to small businesses owned by Veterans or service-disabled Veterans as the VAAR is being updated to remove extraneous procedural information that applies only to VA's internal operating processes or procedures. This rule will ensure clarity for both the public and VA contracting officers to ensure that when such authorities are utilized, they are properly cited and, when required, appropriately documented and publicized. This rulemaking does not change VA's policy regarding small businesses. VA estimates that no cost or economic impact to individual businesses will result from this rule update. VA estimates this final rule is not expected to result in increased or decreased costs to small business entities, and no more than *de minimis* costs. On this basis, the final rule does not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

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

Congressional Review Act

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

List of Subjects in 48 CFR Part 825

Customs duties and inspection, Foreign currencies, Foreign trade, Government procurement.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Brooks D. Tucker, Assistant Secretary for Congressional and Legislative Affairs, Performing the Delegable Duties of the Chief of Staff, Department of Veterans Affairs, approved this document on December 8, 2020, for publication.

Luvenia Potts,

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

Accordingly, under the authority of 40 U.S.C. 121(c), 41 U.S.C. 1702; and 48 CFR 1.301–1.304, VA amends 48 CFR by removing and reserving part 825.

[FR Doc. 2020–27328 Filed 12–23–20; 8:45 am]

BILLING CODE 8320–01–P

Proposed Rules

Federal Register
Vol. 85, No. 248
Monday, December 28, 2020

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

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Chapter I

Food Safety and Inspection Service

9 CFR Chapter III

[Docket No. APHIS–2020–0079]

RIN 0579–AE60

Regulation of the Movement of Animals Modified or Developed by Genetic Engineering

AGENCY: Animal and Plant Health Inspection Service, Department of Agriculture (USDA); Food Safety and Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking and request for comments.

SUMMARY: We are soliciting public comment on establishing regulations for the movement of certain animals modified or developed by genetic engineering. Under the regulatory framework being contemplated, the United States Department of Agriculture would promulgate regulations using the authorities granted to the Department through the Animal Health Protection Act, the Federal Meat Inspection Act (FMIA), and the Poultry Products Inspection Act (PPIA). Pursuant to these authorities, the Animal and Plant Health Inspection Service would conduct a safety assessment of animals subject to the FMIA or PPIA that have been modified or developed using genetic engineering that may increase the animal's susceptibility to pests or diseases of livestock, including zoonotic diseases, or ability to transmit the same. The Food Safety and Inspection Service would conduct a pre-slaughter food safety assessment to ensure that the slaughter and processing of certain animals modified or developed using genetic engineering would not result in a product that is adulterated or misbranded.

DATES: We will consider all comments that we receive on or before February 26, 2021.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0079.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0079, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2020-0079* or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Alan Pearson, Assistant Deputy Administrator, Biotechnology Regulatory Services; APHIS, 4700 River Road, Unit 98, Riverdale, MD 20737–1238; (301) 851–3944; *Alan.Pearson@usda.gov.* Dr. Kis Robertson Hale, Deputy Assistant Administrator, Office of Public Health Science, USDA Food Safety and Inspection Service, 1400 Independence Avenue SW, Room 341–E. Whitten Building; (202) 720–4819; *Kis.Robertson1@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Statutory Authorities

Under the Animal Health Protection Act (7 U.S.C. 8301, *et seq.*) (AHPA), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA) is authorized, among other things, to prohibit or restrict the importation and interstate movement of live animals to prevent the introduction and dissemination of diseases and pests of livestock within the United States. The AHPA broadly defines the terms ''livestock'' as ''all farm-raised animals'' (7 U.S.C. 8302(10)), and ''animal'' as ''any member of the animal kingdom (except a human)'' (7 U.S.C. 8302(1)). Importantly, these definitions do not place any conditions or restrictions on the method by which the animal has been produced, whether it is through conventional breeding or genetic engineering. (We provide illustrative examples of conventional breeding and a working definition of the term *genetic engineering* later in this document, beneath the heading ''Contemplated Regulatory Framework.'') The AHPA also establishes broad definitions of ''import,'' ''interstate commerce,'' and how animals and products ''move'' in commerce. (7 U.S.C. 8302(7), (9), (12)). The statute provides that the term ''disease'' has the meaning given the term by the Secretary of Agriculture (7 U.S.C. 8302(3)), although that term has remained undefined to date, and provides that the Secretary may promulgate such regulations and issue such orders as the Secretary determines necessary to carry out the responsibilities under the AHPA. (7 U.S.C. 8315). Collectively, these provisions provide ample authority for the Secretary of Agriculture to promulgate regulations for the pre-market review and oversight of animals modified or developed using genetic engineering and intended for importation, interstate movement, or environmental release if there is reason to believe that such movement may present a pest or disease risk to livestock.

USDA's Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA, 21 U.S.C. 601, *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*). Specifically, FSIS protects the public by verifying that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged. FSIS verification programs include ante-mortem and post-mortem inspection of livestock and poultry intended for use as human food, as well as the inspection of meat and poultry products for processing. Livestock subject to FSIS jurisdiction under the FMIA (defined as ''amenable species'' at 21 U.S.C. 601(w)) are cattle, sheep, swine, goats, horses, mules, or other equines, and fish of the order Siluriformes. Poultry subject to FSIS jurisdiction under the PPIA (defined as ''any domesticated bird,

whether live or dead'' at 21 U.S.C. 453(3)) are chickens, turkeys, ducks, geese, guineas, ratites, and squabs, as listed in the regulations at 9 CFR 381.1. Under both statutes, FSIS prevents adulterated or misbranded meat and poultry products from entering commerce, working with the Food and Drug Administration (FDA), which determines the safety of food additives and animal drug residues. ''Adulterated'' is defined in the FMIA and PPIA (21 U.S.C. 601(m) and 453(g), respectively) as a number of conditions that may render meat or poultry to be injurious to human health, otherwise cause meat or poultry to be unfit for human food, or make a meat or poultry product appear better or of greater value than it is. ''Misbranded'' is defined in the FMIA and PPIA (21 U.S.C. 601(n) and 453(h), respectively) as several types of product labeling or representation of a meat or poultry product that are false or misleading.

USDA acknowledges that the number of species subject to APHIS' purview under the AHPA is significantly greater than the number of species subject to FSIS' purview under the FMIA and PPIA. For purposes of this document and the contemplated regulatory framework discussed in it, USDA limits its discussion to species subject to both APHIS and FSIS purview.[1] This is not intended to infer any limitations or restrictions regarding APHIS' statutory authority in this matter.

Coordinated Framework for the Regulation of Biotechnology

Along with the Environmental Protection Agency (EPA) and FDA, USDA (APHIS and FSIS) is responsible for the oversight and review of organisms modified or developed using genetic engineering and the foods derived from them. In 1986, the Coordinated Framework for the Regulation of Biotechnology (Coordinated Framework) [2] was published by the Office of Science and Technology Policy (OSTP). The Coordinated Framework explains the regulatory roles for USDA (APHIS and FSIS), EPA, and the FDA, and how Federal agencies use existing Federal statutes to ensure public health and environmental safety while maintaining regulatory flexibility to avoid impeding the growth of the biotechnology industry. The Coordinated Framework was subsequently updated in 1992 (*see* 57 FR 6753). A 2016 document issued by OSTP, discussed immediately below, led to a third update to the Coordinated Framework in 2017.

In 2016, OSTP issued the National Strategy for Modernizing the Regulatory System for Biotechnology Products (National Strategy).[3] Recognizing that rapid scientific advances would result in novel types of products, the National Strategy stated that EPA, FDA, and USDA should continue to examine their regulatory structures with the goal of clarifying how the Federal Government will regulate genetically engineered insects and noted that the agencies are working to better align their responsibilities over genetically engineered insects with their traditional oversight roles. (For example, the 2016 National Strategy highlighted the agencies' work to consider mechanisms that would enable EPA to regulate mosquitoes under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136, *et seq.*) as a pesticide, when the developer claims the mosquitoes are intended for population control, FDA to regulate them when a developer makes a disease claim,[4] and USDA to regulate them using its authorities [5] to control of certain plant or animal pest insects.

As a result of the National Strategy, the Coordinated Framework was then updated in 2017,[6] taking into account advances that had occurred in the field of biotechnology. The 2017 update pointed out that the complexities of the regulatory systems make it difficult for the public to understand how the safety of biotechnology products is evaluated and create challenges for small and mid-sized businesses navigating the regulatory process for the products.

Further, on June 11, 2019, the President signed an Executive Order on Modernizing the Regulatory Framework for Agriculture Biotechnology products in order to conduct improved Federal oversight of agricultural biotechnology products that is science-based, timely, efficient, and transparent. The Executive Order pointed out that for many national imperatives for food production and rural prosperity to be realized, the Federal biotechnology regulatory system must both foster public confidence in the technology and avoid undue regulatory burdens.

Current Federal Regulatory Approach for Animals Modified or Developed Through Genetic Engineering

Currently, FDA regulates intentional genomic alterations in animals as animal drugs under the FD&C Act; *Institute for Fisheries Resources* v. *Hahn,* 424 F. Supp. 3d 740, 751 (N.D. Cal. 2019), except for mosquito products as described in the 2017 FDA Guidance for Industry #236 entitled ''Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products,'' [7] and genetically engineered plant pests, which are subject to APHIS regulation under the Plant Protection Act (7 U.S.C. 7701, *et seq.*).[8] FDA's oversight of intentional genomic alterations in animals includes an evaluation of food safety, safety to the animal, and effectiveness. Although sponsors are generally required to have an approved new animal drug application for intentional genomic alterations in animals prior to marketing, FDA has exercised enforcement discretion for certain low-risk alterations, such as intentional genomic alterations in aquarium fish intended to cause the fish to fluoresce or intentional genomic alterations in animals of food-producing species intended for use as models of disease.

Contemplated Regulatory Framework

In consultation with FDA, USDA is contemplating regulations that would establish a flexible, risk- and science-based regulatory framework for the regulation of certain animals modified or developed using genetic engineering that are intended for agricultural purposes. (For purposes of our contemplated regulatory framework, we envision *genetic engineering* to mean ''techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome'' (*see* 7 CFR 340.3). Thus, it would not include conventional breeding methods such as directed breeding, artificial insemination, embryo transfer, selective breeding, cross breeding, genetic

[1] For example, although APHIS has authority over all farmed aquaculture under the AHPA, the contemplated regulatory framework would pertain only to farmed Siluriformes intended for human food because this is the only aquaculture subject to FSIS authority under the FMIA.

[2] To view the 1986 framework, go to *https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf.*

[3] To view, go to *https://www.epa.gov/sites/production/files/2016-12/documents/biotech_national_strategy_final.pdf.*

[4] Under the Federal Food, Drug, and Cosmetic Act (FD&C Act, 21 U.S.C. 301, *et seq.; see* 21 U.S.C. 321(g)).

[5] Plant Protection Act of 2000; (PPA, 7 U.S.C. 7701 *et seq.*) and Animal Health Protection Act (7 U.S.C. 8301, *et seq.*).

[6] To view the 2017 update to the Coordinated Framework, go to: *https://www.aphis.usda.gov/biotechnology/downloads/2017_coordinated_framework_update.pdf.*

[7] To view GFI #236, go to: *https://www.fda.gov/media/102158/download.*

[8] FDA has exercised enforcement discretion over certain intentional genomic alterations in animals of non-food-species that are regulated by other government agencies or entities, such as plant or animal pest insects modified or developed using genetic engineering for plant pest control or animal health protection, which are under APHIS oversight.

backgrounding for purposes of studding, or other practices commonly available to and employed by producers.) Under this contemplated regulatory framework, USDA would in most instances provide end-to-end regulatory oversight from pre-market reviews through post-market food safety monitoring for animals modified or developed using genetic engineering intended for use as human food that are subject to the FMIA or the PPIA (cattle, sheep, goats, swine, horses, mules, or other equines,[9] and fish of the order Siluriformes, domesticated chickens, turkeys, ducks, geese, guineas, ratites, and squabs). Instances where this would not be the case are discussed later in this document. USDA also would provide pre-market animal health regulatory oversight for cattle, sheep, goats, swine, horses, mules, other equines, fish of the order Siluriformes, domesticated chickens, turkeys, ducks, geese, guineas, ratites, and squabs modified or developed using genetic engineering intended for agricultural purposes other than human or animal food (*e.g.,* fiber or labor). For ease of reading, we refer to the animals listed in this paragraph that are modified or developed using genetic engineering and intended for agricultural purposes as ''amenable species modified or developed using genetic engineering.'' As discussed above, ''amenable species'' is a statutorily defined phrase under the FMIA and used generally by FSIS to refer to livestock and poultry species subject to the FMIA or PPIA. Since the contemplated regulatory framework would apply to certain foods only from those species, we use this phrase for the rest of the document, except where context dictates otherwise (*e.g.,* when the use of the phrase could be misconstrued to suggest that a USDA determination that would apply only to a particular animal would instead apply to the entire species). USDA's safety reviews would focus on risks to animal health and human health, by:

- Ensuring that the animal of the amenable species that has been modified or developed using genetic engineering and that is subject to the review is not more susceptible to pests or disease of livestock (infectious and non-infectious), or more likely to spread pests or infectious diseases of livestock, including zoonotic diseases, than animals from the same species that were not modified or developed using genetic engineering.
- Regulating the importation, interstate movement, and environmental release of the animal of the amenable species that has been modified or developed using genetic engineering accordingly.
- Ensuring that animals of the amenable species modified or developed using genetic engineering that are intended to enter the food supply are safe for human consumption by ensuring such animals would not result in a meat or poultry product that is adulterated or misbranded, using the same statutory criteria used for meat and poultry products made from animals produced without genetic engineering.
- Providing permits for the import, interstate movement, or environmental release (*i.e.,* controlled field trials to evaluate the animals) of amenable species modified or developed using genetic engineering.
- Having clear mechanisms for APHIS deregulation when the animal under review is found to pose no greater risk to animal health than the animal from which it was derived.

The contemplated regulatory framework for amenable species modified or developed using genetic engineering is intended to operate under a Memorandum of Understanding (MOU) with FDA consistent with each agency's authorities and statutory obligations and informed by the comments received in response to this advance notice of proposed rulemaking and request for comments. A MOU would facilitate an orderly transition of the oversight of amenable species modified or developed using genetic engineering for certain intended uses from FDA to USDA once USDA's regulatory program is established. A MOU would set clear roles, responsibilities, and timeframes for the interaction between FDA and USDA.

As described, under the contemplated regulatory framework, USDA would in most instances serve as a single point of entry for amenable species modified or developed using genetic engineering that are intended for agricultural purposes and would provide coordinated end-to-end regulatory oversight from pre-market animal pest and disease risk and human food safety reviews through post-market human food safety reviews for amenable species modified or developed using genetic engineering intended for use as human food. USDA also would provide pre-market animal health regulatory oversight of amenable species modified or developed using genetic engineering intended for agricultural purposes other than human food (*e.g.,* fiber or labor). Under the contemplated regulatory framework, USDA would not regulate amenable species modified or developed using genetic engineering intended for non-agricultural purposes, including medical and pharmaceutical purposes (other than veterinary biologics), and gene therapies. FDA would continue its review of intentional genomic alterations in these amenable species as well as the regulation of dairy products, table and shell eggs, and animal food (feed) that are derived from amenable species. In addition, FDA would continue its review of intentional genomic alterations in animals and the animal food products derived from them that are not subject to the FMIA or PPIA and not previously determined by FDA to be low risk.

The regulatory framework that USDA is considering would be conceptually similar to the recently updated USDA regulations for the movement of organisms, notably plants, modified or developed using genetic engineering, which are found in 7 CFR part 340. However, due to the differences in experience, biology, and breeding practices of animals as compared to plants, there would be some differences between these regulatory frameworks. For example, although 7 CFR part 340 includes up-front exemptions from the regulations for certain types of modifications, we envision that all amenable species modified or developed using genetic engineering and intended for agricultural purposes would be subject to permitting requirements for their import, interstate movement, or environmental release until they have undergone an expedited safety review or an animal health risk assessment and been determined not to pose an increased risk to animal health. We do seek comment on this issue.

Under the contemplated regulatory framework, developers could request that USDA conduct a risk-based and science-based safety review focused on animal health; if the animal of an amenable species has been modified or developed using genetic engineering and is intended for use as human food, then the risk-based and science-based safety review would also be focused on food safety. Depending on the conclusions of the review, the animal subject to the safety review could be determined to not require a permit for import, interstate movement, or environmental release under regulations issued pursuant to this framework, and, if such animal is intended for use as human food, it could be eligible for inspection and to be marked ''Inspected

[9] Horses, mules, and other equines are subject to FSIS jurisdiction under the FMIA, but there are no USDA-inspected horse slaughter establishments in the United States, and USDA is currently prohibited from spending funds to perform ante-mortem inspection of horses for human consumption.

and Passed,'' as free from adulteration, at any USDA-inspected meat packing facility.

We envision a two-tiered system for such reviews. First, USDA is considering an expedited safety review for any genetic modification made that is already known to occur in the gene pool of the species, except in cases where an animal health claim is made for the animal or the modification is known to adversely affect animal health.[10] The purpose of the review would be to verify, through a molecular characterization of the modification and an understanding of the process by which it was introduced, that the intended change was made and that there were no unintended disruptions of endogenous genes,[11] unintended DNA insertions, or off-target changes if the genome was modified without inserting DNA. The expedited safety review would assess whether the modification made using genetic engineering is equivalent to what can be accomplished through conventional breeding practices to ensure that the animal presents no increased risk relative to the animal from which it was derived, including the verification process described above. If USDA finds that the modification made using genetic engineering is equivalent to what can be accomplished through conventional breeding practices, the animal would not be subject to further regulation under the contemplated regulatory framework, and USDA would issue a notice in the **Federal Register** that the animal of the amenable species modified or developed using genetic engineering poses no increased risk to animal health or human health relative to the animal from which it was derived.

If, as part of the expedited safety review, USDA finds that the animal of the amenable species modified or developed using genetic engineering has one of the aforementioned unintended changes, the submitter will be informed. A permit would be required for import, interstate movement, or environmental release of such animal until USDA completes a full animal health risk assessment, and, if the animal of the amenable species modified or developed using genetic engineering is intended for use as human food, a food safety assessment, as described below. For all other types of modifications that are not eligible for expedited safety review, a permit would likewise be required for the importation, interstate movement, or environmental release of the animal of the amenable species that had been modified or developed using genetic engineering, until USDA conducted an animal health risk assessment of the animal and, if the animal is intended for use as human food, a food safety assessment, and determined that there was no additional animal health risk relative to an appropriate comparator.

Review Under the AHPA

The animal health risk assessment would identify any plausible increased risks to animal health or to human health, relative to the risk posed by animals from the same species that were not modified or developed using genetic engineering. In particular, the risk assessment would examine whether the animal could plausibly exhibit increased susceptibility to pests, non-infectious diseases, or infectious diseases of livestock, including zoonotic diseases, or increased ability to transmit such pests or diseases. If a plausible increased risk is identified, USDA would evaluate the scientific data submitted by the developer to ensure that the animal of the amenable species modified or developed using genetic engineering would not pose an increased risk to animal health as compared with animals from the same species that were not modified or developed using genetic engineering.

If the risk assessment concludes that the animal is unlikely to pose an increased risk to animal health relative to the animal from which it was derived, USDA would make the risk assessment available for public comment through a notice published in the **Federal Register**. If no new information emerges that changes USDA's conclusion, USDA would determine that the animal of the amenable species that had been modified or developed using genetic engineering is not regulated under the contemplated regulatory framework. If the risk assessment is unable to reach such conclusion, the animals of the amenable species that had been modified or developed using genetic engineering would remain regulated, and a permit would be needed for importation, interstate movement, or environmental release. APHIS and FSIS would coordinate in these situations to determine whether such animals would be eligible for slaughter. A developer could request a re-review at any time and would be able to provide additional information. USDA would keep the developer apprised of the review's progress.

Additionally, when USDA is unable to reach a conclusion that the animal is unlikely to pose an increased risk to animal health relative to the animal from which it was derived, the developer could request that USDA seek public comment on its risk assessment. Where appropriate when conducting this review, USDA would consult with FDA as described in a MOU.

At a minimum, the animal health risk assessment would include an evaluation of the following issues:

- *Molecular Characterization:* What is the genetic modification(s) in the animal, how was the genetic modification(s) introduced, and how does the genetic modification(s) alter protein or ribonucleic acid (RNA expression)?
- *Animal Health:* Is there scientific evidence that the modified animal could plausibly, either directly or indirectly, increase susceptibility of livestock, including of the animal itself, to pests, non-infectious diseases, or infectious diseases of livestock, including zoonotic diseases? Is there scientific evidence that the modified animal could plausibly increase the spread of pests or infectious diseases of livestock, including zoonotic diseases? When a plausible pathway to such an increased risk is identified, further analysis would be conducted to evaluate the pathway. When an animal health claim is made or a modification is known to adversely affect animal health, the review would assess the animal health claim.
- *Environmental Factors:* Is there scientific evidence that introduction of the modified animal into the environment may result in environmental impacts that would warrant review pursuant to the National Environmental Policy Act (NEPA) or other statutes?

Review Under the FMIA and PPIA

Under the contemplated regulatory framework, FSIS would require food safety assessments of animals of amenable species modified or developed using genetic engineering pursuant to its authorities under the FMIA and PPIA, primarily using its authority to conduct ante-mortem inspections of livestock and poultry presented for slaughter. A discussion of these authorities and how they might be applied within the contemplated regulatory framework for amenable species modified or developed using genetic engineering follows.

[10] When an animal health claim is made or a modification is known to adversely affect animal health and the animal otherwise qualifies for an expedited safety review, USDA would undertake additional review that focuses on the animal health modification, including validation of any animal health claim.

[11] Endogenous genes are pre-existing genes in the genome of the animal being modified or developed using genetic engineering.

As discussed above, under FMIA, FSIS has authority to prevent adulterated meat and meat food products derived from amenable livestock and intended for human consumption from entering commerce. Currently, the amenable livestock eligible for inspection include cattle, sheep, swine, goats, horses, mules, and other equines, and fish of the order Siluriformes. The statute defines ''meat food product'' as ''any product capable of use as human food which is made wholly or in part from any meat or other portion of the carcass of any cattle, sheep, swine, or goats, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat food industry, and which are exempted from definition as a meat food product by the Secretary under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat food products'' (21 U.S.C. 601(j)). The statute provides that ''this term as applied to food products of equines shall have a meaning comparable to that provided . . . with respect to cattle, sheep, swine, and goats.'' *Id.*

The FMIA requires that, ''for the purpose of preventing the use in commerce of meat or meat food products which are adulterated, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species *before* they shall be allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce . . . '' (21 U.S.C. 603(a)) (emphasis added). The FMIA also provides for the post-mortem inspection of meat and meat food products. Specifically, the statute provides that ''[t]he Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment, and for the purposes of any examination and inspection and inspectors shall have access at all times, by day or night, whether the establishment be operated or not, to every part of said establishment; and said inspectors shall mark, stamp, tag, or label as 'Inspected and passed' all such products found *to be not adulterated;* and said inspectors shall label, mark, stamp, or tag as 'Inspected and condemned' all such products found adulterated; and all such condemned meat food products shall be destroyed for food purposes, as hereinbefore provided and the Secretary may remove inspectors from any establishment which fails to so destroy such condemned meat food products'' (21 U.S.C. 606) (emphasis added).

Similarly, the PPIA provides FSIS with authority to prevent adulterated poultry and poultry products for human consumption from entering commerce (21 U.S.C. 451, *et seq.*). The statute defines ''poultry'' as ''any domesticated bird, whether live or dead'' (21 U.S.C. 451(e)). Regulations promulgated under the Act define the domesticated poultry species to include chickens, turkeys, ducks, geese, guineas, ratites and squabs (9 CFR 381.1(b)). The statute defines ''poultry product'' as ''any poultry carcass, or part thereof; or any product which is made wholly or in part from any poultry carcass or part thereof, excepting products which contain poultry ingredients only in a relatively small proportion or historically have not been considered by consumers as products of the poultry food industry, and which are exempted by the Secretary from definition as a poultry product under such conditions as the Secretary may prescribe to assure that the poultry ingredients in such products are not adulterated and that such products are not represented as poultry products'' (21 U.S.C. 451(f)).

The PPIA permits the Secretary to conduct an ante-mortem inspection of every live animal before slaughter. Specifically, the statute provides: ''For the purpose of preventing the entry into or flow or movement in commerce of, or the burdening of commerce by, any poultry product which is capable of use as human food *and is adulterated,* the Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante-mortem inspection of poultry . . .'' (21 U.S.C. 455(a)) (emphasis added). Like the FMIA, the PPIA contemplates an inspection of live animals in order to exclude animals from the slaughter process that could result in the production of adulterated product. The PPIA also requires the Secretary to conduct a post-mortem inspection of every carcass and to inspect processed products as the Secretary deems necessary (21 U.S.C. 455(b)): ''The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post-mortem inspection of the carcass of each bird processed, and at any time such quarantine, segregation and reinspection as he deems necessary of poultry and poultry products capable of use as human food in each official establishment processing such poultry or poultry products for commerce or otherwise subject to inspection under this Act'' (21 U.S.C. 455(b)). Further, ''[a]ll poultry carcasses and parts thereof and other poultry products *found to be adulterated* shall be condemned and shall, if no appeal be taken from such determination of condemnation, be destroyed for human food purposes under the supervision of an inspector; *Provided,* That carcasses, parts, and products, which may by reprocessing be made not adulterated, need not be so condemned and destroyed if so reprocessed under the supervision of an inspector and thereafter found to be not adulterated'' (21 U.S.C. 455(c)) (emphasis added).

Both the FMIA and PPIA contain definitions of the term ''adulterated'' (21 U.S.C. 601(m) and 453(g), respectively) that describe a number of conditions that may render meat or poultry to be injurious to human health, otherwise cause meat or poultry to be unfit for human food, or make a meat or poultry product appear better or of greater value than it is. As previously noted, meat, meat food products, poultry, and poultry products cannot be sold or distributed in commerce for use in human food until an inspector makes an affirmative determination that the product is not adulterated. Both statutes also define ''misbranded'' as several types of product labeling or representation of a meat or poultry product that are false or misleading (21 U.S.C. 453(h) and 601(n)). Under the approach contemplated in this document, USDA would conduct a pre-slaughter food safety assessment utilizing the ante-mortem and adulteration provisions of the FMIA and PPIA cited above to ensure that an animal of the amenable species modified or developed using genetic engineering would not result in a product that is adulterated or misbranded.

An issue to be addressed would be the timing of the pre-slaughter food safety assessment for animals modified or developed using genetic engineering. As discussed above, both statutes provide for ante-mortem inspection of live animals in order to prevent adulterated product from being sold or distributed in commerce (21 U.S.C. 455(a), 603(a)). Neither statute specifies how far in advance examinations or reviews relative to this inspection can occur. Thus, on their face, these statutes would appear to authorize USDA to

promulgate a regulation requiring a food safety review of animals of amenable species modified or developed using genetic engineering before arrival at the slaughter facility in order to ensure that the meat or poultry derived from such animals would not be adulterated under the FMIA and PPIA.

Such a conclusion would appear to be consistent with the text of these statutory provisions and the purposes that the statutory text was enacted to further. Providing for review before arrival at the slaughter facility would further the purposes of the provisions of the FMIA and the PPIA that provide for ante-mortem inspection of live animals and, more generally, of the inspection regimes established by the FMIA and the PPIA. Historically, inspectors assigned to work in slaughtering and processing facilities have used a variety of tools, including sensory examination and available laboratory testing, to determine whether meat or poultry products are adulterated within the meaning of the statutes at the time of slaughter or processing. Because certain laboratory tests can take days to finalize, the inspectors require sampled carcasses and products to be held at the establishment until the laboratory tests are completed. For animals of the amenable species modified or developed using genetic engineering, however, a FSIS inspector would likely be unable to make an ''on the spot'' determination about whether the live animal should be segregated, or whether the meat or poultry product is adulterated at the time the animal is presented for inspection at the slaughter facility using currently available testing methodologies and inspection techniques. Live animals of the amenable species modified or developed using genetic engineering and their carcasses typically will not be distinguishable from conventionally produced animals based on their physical appearance. Also, there currently is no generally applicable test that could be administered in the slaughter facility to determine whether the animal was modified or developed using genetic engineering or whether the genetic modification would render the resulting meat or poultry product adulterated within the meaning of the statutes. Therefore, as a practical matter, unless there is a pre-slaughter (or pre-market) safety review, FSIS inspectors would be unable to determine that meat or poultry products derived from animals modified or developed using genetic engineering are not adulterated. By operation of the statutes and regulations, such a product would be precluded from being marked as ''Inspected and Passed,'' and thus could not be sold or distributed in commerce for human food, until a food safety assessment was completed and the meat was determined to not be adulterated.

FSIS Review

For the food safety assessment, FSIS would evaluate the scientific data submitted by the developer to ensure that the animal of amenable species modified or developed using genetic engineering would not result in products that are adulterated as defined under the Acts. FSIS would also examine whether genetic engineering may result in meat and poultry products being misbranded, *i.e.,* labeled in a false or misleading manner, which is prohibited by both the FMIA and PPIA. At a minimum, the FSIS assessment would include an evaluation of the following issues:

- *Evaluation of expressed substances:* Is there scientific evidence that the genetic modification could result, directly or indirectly, in toxins, chemical residues, or other potentially deleterious substances in meat or poultry products?
- *Allergenicity:* Is there scientific evidence that the genetic modification would directly or indirectly alter the allergenic potential of meat or poultry products derived from the animal?
- *Food storage and processing:* Is there scientific evidence that meat or poultry products derived from the modified animal could mislead consumers regarding wholesomeness or the need for appropriate storage (*e.g.,* meat that maintains a red appearance even when spoiled)?
- *Compositional analyses of key components:* Is there scientific evidence that meat or poultry products from the modified animal are compositionally (*e.g.,* nutritionally or functionally) no different than meat from conventional animals, such that it meets any regulatory definition, standard of identity or other labeling requirement, and consumer expectations for the applicable product?

Request for Comments

We are soliciting public comments on all aspects of this document, including the contemplated regulatory framework as described herein, with particular attention on the following questions:

Scope of Regulations and Review

- The contemplated regulatory framework would apply to animals of the ''amenable species'' (cattle, sheep, goats, swine, horses, mules, other equines, fish of the order Siluriformes, chickens, turkeys, ducks, geese, guineas, ratites, and squabs) modified or developed using genetic engineering that are ''intended for agricultural purposes'' such as human or animal food, fiber, and labor. What are the agricultural uses for ''amenable species'' other than use as human or animal food? Should the contemplated regulatory framework define ''agricultural purposes other than food''? If so, how should it be defined?
- Is the safety review process described above (see ''Contemplated Regulatory Framework'') appropriate to protect human health, including for both human consumption and disease transmission? Why or why not?
- Is the safety review process described above (see ''Contemplated Regulatory Framework'') appropriate to protect livestock health of both the target animal and its herd or flock? Why or why not?
- Are there types of modifications that should make an animal of an amenable species modified or developed using genetic engineering eligible or ineligible for the expedited safety review process outlined above?
- How should USDA define ''off-target changes'' for the purposes of expedited review of animals in which modifications already known to occur in the gene pool of the species are made without the insertion of DNA?
- Should USDA exempt certain types of genetic modifications of amenable species intended for agricultural use from regulation? If so, what types of modifications and why?
- Which types of genetic modifications should not be exempted from regulation? Why?
- Should any entities or activities be exempt from regulation? If so, what types of entities and why? If not, why not?
- Are there any statutory or regulatory constraints and/or advantages that need to be considered?

Risk Assessment Process

- How should USDA assess risks to animal health? Which pest or disease risks should be considered? Should any other adverse effects (*e.g.,* specific adverse effects on the biology of the animal modified or developed using genetic engineering) be considered? Please be specific and include examples when possible.
- Under what circumstances would a controlled animal safety study be needed versus general surveillance over the health of the herd?
- What information, beyond that described in the ''Contemplated Regulatory Framework'' section of the

document, would USDA need to consider in order to properly review and assess risks associated with amenable species modified or developed using genetic engineering that are intended for agricultural purposes? Are there limitations to the types of information that could be gathered or technologies that could be used to inform the evaluation of animal health claims? If so, please describe the limitations.

- What is the minimal information would need to consider to evaluate animal disease claims made for the animals of the amenable species modified or developed using genetic engineering? What are the limitations of current technologies that exist to evaluate animal disease claims?
- What other animal health claims, aside from disease resistance, should USDA require developers to validate? Why?
- Under the current proposal, USDA is not performing a post-market evaluation of animal health. Should USDA require developers to submit information in order to monitor risks to animal health post-market? Why?
- Are there any gaps in the contemplated framework with respect to animal and human health, and if so, how might they be addressed?

Regulatory Authority and Framework

- Does the contemplated regulatory framework provide adequate scope and flexibility to regulate current and future advances in agricultural animals developed using genetic engineering?
- What, if any, terms related to the regulation of animals of the amenable species modified or developed using genetic engineering would need to be defined under the contemplated regulatory framework?
- Should animals of the amenable species modified or developed using genetic engineering with multiple uses (such as an amenable species modified or developed using genetic engineering and intended for both biomedical/pharmaceutical purposes and agricultural purposes) receive any different treatment than other amenable species during USDA's review processes? What steps should USDA take to ensure efficient review of these products? What steps should USDA take to account for existing regulatory burden when a product must be reviewed both by USDA and by another agency?
- Do you have any other specific concerns or recommendations for appropriately reducing regulatory burdens involving the regulation of amenable species modified or developed using genetic engineering by USDA as described in this document?

Genetic Engineering and Conventional Breeding

- What are the known current limits of conventional breeding in animals in terms of generating and/or selecting for a specific trait, or multiple traits?
- What problems are entities currently attempting to solve using animals modified or developed using genetic engineering?

FSIS Assessment

- Would the pre-slaughter assessment ever require physical examination or testing by FSIS of amenable species modified or developed using genetic engineering, specifically examination or testing in regard to their genetic modifications, prior to arrival at the slaughter facility? If so, under what circumstances?
- What documentation, if any, should accompany amenable species modified or developed using genetic engineering destined for slaughter, certifying that their modifications have been assessed by USDA (APHIS and FSIS)?

Economic Considerations

- What classes of entities are currently engaged in the modification, production, breeding, distribution, commercialization or any related activities involving animals modified or developed using genetic engineering? How many of these entities fall within or below the threshold for ''small entity'' size standards according to the Small Business Administration?
- What markets are there where animals for agricultural use modified or developed using genetic engineering have been produced and commercialized? What challenges and opportunities (regulatory, economic, or otherwise) have been encountered by the relevant authorities?
- How often does a start-up company or not-for-profit university or research organization modify or develop an animal using genetic engineering?
- Could the contemplated regulatory framework have adverse impacts on international trade (imports or exports)? If so, what?
- Should USDA assess user fees in connection with conducting reviews for animals modified or developed using genetic engineering? If so, how should USDA structure the fees? What factors should USDA consider in assessing fees?

We welcome all comments on the questions outlined above and on all aspects of this document.

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 18th day of December 2020.

Lorren Walker,

Acting Under Secretary for Marketing and Regulatory Programs.

Paul Kiecker,

Administrator, Food Safety and Inspection Service.

[FR Doc. 2020–28534 Filed 12–23–20; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1165; Project Identifier 2019–SW–027–AD]

RIN 2120–AA64

Airworthiness Directives; Airbus Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Airbus Helicopters Model SA341G and SA342J helicopters. This proposed AD was prompted by the determination that a new life limit was necessary for certain tail rotor blades (TRBs). This proposed AD would require replacing certain TRBs, re-identifying certain TRBs, and repairing certain other TRBs, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by February 11, 2021.

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

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

For material that will be incorporated by reference (IBR) in this AD, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this IBR material on the EASA website at *https://ad.easa.europa.eu.* You may view this IBR material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. It is also available in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1165.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1165; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Blaine Williams, Aerospace Engineer, Los Angeles ACO Branch, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5371; email *blaine.williams@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2020–1165; Project Identifier 2019–SW–027–AD'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Blaine Williams, Aerospace Engineer, Los Angeles ACO Branch, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5371; email *blaine.williams@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

The EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2019–0034, dated February 14, 2019 (EASA AD 2019–0034) (also referred to as the Mandatory Continuing Airworthiness Information, or the MCAI), to correct an unsafe condition for all Airbus Helicopters Model SA341G and SA342J helicopters.

This proposed AD was prompted by the determination that a new life limit was necessary for TRBs that were manufactured without a new process that affects the structural characteristics. The FAA is proposing this AD to address TRBs that might break, resulting in loss of tail rotor control and consequent loss of control of the helicopter. See the MCAI for additional background information.

Related Service Information Under 1 CFR Part 51

EASA AD 2019–0034 describes procedures for replacing TRBs having certain part numbers, re-identifying TRBs having a certain part number and certain serial numbers, and repairing TRBs that have been reworked/repaired/modified before being re-identified.

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

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the bilateral agreement with the State of Design Authority, the FAA has been notified of the unsafe condition described in the MCAI referenced above. The FAA is proposing this AD because the FAA evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in EASA AD 2019–0034, described previously, as incorporated by reference, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA initially worked with Airbus and EASA to develop a process to use certain EASA ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and civil aviation authorities (CAAs) to use this process. As a result, EASA AD 2019–0034 will be incorporated by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2019–0034 in its entirety, through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in the EASA AD. Service information specified in EASA AD 2019–0034 that is required for compliance with EASA AD 2019–0034 will be available on the internet at *https://www.regulations.gov* by searching for and locating Docket No.

FAA–2020–1165 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this proposed AD affects 20 helicopters of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hour × $85 per hour = $85	$3,900	$3,985	$79,700

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Airbus Helicopters: Docket No. FAA–2020–1165; Project Identifier 2019–SW–027–AD.

(a) Comments Due Date

The FAA must receive comments by February 11, 2021.

(b) Affected Airworthiness Directives (ADs)

None.

(c) Applicability

This AD applies to Airbus Helicopters Model SA341G and SA342J helicopters, certificated in any category, equipped with any tail rotor blade (TRB) specified in paragraph (c)(1) or (2) of this AD.

(1) An affected part as defined in European Union Aviation Safety Agency (EASA) AD 2019–0034, dated February 14, 2019 (EASA AD 2019–0034).

(2) A TRB having part number (P/N) 341A335101.01, P/N 341A335130.05, or P/N 341A335130.06.

(d) Subject

Joint Aircraft System Component (JASC) Code 6410, Tail Rotor Blades.

(e) Reason

This AD was prompted by the determination that a new life limit was necessary for TRBs that were manufactured without a new process that affects the structural characteristics. The FAA is issuing this AD to address TRBs that might break, resulting in loss of tail rotor control and consequent loss of control of the helicopter.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2019–0034.

(h) Exceptions to EASA AD 2019–0034

(1) Where EASA AD 2019–0034 refers to its effective date, this AD requires using the effective date of this AD.

(2) The ''Remarks'' section of EASA AD 2019–0034 does not apply to this AD.

(3) Where EASA AD 2019–0034 refers to flight hours (FH), this AD requires using hours time-in-service.

(4) Where paragraph (4) of EASA AD 2019–0034 specifies to contact the manufacturer, for this AD, repair using a method approved by the Manager, Strategic Policy Rotorcraft Section, FAA. For a repair method to be approved by the Manager, Strategic Policy Rotorcraft Section, as required by this paragraph, the Manager's approval letter must specifically refer to this AD.

(5) Where paragraph (5) of EASA AD 2019–0034 specifies it must be determined that the rework/repair/modification is valid for part number 341A335130.06, for this AD, rework/repair/modification of an affected part is prohibited.

(i) Special Flight Permit

Special flight permits, as described in 14 CFR 21.197 and 21.199, are not allowed.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, Strategic Policy Rotorcraft Section, FAA, may approve AMOCs for this AD. Send your proposal to: Manager, Strategic Policy Rotorcraft Section, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone 817–222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(k) Related Information

(1) For EASA AD 2019–0034, contact the EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 89990 000; email *ADs@easa.europa.eu;* internet *www.easa.europa.eu.* You may find this EASA AD on the EASA website at *https://ad.easa.europa.eu.* You may view this material at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call 817–222–5110. This material may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1165.

(2) For more information about this AD, contact Blaine Williams, Aerospace Engineer, Los Angeles ACO Branch, 3960 Paramount Blvd., Lakewood, California 90712; telephone

(562) 627–5371; email *blaine.williams@faa.gov.*

Issued on December 17, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–28440 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID DoD–2020–OS–0094]

RIN 0790–AL17

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary of Defense (OSD), Department of Defense (DoD).

ACTION: Proposed rule.

SUMMARY: The Department of Defense (Department or DoD) is giving concurrent notice of a new Department-wide system of records pursuant to the Privacy Act of 1974 for the DoD 0005 ''Defense Training Records'' system of records and this proposed rulemaking. In this proposed rulemaking, the Department proposes to exempt portions of the Defense Training Records system of records from certain provisions of the Privacy Act because of national security requirements and to preserve the objectivity and fairness of testing and examination material.

DATES: Send comments on or before February 26, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods.

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

* *Mail:* The DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Lyn Kirby, Defense Privacy, Civil Liberties and Transparency Division, Directorate for Oversight and Compliance, Department of Defense, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700; *OSD.DPCLTD@mail.mil;* (703) 571–0070.

SUPPLEMENTARY INFORMATION:

I. Background

The DoD 0005, ''Defense Training Records'' system of records describes training records created and maintained by all component parts of the DoD, wherever they are maintained. The system consists of both electronic and paper records and will be used by DoD components and offices to maintain records about training provided to DoD-affiliated individuals, including Military Service members, civilian employees, dependents and family members, contractors, and other individuals enrolled in courses administered by the DoD. These records may include information pertaining to class schedules, enrollment, participation, programs, and instructors; training trends and needs; testing and examination materials; and assessments of training efficacy. The collection and maintenance of this information will assist the DoD in meeting its obligations under law, regulation, and policy to provide training on various subjects to ensure that the agency mission can be successfully accomplished.

II. Privacy Act Exemption

The Privacy Act allows federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including those that provide individuals with a right to request access to and amendment of their own records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process to provide public notice and an opportunity to comment on the proposed exemption. This proposed rule explains why an exemption is being claimed for this system of records and invites public comment, which DoD will consider before the issuance of a final rule implementing the exemption.

The DoD proposes to modify 32 CFR part 310 to add a new Privacy Act exemption rule for the DoD 0005 ''Defense Training Records'' system of records. The DoD proposes this exemption because some of its training records may contain classified national security information and disclosure of those records to an individual may cause damage to national security. The Privacy Act, pursuant to 5 U.S.C. 552a(k)(1), authorizes agencies to claim an exemption for systems of records that contain information properly classified pursuant to executive order. The DoD is proposing to claim an exemption from the access and amendment requirements of the Privacy Act, pursuant to 5 U.S.C. 552a(k)(1), to prevent disclosure of any information properly classified pursuant to executive order, as implemented by DoD Instruction 5200.01 and DoD Manual 5200.01, Volumes 1 and 3.

The DoD also proposes an exemption for DoD 0005 ''Defense Training Records'' because these records contain testing and examination material, the release of which could undermine the objectivity and fairness of the testing and examination process. The Privacy Act, pursuant to 5 U.S.C. 552a(k)(6), authorizes agencies to claim an exemption for systems of records that contain examination and testing material used solely to determine individual qualification for appointment or promotion in the Federal service. The DoD is proposing to claim an exemption from the access and amendment requirements of the Privacy Act, pursuant to 5 U.S.C. 552a(k)(6), to prevent disclosure of any information that would compromise the objectivity or fairness of testing and examination material.

If implemented, this rule will deny an individual access under the Privacy Act to only those portions of records for which one or more claimed exemptions apply. In addition, records in the DoD 0005 ''Defense Training Records'' system of records are only exempt from the Privacy Act to the extent the purposes underlying the exemption pertain to the record.

A notice of a new system of records for DoD 0005 ''Defense Training Records'' is also published in this issue of the **Federal Register**.

Regulatory Analysis

Executive Order 12866, ''Regulatory Planning and Review'' and Executive Order 13563, ''Improving Regulation and Regulatory Review''

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this proposed rule is not a significant regulatory action.

Executive Order 13771, ''*Reducing Regulation and Controlling Regulatory Costs*''

This proposed rule has been deemed not significant under Executive Order (E.O.) 12866, ''Regulatory Planning and Review,'' therefore, the requirements of E.O. 13771, ''Reducing Regulation and Controlling Regulatory Costs'' do not apply.

Congressional Review Act

This proposed rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Public Law 96–354, ''*Regulatory Flexibility Act*'' *(5 U.S.C. Chapter 6)*

It has been certified that Privacy Act rules for the DoD do not have significant economic impact on a substantial number of small entities because they are concerned only with the administration of Privacy Act systems of records within the DoD.

Public Law 96–511, ''*Paperwork Reduction Act*'' *(44 U.S.C. Chapter 35)*

It has been determined that this proposed rule does not impose additional information collection requirements on the public under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Section 202, Public Law 104–4, ''*Unfunded Mandates Reform Act*''

It has been determined that this proposed rule does not involve a Federal mandate that may result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million or more and that it will not significantly or uniquely affect small governments.

Executive Order 13132, ''*Federalism*''

It has been determined that this proposed rule does not have federalism implications. This rule does not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

List of Subjects in 32 CFR Part 310

Privacy.

Accordingly, 32 CFR part 310 is proposed to be amended as follows:

PART 310—PROTECTION OF PRIVACY AND ACCESS TO AND AMENDMENT OF INDIVIDUAL RECORDS UNDER THE PRIVACY ACT OF 1974

■ 1. The authority citation for 32 CFR part 310 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Section 310.13 is amended by adding paragraph (e)(3) to read as follows:

§ 310.13 Exemptions for DoD-wide systems.

* * * * *

(e) * * *

(3) *System identifier and name:* DoD–0005, ''Defense Training Records.''

(i) *Exemptions:* This system of records is exempt from 5 U.S.C. 552a(c)(3) and (d)(1), (2), (3), and (4).

(ii) *Authority:* 5 U.S.C. 552a(k)(1) and (6).

(iii) *Exemption from the particular subsections.* Exemption from the particular subsections is justified for the following reasons:

(A) *Subsections (c)(3), (d)(1), and (d)(2)—*

(1) Exemption (k)(1). Training records in this system of records may contain information concerning DoD personnel or training materials that is properly classified pursuant to executive order. Application of exemption (k)(1) for such records may be necessary because access to and amendment of the records, or release of the accounting of disclosures for such records, could reveal classified information. Disclosure of classified records to an individual may cause damage to national security.

(2) Exemption (k)(6). Training records in this system of records may contain information relating to testing or examination material used solely to determine individual qualifications for appointment or promotion in the Federal service. Application of exemption (k)(6) for such records may be necessary when access to and amendment of the records, or release of the accounting of disclosure for such records, may compromise the objectivity and fairness of the testing or examination process. Amendment of such records could also impose a highly impracticable administrative burden by requiring testing and examinations to be continuously re-administered.

(B) *Subsections (d)(3) and (4).* These subsections are inapplicable to the extent an exemption is claimed from (d)(2). Moreover, applying the amendment appeal procedures to training and examination materials could impose a highly impractical administrative burden by requiring testing and examinations to be continuously re-administered.

(iv) *Exempt records from other systems.* In the course of carrying out the overall purpose for this system, exempt records from other systems of records may in turn become part of the records maintained in this system. To the extent that copies of exempt records from those other systems of records are maintained in this system, the DoD claims the same exemptions for the records from those other systems that are entered into this system, as claimed for the prior system(s) of which they are a part, provided the reason for the exemption remains valid and necessary.

Dated: November 25, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–26547 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–06–P

LIBRARY OF CONGRESS

Copyright Royalty Board

37 CFR Part 303

[Docket No. 20–CRB–0013–RM]

Procedural Regulations of the Copyright Royalty Board Regarding Electronic Filing System (eCRB)

AGENCY: Copyright Royalty Board, Library of Congress.

ACTION: Proposed rule.

SUMMARY: The Copyright Royalty Judges propose to amend regulations governing the electronic filing of documents through the Copyright Royalty Board's electronic filing system (eCRB) to permit attorney designees with approved eCRB user accounts to file on behalf of attorneys. The Judges solicit comments on the proposed amendments.

DATES: Comments are due no later than January 27, 2021.

ADDRESSES: You may send comments, identified by docket number 20–CRB–0013–RM, online through eCRB at *https://app.crb.gov.*

Instructions: All submissions received must include the Copyright Royalty Board name and the docket number for this proposed rule. All comments received will be posted without change to eCRB at *https://app.crb.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to eCRB at *https://app.crb.gov* and perform a case search for docket 20–CRB–0013–RM.

FOR FURTHER INFORMATION CONTACT: Anita Blaine, CRB Program Specialist, at 202–707–7658 or *crb@loc.gov.*

SUPPLEMENTARY INFORMATION: In 2017, the Copyright Royalty Board (CRB) codified the process for filing documents through its electronic filing system (eCRB) in a set of rules,

including what is currently Rule 303.5 (37 CFR 303.5).[1] Rule 303.5(c) lists three categories of people who may obtain eCRB passwords that will authorize them to electronically file documents: (1) Attorneys, (2) *pro se* parties, and (3) claimants. 37 CFR 303.5(c). The Copyright Royalty Judges (Judges) recognized a fourth category of people who might file documents using an attorney's password, namely, an authorized employee or agent of an attorney's law office or organization that would file on the attorney's behalf. *See* 37 CFR 303.5(d). The Judges refer to this fourth category of filers as an ''attorney designee.''

Although the Judges understand and expect that attorneys may not typically personally file the electronic documents that they submit to the CRB, the Judges believe that it is necessary to expressly authorize such practice and to set forth the obligations of attorneys and their designees for the documents that the designees file. eCRB will soon implement multifactor authentication at login which will make the current practice of a designee using an attorney's password impractical. The Judges thus propose adding to Rule 303.5(c) a fourth category of filer that would be required to obtain an eCRB password: Attorney designee. An attorney designee would be defined as ''a person authorized to file documents on behalf of an attorney.''

Under the proposal, an attorney designee would be required to register for an eCRB user account and create a password in order to file documents on an attorney's behalf. The attorney designee's user account would be activated upon approval by the CRB of the attorney designee's completed online registration form. The designating attorney would then authorize the attorney designee using a new function in eCRB. The designating attorney would be responsible for all documents filed on his or her behalf using the attorney designee's password, which would serve as the designating attorney's signature.

The Judges also propose a number of non-substantive changes to Rule 303.5 to account for the addition of the attorney designee and generally to enhance clarity.[2]

The Judges seek comments on all aspects of the proposal, including whether or not the proposed new category of filer—attorney designee—is necessary to clarify the obligations and responsibilities of those authorized to file documents electronically on behalf of attorneys.

List of Subjects in 37 CFR Part 303

Administrative practice and procedure, Copyright, Lawyers.

Proposed Regulations

For the reasons set forth in the preamble, the Copyright Royalty Judges propose to amend part 303 of title 37 of the Code of Federal Regulations as follows:

SUBCHAPTER A—GENERAL PROVISIONS

PART 303—GENERAL ADMINISTRATIVE PROVISIONS

Subchapter A—

■ 1. The authority citation for part 303 continues to read as follows:

Authority: 17 U.S.C. 803.

§ 303.5 [Amended]

■ 2. Amend § 303.5 by revising it to read as follows:

§ 303.5 Electronic filing system (eCRB).

(a) *Documents to be filed by electronic means.* Except as otherwise provided in this chapter, all attorneys must file documents with the Copyright Royalty Board through eCRB. Pro se parties may file documents with the Copyright Royalty Board through eCRB, subject to § 303.4(c)(2).

(b) *Official record.* The electronic version of a document filed through and stored in eCRB will be the official record of the Copyright Royalty Board.

(c) *Obtaining an electronic filing password*—(1) *Attorneys.* An attorney must register for an eCRB account and create an eCRB password in order to file documents or to receive copies of orders and determinations of the Copyright Royalty Judges. The attorney's eCRB account and password will be activated upon approval by the Copyright Royalty Board of the attorney's completed online application form available on the eCRB website.

(2) *Attorney designees.* A person authorized by an attorney to file documents on behalf of that attorney (an attorney designee) must register for an eCRB account and create an eCRB password in order to file documents on the attorney's behalf. The attorney designee's eCRB account and password will be activated upon approval by the Copyright Royalty Board of the attorney designee's completed online registration form available on the eCRB website.

(3) *Pro se parties.* A party not represented by an attorney (a pro se party) may register for an eCRB account and create an eCRB password. The pro se party's eCRB account and password will be activated if the Copyright Royalty Judges, in their discretion, approve the pro se party's completed online application form available on the eCRB website. Once a pro se party's application has been approved, that party must make all subsequent filings by electronic means through eCRB.

(4) *Claimants.* Any person desiring to file a claim with the Copyright Royalty Board for copyright royalties must register for an eCRB account and create an eCRB password for the limited purpose of filing claims by completing the registration form available on the eCRB website.

(d) *Use of an eCRB password.* An eCRB password may be used only by the person to whom it is assigned. The person to whom an eCRB password is assigned is responsible for any document filed using that password, except that designating attorneys are responsible for any document filed on the attorney's behalf by an attorney designee.

(e) *Signature.* The use of an eCRB password to log in and submit documents creates an electronic record. The password operates and serves as the signature of the person to whom the password is assigned for all purposes under this chapter III, except that the password of an attorney designee serves as the signature of the designating attorney on whose behalf the document is filed.

(f) *Originals of sworn documents.* The electronic filing of a document that contains a sworn declaration, verification, certificate, statement, oath, or affidavit certifies that the original signed document is in the possession of the attorney or pro se party responsible for the filing and that it is available for review upon request by a party or by the Copyright Royalty Judges. The filer must file through eCRB a scanned copy of the signature page of the sworn document together with the document itself.

(g) *Consent to delivery by electronic means.* An attorney or pro se party who obtains an eCRB password consents to electronic delivery of all documents, subsequent to the petition to participate, that are filed by electronic means through eCRB. Attorneys and pro se parties are responsible for monitoring their email accounts and, upon receipt of notice of an electronic filing, for retrieving the noticed filing. Parties and their counsel bear the responsibility to keep the contact information in their eCRB profiles current.

[1] The rules establishing eCRB were adopted in 2017. Certain of those rules have subsequently been amended and renumbered. *See* 82 FR 18563 (Apr. 20, 2017) and 84 FR 32296 (July 8, 2019).

[2] The proposal to revise the entire section is for ease of reading, but substantive changes are proposed only to the text of paragraphs (c), (d), and (e).

(h) *Accuracy of docket entry.* A person filing a document by electronic means, or, if the filer is an attorney designee, the designating attorney, is responsible for ensuring the accuracy of the official docket entry generated by the eCRB system, including proper identification of the proceeding, the filing party, and the description of the document. The Copyright Royalty Board will maintain on its website (*www.loc.gov/crb*) appropriate guidance regarding naming protocols for eCRB filers.

(i) *Documents subject to a protective order.* A person filing a document by electronic means must ensure, at the time of filing, that any documents subject to a protective order are identified to the eCRB system as ''restricted'' documents. This requirement is in addition to any requirements detailed in the applicable protective order. Failure to identify documents as ''restricted'' to the eCRB system may result in inadvertent publication of sensitive, protected material.

(j) *Exceptions to requirement of electronic filing*—(1) *Certain exhibits or attachments.* Parties may file in paper form any exhibits or attachments that are not in a format that readily permits electronic filing, such as oversized documents; or are illegible when scanned into electronic format. Parties filing paper documents or things pursuant to this paragraph must deliver legible or usable copies of the documents or things in accordance with § 303.6(a)(2) and must file electronically a notice of filing that includes a certificate of delivery.

(2) *Pro se parties.* A pro se party may file documents in paper form and must deliver and accept delivery of documents in paper form, unless the pro se party has obtained an eCRB password.

(k) *Privacy requirements.* (1) Unless otherwise instructed by the Copyright Royalty Judges, parties must exclude or redact from all electronically filed documents, whether designated ''restricted'' or not:

(i) *Social Security numbers.* If an individual's Social Security number must be included in a filed document for evidentiary reasons, the filer must use only the last four digits of that number.

(ii) *Names of minor children.* If a minor child must be mentioned in a document for evidentiary reasons, the filer must use only the initials of that child.

(iii) *Dates of birth.* If an individual's date of birth must be included in a pleading for evidentiary reasons, the filer must use only the year of birth.

(iv) *Financial account numbers.* If a financial account number must be included in a pleading for evidentiary reasons, the filer must use only the last four digits of the account identifier.

(2) Protection of personally identifiable information. If any information identified in paragraph (k)(1) of this section must be included in a filed document, the filing party must treat it as confidential information subject to the applicable protective order. In addition, parties may treat as confidential, and subject to the applicable protective order, other personal information that is not material to the proceeding.

(l) *Incorrectly filed documents.* (1) The Copyright Royalty Board may direct an eCRB filer to re-file a document that has been incorrectly filed, or to correct an erroneous or inaccurate docket entry.

(2) If an attorney or a pro se party who has been issued an eCRB password inadvertently presents a document for filing in paper form, the Copyright Royalty Board may direct that person to file the document electronically. The document will be deemed filed on the date it was first presented for filing if, no later than the next business day after being so directed by the Copyright Royalty Board, the attorney or pro se participant files the document electronically. If the filer fails to make the electronic filing on the next business day, the document will be deemed filed on the date of the electronic filing.

(m) *Technical difficulties.* (1) A filer encountering technical problems with an eCRB filing must immediately notify the Copyright Royalty Board of the problem either by email, or by telephone, followed promptly by written confirmation.

(2) If a filer is unable, due to technical problems, to make a filing with eCRB by an applicable deadline, and makes the notification required by paragraph (m)(1) of this section, the filer shall use electronic mail to make the filing with the Copyright Royalty Board and deliver the filing to the other parties to the proceeding. The filing shall be considered to have been made at the time it was filed by electronic mail. The Copyright Royalty Judges may direct the filer to refile the document through eCRB when the technical problem has been resolved, but the document shall retain its original filing date.

(3) The inability to complete an electronic filing because of technical problems arising in the eCRB system may constitute ''good cause'' (as used in § 303.6(b)(4)) for an order enlarging time or excusable neglect for the failure to act within the specified time, provided the filer complies with paragraph (m)(1) of this section. This section does not provide authority to extend statutory time limits.

Dated: December 15, 2020.

Jesse M. Feder,

Chief Copyright Royalty Judge.

[FR Doc. 2020–27941 Filed 12–23–20; 8:45 am]

BILLING CODE 1410–72–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 595

[Docket No. NHTSA–2016–0031]

RIN 2127–AL67

Make Inoperative Exemptions; Vehicle Modifications To Accommodate People With Disabilities

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

ACTION: Supplemental notice of proposed rulemaking (SNPRM).

SUMMARY: In 2016, NHTSA published a notice of proposed rulemaking (NPRM) to amend our regulations, ''Make Inoperative Exemptions, Vehicle Modifications to Accommodate People With Disabilities,'' to include a new exemption relating to the Federal motor vehicle safety standard (FMVSS) for roof crush resistance. The exemptions facilitate the mobility of drivers and passengers with physical disabilities. This SNPRM expands the scope of NHTSA's 2016 NPRM in two ways. First, it grants a petition from Bruno Independent Living Aids, Inc., and proposes to include in part 595 an exemption relating to the rear visibility requirements in FMVSS No. 111. Second, in response to an inquiry from Enterprise Holdings Co. (Enterprise), this document proposes to permit rental car companies to make inoperative a knee bolster air bag, on a temporary basis, to permit the temporary installation of hand controls to accommodate persons with physical disabilities seeking to rent the vehicle.

DATES: Comments concerning this SNPRM should be submitted early enough to ensure that the Docket receives them not later than January 27, 2021. In compliance with the Paperwork Reduction Act, NHTSA is also seeking comment on a revised information collection. See the Paperwork Reduction Act section under Regulatory Analyses

and Notices below. Comments concerning the revised information collection requirements are due February 26, 2021 to NHTSA and to the Office of Management and Budget (OMB) at the address listed in the **ADDRESSES** section.

ADDRESSES: You may submit comments to the docket number identified in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9332 before coming.
- *Fax:* 202–493–2251.

Comments on the proposed information collection requirements should be submitted to: Office of Management and Budget, Office of Information and Regulatory Affairs, Washington, DC 20503, Attn: Desk office for NHTSA. It is requested that comments sent to the OMB also be sent to the NHTSA rulemaking docket identified at the heading of this document.

Instructions: For detailed instructions on submitting comments and additional information on the rulemaking process, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. To be sure someone is there to help you, please call (202) 366–9332 before coming. Follow the online instructions for accessing the dockets.

FOR FURTHER INFORMATION CONTACT: Gunyoung Lee, NHTSA Office of Crash Avoidance Standards (phone: 202–366–6005; fax: 202–493–0073); Daniel Koblenz, NHTSA Office of Chief Counsel (phone: 202–366–5329; fax 202–366–3820); or David Jasinski (phone: 202–366–5552; fax 202–366–3820. The mailing address for these officials is: National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

I. Introduction

This SNPRM supplements an NPRM [1] published on March 11, 2016, proposing to amend 49 CFR part 595, subpart C to include a new exemption relating to FMVSS No. 216, ''Roof crush resistance.'' This SNPRM does not propose any substantive changes to that NPRM as it relates to the proposed exemption for FMVSS No. 216. This SNPRM simply proposes to expand the scope of the 2016 NPRM to include an additional make inoperative exemption from certain sections of FMVSS No. 111, ''Rear visibility,'' and to create a new exemption for rental car companies having to temporarily disable a knee bolster air bag to install hand controls. The three rulemakings are related as they each propose to amend part 595. The Agency has decided to propose these changes as an SNPRM, rather than as separate individual NPRMs, for the sake of administrative simplicity and the convenience of the reader.

II. Statutory Background

The National Traffic and Motor Vehicle Safety Act (49 U.S.C. Chapter 301) (''Safety Act'') and NHTSA's regulations require vehicle and equipment manufacturers to certify that their vehicles or vehicle equipment comply with all applicable FMVSS (*see* 49 U.S.C. 30112; 49 CFR part 567). A vehicle manufacturer, distributor, dealer, rental company, or repair business generally may not knowingly make inoperative any part of a device or element of design installed in or on a motor vehicle in compliance with an applicable FMVSS (*see* 49 U.S.C. 30122). NHTSA has the authority to issue regulations that exempt regulated entities from the ''make inoperative'' provision (49 U.S.C. 30122(c)), if the Agency finds that the exemption would be consistent with motor vehicle safety and with 49 U.S.C. 30101.[2] The Agency has used that authority to promulgate 49 CFR part 595, subpart C, ''Make Inoperative Exemptions, Vehicle Modifications to Accommodate People with Disabilities'' (hereafter, ''subpart C'').

Subpart C sets forth exemptions to permit, under limited circumstances, vehicle modifications that make certain systems installed in compliance with an FMVSS inoperative when the vehicles are modified to be used by persons with disabilities after the first retail sale of the vehicle for purposes other than resale. The regulation was promulgated to facilitate the modification of motor vehicles so that persons with disabilities can drive or ride in them. The regulation involves information and disclosure requirements and limits the extent of modifications that may be made.

Under the regulation, a motor vehicle repair business [3] that modifies a vehicle to enable a person with a disability to operate or ride as a passenger in the motor vehicle and that avails itself of the exemption provided by subpart C must register with NHTSA. The modifier is exempted from the make inoperative provision of the Safety Act, but only to the extent that the modifications affect compliance with the FMVSSs specified in 49 CFR 595.7(c) and only to the extent specified in § 595.7(c).[4] The modifier must affix a permanent label to the vehicle identifying itself as the modifier and the vehicle as no longer complying with all FMVSS in effect at original manufacture, and must provide and retain a document listing the affected FMVSSs, and indicating any reduction in the load carrying capacity of the vehicle of more than 100 kilograms (220 pounds).

[1] 81 FR 12852, Docket No. NHTSA–2016–0031.

[2] Section 30101, ''Purpose and Policy,'' of the Safety Act states: ''The purpose of this chapter is to reduce traffic accidents and deaths and injuries resulting from traffic accidents. Therefore it is necessary—(1) to prescribe motor vehicle safety standards for motor vehicles and motor vehicle equipment in interstate commerce; and (2) to carry out needed safety research and development.''

[3] Section 595.4 of subpart C states: ''The term *motor vehicle repair business* is defined in 49 U.S.C. 30122(a) as 'a person holding itself out to the public to repair for compensation a motor vehicle or motor vehicle equipment.' This term includes businesses that receive compensation for servicing vehicles without malfunctioning or broken parts or systems by adding or removing features or components to or from those vehicles or otherwise customizing those vehicles.''

[4] Modifications that would affect systems installed in compliance with any other FMVSS, or with an FMVSS listed in § 595.7(c) but in a manner not specified in that paragraph, are not covered under Part 595, Subpart C.

III. New Make Inoperative Exemption in Subpart C for Portions of FMVSS No. 111, ''Rear Visibility''

a. Background on the FMVSS No. 111 Requirements

To satisfy a statutory mandate in the Cameron Gulbransen Kids Transportation Safety Act of 2007 (the K.T. Safety Act), NHTSA published a final rule [5] on April 7, 2014 amending FMVSS No. 111, to require, effectively, that all light vehicles be equipped with a backup camera system that, among other things, displays a certain specified field of view to the driver. The K.T. Safety Act directed NHTSA to amend the FMVSS to expand the rearward field of view for all passenger cars, trucks, multipurpose passenger vehicles, buses, and low-speed vehicles with a gross vehicle weight rating (GVWR) of less than 4,536 kilograms (kg) (10,000 pounds). The rule, which became fully phased in on May 1, 2018, requires that vehicles be equipped with a system that provides the driver with an image of the area directly behind the vehicle. The purpose of this requirement is to reduce the number of back-over crashes involving pedestrians, particularly children and other high-risk persons.

The standard requires that each passenger car must display a rearview image to the driver that meets the requirements of FMVSS No. 111 S5.5.1 through S5.5.7, and that each multipurpose passenger vehicle, low-speed vehicle, truck, bus, and school bus with a GVWR of 4,536 kg or less must meet the requirements of S6.2.1 through S6.2.7. Both sets of requirements state that the rearview image must have a field of view that covers 5 feet from either side of the vehicle center line to 20 feet longitudinally from the vehicle's rear bumper, and that the rearview image be large enough that the driver will see objects in the field of view. The standard also sets requirements for when the rearview image must be displayed. NHTSA assesses compliance with these requirements by placing cylindrical test objects along the perimeter of the minimum field of view requirement, and assessing whether the test cylinders are visible to the driver in the rearview image, and whether the rearview image is displayed under the required circumstances. Although the rear visibility requirements in FMVSS No. 111 are written in a technology-neutral way that states only that a vehicle must display a ''rearview image'' without reference to what technology is used to display the image, it is NHTSA's understanding that all manufacturers comply with the rearview image requirements using a backup camera system (*i.e.,* a rear-facing camera behind the vehicle that transmits a video image to a digital display in view of the driver).

During the rulemaking that established the FMVSS No. 111 rear visibility requirements, the issue of temporary equipment obstructing a backup camera system's field of view was raised in a comment by the National Truck Equipment Association (NTEA) to the NPRM. In this comment, NTEA noted that, because it was expected that manufacturers would meet the new rear visibility requirements with a backup camera system, it would be possible for the camera's field of view to be obstructed by the installation of certain types of temporarily-attached vehicle equipment, such as a salt or sand spreader, which can be temporarily mounted to the trailer hitch of a pickup truck. NHTSA responded to this comment in the final rule by stating that the rule was not intended to apply ''to trailers and other temporary equipment that can be installed by the vehicle owner.'' However, NHTSA did not address the question of whether the installation of such equipment would violate the make inoperative prohibition (49 U.S.C. 30122) if done by an entity subject to § 30122.

b. Bruno's Petition for Rulemaking

On April 17, 2018, NHTSA received a petition for rulemaking from Bruno requesting NHTSA to amend subpart C so that it would include paragraphs S5.5 and S6.2 of FMVSS No. 111.

Bruno states it is a manufacturer of several products that allow a vehicle owner to transport unoccupied personal mobility devices (PMD) such as wheelchairs, powered wheelchairs, and powered scooters intended for use by vehicle occupants with mobility impairments. Bruno states that there are two types of PMD transport devices that it manufactures. The first type is what the petition describes as a platform lift that can be attached to the exterior of the vehicle by means of a trailer hitch. This first type of PMD transport device is fully supported by the trailer receiver hitch without ground contact. The second type of PMD transport device is supported in part by contact with the ground. As such it is a ''trailer'' under NHTSA's definitions.[6]

Bruno states that most backup cameras that are installed pursuant to FMVSS No. 111 are mounted at a low height along the horizontal centerline of the vehicle, often near the vehicle's rear license plate mounting. The placement of the backup camera in this location means that it may be obstructed by a rear-mounted PMD transport device, or by a PMD that is mounted onto the transport device. Since the PMD transport devices may obstruct the rear view from the vehicle's rearview video system, installation of the devices could arguably violate the ''make inoperative'' prohibition (49 U.S.C. 30122). Bruno argues in its petition that PMD transport devices are ''temporary equipment,'' to which NHTSA said the final rule was not intended to apply. However, the petitioner states that, to avoid potential uncertainty regarding the manufacture, sale or installation of both types of PMD transport device Bruno manufactures, Bruno requests that subpart C be amended to cover the backup camera requirements (S5.5 and S6.2) of FMVSS No. 111.

After filing the petition, Bruno submitted additional material in which the petitioner contends that the final rule of FMVSS No. 111 specifically excluded trailers such as the Bruno Chariot (*i.e.,* a ''trailer'' type of PMD transport device), even though the body of current FMVSS No. 111 does not include explicit language for the exclusion of trailers, and even though the preamble was referring to trailers attached by the vehicle owner.

Response to Petition

NHTSA recognizes that the petitioner's request presents a trade-off between the benefits of a camera system for rear visibility balanced against enhanced mobility for people with disabilities. Comments are requested on the proposed exemption. To achieve the maximum safety benefit of the regulations, it is our desire to provide the narrowest exemption possible to accommodate the needs of persons with physical disabilities, while minimizing unintended safety consequences that could occur by creating a pathway for unforeseen and unintended uses.

NHTSA has decided to grant the petition. The modifications permitted under the proposed exemption would be temporary in that they do not permanently affect the vehicle's design or structure, and would not be widely available beyond the population of persons with disabilities who wish to have a covered entity install a PMD transport device on their vehicle. It is important to note that statements in the preamble to the K.T. Act final rule cannot provide regulatory certainty that PMD transport devices are excluded from the make inoperative provision.

[5] 79 FR 19178, Docket No. NHTSA–2010–0162.

[6] 49 CFR 571.3.

Further, unlike with the examples of salt and sand spreaders referenced in the preamble, it is NHTSA's understanding that PMDs transport devices are generally installed by dealers and motor vehicle repair businesses that specialize in modifications to provide mobility solutions to people with physical disabilities, both of which are subject to the make inoperative prohibition.[7] Accordingly, we believe a regulatory exemption can provide the appropriate regulatory certainty to allow for installation of PMD transport devices, even if not necessary for other types of temporary equipment installed by the vehicle owner.

Based on the above analysis NHTSA proposes to amend subpart C to add a ''make inoperative'' exemption for S5.5.1, S5.5.2, S6.2.1, and S6.2.2 of FMVSS No. 111, to allow for the temporary installation of a PMD transport device that could obstruct the vehicle's backup camera system. NHTSA seeks comment on this proposal.

In particular, NHTSA seeks comment on its decision to limit the proposed exemption to the temporary installation of a PMD transport device on a vehicle, which precludes entities from permanently disabling the backup camera system, or from making the backup camera system inoperative in contexts other than when attaching a PMD transport device to the vehicle. NHTSA included these restrictions on the proposed exemption so that the exemption would be as narrow as possible while still addressing the mobility needs for persons with disabilities.

NHTSA also seeks comment on its tentative decision to limit the exemption to include only the ''field of view'' (S5.5.1 and S6.2.1) and ''size'' (S5.5.2 and S6.2.2) requirements, and not the other rearview image requirements in S5.5 and S6.2, such as ''linger time.'' NHTSA did not include these other requirements in the proposed exemption because they would not be impacted by placing an object in front of the camera that blocks its view.

IV. Make Inoperative Exemptions for Rental Companies

a. FAST Act

The Fixing America's Surface Transportation Act (FAST Act), Public Law 114–94 (December 4, 2015), made rental companies subject to the ''make inoperative'' prohibition. The FAST Act also defined terms related to rental companies. For example, a ''rental company'' is defined as a person who is engaged in the business of renting covered rental vehicles and uses for rental purposes a motor vehicle fleet of 35 or more covered rental vehicles, on average, during the calendar year. A ''covered rental vehicle'' is defined as a vehicle that meets three requirements: (1) It has a GVWR of 10,000 pounds or less; (2) it is rented without a driver for an initial term of less than four months; and (3) it is part of a motor vehicle fleet of 35 or more motor vehicles that are used for rental purposes by a rental company.

Thus, beginning in December 2015, rental companies, as the term is defined in the FAST Act, were subject to the make inoperative prohibition for the first time. One effect of this FAST Act provision was to subject rental companies to § 30122 prohibitions for making inoperative systems installed to comply with the FMVSS—even if doing so to accommodate the installation of adaptive equipment for use by persons with disabilities, and even if the modification were only temporary.[8]

b. Enterprise Request for Interpretation

In a letter dated August 12, 2019, Enterprise, through its counsel, submitted a request for interpretation to NHTSA regarding the effect of the ''make inoperative'' prohibition on its obligations under the Americans with Disabilities Act of 1990 (ADA).[9] Specifically, Enterprise asked whether the ''make inoperative'' prohibition applies to modifications by rental companies to temporarily disable knee bolster air bags to accommodate the installation of hand controls for drivers with physical disabilities. Following receipt of the letter, NHTSA met with Enterprise to discuss its request further. Some of the information provided by Enterprise has formed the basis for this rulemaking.

In its letter, Enterprise stated that, to provide service to customers with disabilities and ensure compliance with the ADA, rental companies install adaptive equipment, such as hand controls, upon request. Enterprise stated that, when installing adaptive equipment in a motor vehicle, ''equipment or features that were installed in compliance with NHTSA's safety standards may need to be modified. In these cases, the vehicle modification may render the affected equipment or features, as originally certified, 'inoperative.' ''

Enterprise specifically addressed safety concerns with installing hand controls in rental vehicles equipped with knee bolster air bags.[10] Hand controls consist of a metal bar that connects to the accelerator and brake pedals of a vehicle to enable operation by a person unable to control the pedals with their feet. Knee bolster air bags are installed by manufacturers to prevent or reduce the severity of leg injuries in the event of a frontal collision. Since knee bolster air bags, like all air bags, deploy at high speeds with a great degree of force, installed hand controls could either break apart, creating and propelling dangerous metal fragments, or otherwise be propelled into the driver at great forces—either of which would create a serious safety risk.

Enterprise stated that manufacturers of hand controls owned by Enterprise specify that a driver's side knee bolster air bag must be disabled (including removal in some instances)[11] for safe operation of the hand controls, both because the presence of a knee bolster air bag may interfere with safe operation of the hand controls, and because the presence of hand controls would interfere with the air bag should it be deployed in the event of a crash.

Enterprise noted that 49 CFR part 595, subpart C, includes exemptions for certain entities from the ''make inoperative'' prohibition in certain circumstances to accommodate the modification of vehicles for persons with disabilities. However, the subpart does not include ''rental companies'' within the entities who could use those exemptions in subpart C.

Pertaining specifically to knee bolster air bags, Enterprise noted that they are not specifically required by FMVSS No. 208. However, Enterprise observed that vehicle manufacturers are increasingly

[7] Note that ''dealer'' is defined in the Safety Act as a seller of motor vehicles or motor vehicle equipment, which includes retail outlets that sell PMD transport devices.

[8] Although the ''make inoperative'' prohibition does contain an exception for temporarily taking vehicles or equipment out of compliance, that limited exception only applies where the entity taking the vehicles out of compliance does not believe the vehicle or equipment will not be used when the device is inoperative. Obviously, a rental company would intend a rental vehicle that has a device or element temporarily ''made inoperative'' to accommodate a disability to be used while the device or element is inoperative.

[9] A copy of this letter has been included in the docket number identified at the beginning of this document.

[10] Enterprise did not provide an example other than the situation posed by installation of hand controls and its effect on knee bolster air bags.

[11] This document generally refers to the act of ''disabling'' the knee bolster air bag. For the purposes of the applicability of the ''make inoperative'' prohibition and exemption discussed in this document, the act of ''disabling'' the knee bolster air bag may also include removing the air bag. In other words, removal is one means of disabling the air bag.

making knee bolster air bags standard equipment on all models such that it is becoming difficult for Enterprise to purchase new vehicles that do not include knee bolster air bags. Further, Enterprise stated that vehicles with knee bolster air bags are not crash tested with the knee bolster air bags removed or disabled, meaning Enterprise cannot know whether disabling knee bolster air bags affects compliance with FMVSS No. 208.

Enterprise concluded that, based upon its ADA obligations to provide hand controls for drivers requesting them and the increasing trend of knee bolster air bags being standard equipment, Enterprise expects to need to disable knee bolster air bags temporarily on rental vehicles to continue to make vehicles available to rent by drivers with physical disabilities. Enterprise requested NHTSA's opinion on the applicability of the ''make inoperative'' prohibition to these circumstances.

c. Applicability of ''Make Inoperative'' Prohibition to Enterprise

The question raised by Enterprise's letter is whether disabling the knee bolster air bag would constitute a violation of the ''make inoperative'' prohibition. NHTSA does not have sufficient information to determine whether the knee bolster air bag is a part or element of design installed ''in compliance with an applicable motor vehicle safety standard,'' but notes that knee bolster air bags are installed to reduce femur loading, and FMVSS No. 208 does provide specific requirements for femur load.[12] While NHTSA has made general inquiries with vehicle manufacturers through their trade association about whether knee bolster air bags are installed as part of an element of design installed in compliance with the motor vehicle safety standards, their association has not yet provided information to resolve this question.

After considering the issue, NHTSA has determined that it cannot affirmatively state that § 30122 would not prohibit making inoperative knee bolster air bags to install hand controls to enable service to customers with physical disabilities. The Agency appreciates the difficulties this issue poses to Enterprise and other rental companies. As knee bolster air bags are already becoming standard equipment across much of the light duty fleet, this situation could result in rental companies facing the untenable position of being forced to either: (1) Retain a number of older vehicles in its fleet (without knee bolster air bags) and on its premises to rent to drivers requesting hand controls; (2) cease the rental of vehicles to drivers requesting hand controls; (3) disable the air bag and potentially violate § 30122; or (4) install hand controls on vehicles with knee bolster air bags and create serious safety risks for their customers. None of these results is acceptable to NHTSA. The first action would prevent Enterprise from renting newer vehicles, which include newer safety innovations, to drivers requiring the use of hand controls, would be impracticable given the inability to guarantee availability of sufficient vehicles at all relevant rental facilities, and would eventually be impossible as those vehicle age out of their useful service lives. The second action would eliminate a critical service for people with disabilities and may have implications for compliance with the Americans with Disabilities Act. The third action would potentially violate the Safety Act. The fourth option would create an unreasonable risk to the safety of rental customers with physical disabilities. NHTSA is addressing the situation by proposing to use its statutory authority to exempt rental companies conditionally from the Safety Act's ''make inoperative'' prohibition to allow the temporary disabling of knee bolster air bags.

d. Need for a ''Make Inoperative'' Exemption for Rental Companies

NHTSA is issuing this SNPRM after considering the untenable situation faced by prospective vehicle renters with physical disabilities and rental car companies seeking to provide services to people with physical disabilities, and balancing NHTSA's strong interest in promoting motor vehicle safety with the interest (including the statutory interest implicit within the ADA) to provide access to mobility for persons with disabilities. NHTSA has tentatively concluded that it should exercise its statutory authority to exempt rental companies from the make inoperative prohibition in certain circumstances, and with certain conditions, so that rental companies may rent vehicles to drivers requesting hand controls. This action is consistent with NHTSA's decision to promulgate 49 CFR part 595, subpart C, to exempt motor vehicle repair businesses from the make inoperative prohibition to accommodate persons with disabilities. While the balance of safety and accessibility associated with granting an exemption to the make inoperative prohibition to rental companies is identical to the grant of exemption to motor vehicle repair businesses, some aspects are quite different, as will be discussed next.

Therefore, NHTSA is proposing to add a new section to 49 CFR part 595 specifically for rental companies. While this section would be largely similar to 49 CFR 595.7, NHTSA believes that rental companies could not easily be added to section 595.7 for several reasons. First, section 595.7 contemplates permanent modifications and NHTSA expects that rental companies would modify vehicles only temporarily. Therefore, the proposal specifically limits the exemption to the duration of the rental agreement and a reasonable period before and after the rental agreement (a period to perform and reverse the necessary accommodations). Like in 49 CFR 595.7, NHTSA is proposing a requirement that the vehicle have a label affixed indicating that it has been modified such that a device or element of design installed pursuant to the FMVSS may have been made inoperative. However, given the expected temporary nature of the modifications, NHTSA is not proposing that vehicles be permanently labeled. NHTSA also has not proposed to require that rental companies register with NHTSA prior to performing modifications. At this time, NHTSA is only considering allowing rental companies to disable a knee bolster air bag and is not including all of the exemptions applicable to motor vehicle repair businesses in section 595.7(c). These issues are discussed in greater detail later in this document.

NHTSA requests public comment on this SNPRM, including the need of rental companies for relief from the make inoperative prohibition and how the exemption could be narrowly granted.

As part of this discussion, NHTSA requests comment on whether Enterprise's request may be mooted by the use of other models of hand controls or other innovations of adaptive driving equipment suitable for temporary installation. NHTSA has had discussions with the National Mobility Equipment Dealers Association regarding this question and has reached the tentative conclusion that, while there may be models of hand controls on the market that do not require disablement of the knee bolster air bag, those models require custom installations that would not be feasible for a rental company business model. These entities seek to make a temporary modification to their rental vehicles, so that after the rental they may remove the hand controls and revert the vehicle to its former state to rent to the next

[12] *See* 49 CFR 571.208 S15.3.5.

customer. Further, it is likely that necessitating the replacement by Enterprise and other rental companies of their adaptive equipment may unnecessarily result in costs and other impacts on rental companies in seeking to accommodate customers with physical disabilities.

e. Scope of an Exemption for Rental Companies

Although NHTSA is proposing a make inoperative exemption for rental companies, NHTSA has questions regarding the scope of an exemption to rental companies, and the logistics of granting those exemptions. Specifically, NHTSA requests public comment on the following questions in this preamble and on the discussion supporting them. In responding to a question, we would appreciate commenters numbering their answers in accordance with the following numbered questions:

1. Should rental companies be provided exemptions from the make inoperative prohibitions to make temporary vehicle modifications, permanent vehicle modifications, or both?

The wording of the proposed regulatory text would only allow temporary modifications by rental companies that would include the duration of the rental agreement and a reasonable period before and after modification, to allow the rental company to make and reverse the modification, respectively. If the vehicle would be rented to a second person requiring the same modification immediately after the termination of the first rental agreement, a rental company would not be required to reverse the modification and then immediately modify the vehicle again. (Based on information provided by Enterprise, rental companies require flexibility in their fleet usage and, therefore, it is unlikely that a vehicle would be rented to two people requiring the same modification consecutively.) In any event, in light of this information from Enterprise, is there a need to allow rental companies to make permanent modifications to vehicles in order to accommodate drivers with disabilities? Should they be permitted to permanently modify vehicles as repair businesses are under Subpart C, provided they meet all requirements of sections 595.6 and 595.7? NHTSA seeks comments as to whether permanent modification may be necessary or helpful, and may revisit this tentative conclusion in a final rule in response to comments received.

2. Although Enterprise only asked NHTSA about the application of the make inoperative prohibition to disabling knee bolster air bags to accommodate installation of hand controls, should NHTSA provide a make inoperative exemption for other installations of adaptive equipment by rental companies?

This question pertains to the standards and modifications that would be covered by a make inoperative exemption. Enterprise's letter refers only to the disablement of knee bolster air bags to accommodate installation of hand controls. To date, NHTSA has received no other inquiries or requests for relief from the make inoperative prohibition from any other rental company or related to any other accommodation. Accordingly, this proposed rule only addresses the disablement of knee bolster air bags to accommodate the installation of hand controls. If NHTSA receives comments that warrant the granting of exemptions to the make inoperative prohibition for additional accommodations, NHTSA will consider including an exemption from those accommodations in a final rule implementing this proposal.

3. If a temporary modification to install adaptive equipment causes a malfunction telltale to illuminate, should the rental company be allowed to disable the telltale?

This question pertains to the air bag malfunction telltale. One aspect not directly addressed in Enterprise's letter is what effect the modification would have on the air bag malfunction telltale, which is required by FMVSS No. 208. In its conversations with NHTSA, Enterprise stated that its procedure for disabling the knee bolster air bag would involve the installation of a shunt within the electrical circuitry of the air bag system. NHTSA believes that the installation of such a shunt would allow the air bag system, upon its diagnostic check at the time the vehicle is started, to conclude that there is no malfunction within the air bag system. Accordingly, after the diagnostic check, NHTSA believes that the air bag malfunction telltale would not illuminate as a result of disabling the knee bolster air bag.

NHTSA requests comment on whether the disabling of the air bag in this manner is desirable and should be permitted. There are competing safety interests at issue when considering this question. If a shunt were not installed, NHTSA believes that, for vehicles where the knee bolster air bag is disabled, the air bag malfunction telltale would illuminate after the diagnostic check. This would correctly provide the operator of the vehicle with information that the air bag system is not operational, and would provide additional assurance that the disabling of the knee bolster air bag is reversed for later rentals. A subsequent renter of the exempted vehicle, where the modification was inadvertently not reversed, could see the telltale illuminated and inform the rental company of the malfunction.

However, the illumination of the air bag malfunction telltale where the knee bolster air bag is disabled may also have negative safety consequences. If the air bag malfunction telltale is illuminated for the duration of the rental to a driver with a disability, that driver would not have the benefit of the telltale illuminating the event of any other malfunction within the air bag system, including malfunctions affecting air bags that are clearly installed as part of compliance with FMVSS No. 208. NHTSA is also unaware of whether the activation of a malfunction indicator light will result in a suppression of other air bags that are not disabled by the rental company. The proposed regulatory text does not make allowances for making inoperative the telltale in the situation presented by Enterprise. However, NHTSA seeks comment on how this issue should be addressed in a final rule.

4. Would NHTSA need to provide a make inoperative exemption for installation of hand controls? Alternatively stated, would the mere installation of hand controls by a rental company potentially make inoperative systems installed in compliance with an FMVSS, even if no other modifications to the vehicle are made? For example, would a hand control (or any other adaptive equipment typically installed by rental companies) interfere with devices or elements of designs installed in compliance with any FMVSS? If the mere installation of adaptive equipment potentially violates the ''make inoperative'' prohibition, NHTSA would consider broadening the scope of the exemption granted in a final rule issued following this proposal.

f. Procedural Requirements for an Exemption for Rental Companies

NHTSA has questions related to procedural aspects of such an exemption. These questions include:

5. Should rental companies need to request an exemption from NHTSA or should the exemption be provided automatically within the regulation?

NHTSA has tentatively concluded, as with motor vehicle repair businesses,

rental companies should not have to seek an exemption from NHTSA in order to disable knee bolster air bags temporarily to install hand controls. Rather, NHTSA proposes to grant the exemption to rental companies conditionally on their compliance with the proposed amendments to 49 CFR part 595. Given that a rental company may be required to make modifications quickly to provide accommodations when a customer requests a vehicle with hand controls, NHTSA does not find that seeking permission to obtain an exemption would be beneficial to safety or to drivers requesting modifications, or practical to execute in actual situations. Moreover, NHTSA would be limited in its ability to evaluate the merits of a request for an exemption in an approval system, and so it seems obtaining NHTSA approval would serve no useful purpose.

6. If rental companies are granted exemption by the regulation alone rather than on request to NHTSA, should rental companies be required to notify NHTSA of modifications to vehicles? If so, how often and what information should rental companies be required to provide?

As provided in 49 CFR 595.6, a motor vehicle repair business that modifies a vehicle pursuant to part 595 must, not later than 30 days after it modifies a vehicle pursuant to the ''make inoperative'' exemption in part 595, identify itself to NHTSA. NHTSA has tentatively concluded that a similar requirement is not warranted for rental companies. First, there are far fewer rental companies than there are motor vehicle repair businesses, such that NHTSA is aware of the existence of large rental companies. Second, the modifier information furnished to NHTSA under 49 CFR 595.6 is used, in part, to populate a database available to the public of entities that perform modifications to motor vehicles to accommodate persons with disabilities.[13] In the instance of rental companies, they are modifying vehicles to accommodate customers with physical disabilities as part of its business operations, and as part of its efforts to comply with the ADA. Thus, a list of rental companies able to modify vehicles pursuant to 49 CFR part 595 would likely be a list of all rental companies. Such a list would be of limited utility to the public, but would impose a paperwork burden on all rental companies. NHTSA tentatively concludes that, consistent with the goals of the Paperwork Reduction Act, it is not necessary for rental companies to identify themselves to NHTSA prior to modifying vehicles pursuant to a ''make inoperative'' exemption. However, NHTSA seeks comment on how many rental companies would be required to report themselves to NHTSA if such a reporting requirement is included in a final rule.

7. Should rental companies be required to notify customers that a vehicle modified to accommodate the installation of adaptive equipment may have had devices or designs installed in compliance with an applicable FMVSS made inoperative?

NHTSA tentatively concludes the answer is yes, renters of vehicles modified pursuant to this proposed make inoperative exemption would have to be notified that the vehicle's safety device or element of design was made inoperative, similar to the requirements for motor vehicle repair businesses. NHTSA would require the name and address of the rental company modifying the vehicle to be disclosed to the renter. The notification would have to specifically identify that the knee bolster air bag has been temporarily affected by the modification. NHTSA believes, however, that this notification could be accomplished simply by annotating the invoice or rental agreement at the rental counter, which would take a minimum amount of time. The costs to meet this requirement would be insignificant.

This notice proposes to require that the rental company affix a temporary label, meant to remained affixed during the rental, indicating that the knee bolster air bag is disabled. This label would serve both to inform persons driving the vehicle of the status of the air bag and to remind the rental company to reactivate the air bag at the conclusion of the rental. Because this proposal does not apply to permanent modifications, it would not be logical to include a permanent label stating that the vehicle may not comply with all FMVSSs. Unlike a provision in subpart C, this proposal does not include a requirement that the physical location of the rental company modifying the vehicle be on the label affixed to the vehicle. NHTSA believes that this information is provided to renters in the rental agreement and is not necessary to include on the label itself.

8. Should rental companies be required to retain records of vehicles modified pursuant to this ''make inoperative'' exemption. If so, what information and for how long?

Motor vehicle repair businesses who modify vehicles pursuant to the ''make inoperative'' exemption in 49 CFR part 595, subpart C, are required to retain, for five years, information provided to owners of vehicles that are modified. NHTSA tentatively concludes that this type of record retention should be required of rental companies as well. This would facilitate enforcement by NHTSA in the event of potential violations of the terms of the make inoperative exemption in this proposal, or if a safety problem arises in the vehicle at a later date that could possibly relate to the deactivation of the air bag. NHTSA believes the costs associated with this record retention would be minimal since the record could be the rental agreement or invoice itself, which can be stored as part of their general record retention process, electronically or in paper format at their discretion. NHTSA considers the costs of the proposed requirements in the section discussing the applicability of the Paperwork Reduction Act. As with the existing record retention requirement for motor vehicle repair businesses that permanently modify vehicles for people with disabilities, NHTSA is proposing a five-year recordkeeping requirement.

9. Should rental companies be required to notify subsequent renters and/or purchasers of rental vehicles that have been modified pursuant to this proposed ''make inoperative'' exemption that the vehicle was previously modified?

While NHTSA is not proposing such a requirement, the Agency seeks comment on whether such a requirement is warranted and if so, how such a notification would be made. NHTSA notes that it does not have authority over used vehicle sales transactions, and that State laws may be better equipped to handle any general or specific retail disclosure obligations. If the comments or other information available at the time of the issuance of final rule implementing this proposal indicate that such a requirement is warranted, it may be included in the final rule.

10. What procedures could or should NHTSA require of rental companies to ensure the knee bolster air bag will be reenabled when the rental vehicle is returned and the hand controls are disabled?

The make inoperative exemption that would be applicable to rental companies by this proposal would only apply for the period during which a covered rental vehicle is rented to a person with a disability and a reasonable period before and after the rental agreement in order to perform and subsequently reverse the modification to

[13] This list of entities is not intended as an endorsement of any entity, but is solely provided for informational purposes.

accommodate a driver with physical disabilities. However, the proposal does not include any specific requirements for rental companies for reversing modifications to rental vehicles. NHTSA requests comments on whether NHTSA should impose requirements related to reversing a vehicle modification and if so, what those requirements should be.

11. To the extent car sharing companies (*e.g.,* Zipcar) qualify as a ''rental company'' under 49 U.S.C. 30102, would all aspects of this proposal be reasonably applied to ride sharing companies, or would procedural requirements need to be different for them?

NHTSA believes that all aspects of this proposal would be equally applicable to a car sharing company that qualifies as a ''rental company'' under the definition in 49 U.S.C. 30102. However, NHTSA has not conducted any outreach as to the application of this proposal to car sharing companies. Therefore, any comments pertinent to the application of this proposal would be helpful.

V. Rulemaking Analyses and Notices

Executive Order 12866 and DOT Regulatory Requirements

NHTSA has considered the impact of this rulemaking action under E.O. 12866, ''Regulatory Planning and Review,'' E.O. 13563, and the Department of Transportation's regulatory requirements under 49 CFR part 5. This rulemaking document was not reviewed by the Office of Management and Budget under E.O. 12866. It is not considered to be significant under E.O. 12866. NHTSA has determined that the effects are so minor that a regulatory evaluation is not needed to support the rulemaking.

Modifying a vehicle in a way that reduces the rear visibility of a backup camera by installing a trailer or carrying device could reduce crash avoidance features of the vehicle when the vehicle is reversing. However, the number of vehicles potentially modified would be very few in number. The Agency believes it has made the exemption narrow to achieve the goal of increasing mobility of drivers and passengers with physical disabilities while maintaining vehicle safety to the extent possible. This rear visibility proposal does not contain new reporting requirements or requests for information beyond what is already required by 49 CFR part 595 subpart C. This rulemaking would impose minor labeling, and insignificant recordkeeping, costs on rental companies who choose to take advantage of the opportunity to install temporary hand controls to accommodate the needs of customers with physical disabilities, which we expect may be transferred to consumers.

The label and recordkeeping requirements are necessary to ensure the modification that takes the vehicle out of compliance with the FMVSS is temporary and that the vehicle will be restored to full compliance when the rental is over. The proposed 5-year record retention requirement would facilitate enforcement by NHTSA in the event of potential violations of the terms of the make inoperative exemption in this proposal, and to facilitate the investigation and identification of vehicles in the event a subsequent safety problem arises that could relate to the manner in which air bags were deactivated. NHTSA believes that the costs associated with retaining this record would be insignificant since the record could be the rental invoice or agreement itself, which can be stored by rental companies in the same manner that they store their invoices, including electronically.

Rental companies choosing to deactivate knee bolster air bags to facilitate installation of hand controls would incur costs associated with the installation of a shunt and a pedal operating device for a person with disability. However, the proposed rule is an enabling rule and does not require a rental business to engage in this practice. Thus, any costs associated with the installation of these devices are solely related to a rental business that chooses to accommodate consumers with disabilities for business or other reasons. Although the proposed rule would not directly contribute to the potential costs, any such potential costs would likely be transferred to consumers. Modifying a vehicle to install a trailer or carrying device, or temporary hand controls would not only increase business for entities making these modifications, but also increase consumer choices resulting from the perceived usefulness of the installed hardware. The consumer demand for the equipment and service is evidence that the perceived usefulness would be greater than the sum of its cost and any perceived added safety risk (*i.e.,* resulting from making the rearview camera and/or air bag inoperative).

E.O. 13771 (Regulatory Reform)

NHTSA has reviewed this SNPRM for compliance with E.O. 13771 (''Reducing Regulation and Controlling Regulatory Costs'') which requires Federal Agencies to offset the number and cost of new regulations through the repeal, revocation, or revision of existing regulations. As provided in OMB Memorandum M–17–21 (''Implementing E.O. 13771''), a ''regulatory action'' subject to E.O. 13771 is a significant regulatory action as defined in section 3(f) of E.O. 12866 that has been finalized and that imposes total costs greater than zero. As discussed above, this action is not a significant rule under Executive Order 12866. Accordingly, it is not subject to the offset requirements of 13771.

This SNPRM is expected to be a deregulatory action under E.O. 13771. It provides an exemption to dealers and repair businesses that would permit them to facilitate transport of unoccupied personal mobility devices (PMD) such as wheelchairs, powered wheelchairs, and powered scooters intended for use by vehicle occupants with mobility impairments. The SNPRM would permit these entities the ability to attach platform lifts and trailers for carrying PMD and provide more consumer choices, which may result in increased interest in and sales of these devices. The second part of this SNPRM would benefit rental companies by enabling them to modify vehicles for customers with disabilities and allow for the rental of vehicles with hand controls. The rental companies would benefit by enabling a temporary modification that will allow them to satisfy demand for such vehicles. They would not have to turn away customers seeking to rent a vehicle with hand controls due to an absence of such a vehicle on their premises. However, NHTSA is unable at this time to quantify the cost impacts due to the lack of information about the demand for devices such as petitioner Bruno's PMD transporters and, from rental companies, the demand for hand controls on rental vehicles whose installation necessitates deactivating the knee bolster air bag. NHTSA requests comments on estimating the cost savings of this proposed rule.

Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an Agency is required to publish a notice of proposed rulemaking or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions). The Small Business Administration's regulations at 13 CFR part 121 define a small business, in part, as a business entity ''which operates

primarily within the United States.'' (13 CFR 121.105(a)). No regulatory flexibility analysis is required if the head of an Agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the Regulatory Flexibility Act to require Federal Agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

I certify that this proposed rule would not have a significant economic impact on a substantial number of small entities. The entities installing the trailers and PMD-carrying devices could be small entities, and a substantial number of rental companies might also be small entities as well. However, the impacts on them are not expected to be significant. The proposed exemption would be deregulatory and provide additional flexibility to these entities with minimal requirements (there are some labeling and recordkeeping requirements), but overall the Agency does not believe there would be a large number of PMD installed, or a large number of rental car transactions affected by this rulemaking. Therefore, the impacts on any small businesses affected by this rulemaking would not be significant.

Executive Order 13132 (Federalism)

NHTSA has examined today's proposed rule pursuant to Executive Order 13132 (64 FR 43255; Aug. 10, 1999) and concluded that no additional consultation with States, local governments, or their representatives is mandated beyond the rulemaking process. The Agency has concluded that the proposed rule does not have sufficient federalism implications to warrant consultation with State and local officials or the preparation of a federalism summary impact statement. The proposal does not have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This proposed rule would not impose any requirements on anyone. This proposal would lessen restrictions on modifiers and rental companies.

NHTSA rules can have preemptive effect in two ways. First, the National Traffic and Motor Vehicle Safety Act contains an express preemption provision stating that a State (or a political subdivision of a State) may prescribe or continue to enforce a standard that applies to an aspect of performance of a motor vehicle or motor vehicle equipment only if the standard is identical to the FMVSS governing the same aspect of performance. See 49 U.S.C. 30103(b)(1). This provision is not relevant to this rulemaking as it does not involve the establishing, amending or revoking of a Federal motor vehicle safety standard.

Second, the Supreme Court has recognized the possibility, in some instances, of implied preemption of State requirements imposed on motor vehicle manufacturers, including sanctions imposed by State tort law. While NHTSA is unaware of any specific State law or action that would prohibit the actions that this proposed rule would permit, some States may have laws or enforcement postures relating to the disabling of air bags. While NHTSA is generally favors enforcement of such laws (indeed air bag disabling by manufacturers, dealers, motor vehicle repair businesses and rental companies is generally prohibited through NHTSA's make inoperative prohibition), the proposed exemption from this provision for temporary disablement of knee bolster air bags could preempt State laws that include broad prohibitions against disabling air bags or air bag malfunction indicators. NHTSA requests comment from States as to whether such laws or enforcement postures exist.

Civil Justice Reform

When promulgating a regulation, Agencies are required under Executive Order 12988 to make every reasonable effort to ensure that the regulation, as appropriate: (1) Specifies in clear language the preemptive effect; (2) specifies in clear language the effect on existing Federal law or regulation, including all provisions repealed, circumscribed, displaced, impaired, or modified; (3) provides a clear legal standard for affected conduct rather than a general standard, while promoting simplification and burden reduction; (4) specifies in clear language the retroactive effect; (5) specifies whether administrative proceedings are to be required before parties may file suit in court; (6) explicitly or implicitly defines key terms; and (7) addresses other important issues affecting clarity and general draftsmanship of regulations.

Pursuant to this Order, NHTSA notes as follows. The preemptive effect of this proposed rule is discussed above. NHTSA notes further that there is no requirement that individuals submit a petition for reconsideration or pursue other administrative proceeding before they may file suit in court.

National Technology Transfer and Advancement Act

Under the National Technology Transfer and Advancement Act of 1995 (NTTAA) (Pub. L. 104–113), ''all Federal agencies and departments shall use technical standards that are developed or adopted by voluntary consensus standards bodies, using such technical standards as a means to carry out policy objectives or activities determined by the agencies and departments.'' Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies, such as the Society of Automotive Engineers (SAE). The NTTAA directs us to provide Congress, through OMB, explanations when we decide not to use available and applicable voluntary consensus standards. No voluntary standards exist regarding these proposed exemptions for modification of vehicles to accommodate persons with disabilities.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 requires Agencies to prepare a written assessment of the costs, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than $100 million annually (adjusted for inflation with base year of 1995). This proposed exemption would not result in expenditures by State, local or tribal governments, in the aggregate, or by the private sector in excess of $100 million annually.

National Environmental Policy Act

NHTSA has analyzed this rulemaking action for the purposes of the National Environmental Policy Act. The Agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

Paperwork Reduction Act

Under procedures established by the Paperwork Reduction Act of 1995 (PRA), a person is not required to respond to a collection of information by a Federal Agency unless the collection displays a valid Office of Management and Budget (OMB) control number. The proposal adding the backup camera requirements (S5.5 and S6.2) of FMVSS No. 111 to 49 CFR part 595 subpart C does not contain new reporting requirements or requests for information beyond what is already required by subpart C. The proposal

addressing rental companies would be a new Information Collection Request (ICR), and has been forwarded to OMB for review. The ICR describes the nature of the information collection and its expected burden.

This SNPRM would make changes to an existing information collection for exemptions from the make inoperative prohibition for modifiers and related consumer disclosures under 49 CFR part 595, subpart C. In compliance with the requirements of the PRA, NHTSA asks for public comments on the following proposed revision of a currently approved collection of information:

Title: Exemption from Make Inoperative Prohibition Modifier Identification and Consumer Disclosure 49 CFR 595 Subpart C.

Type of Request: Revision of a currently approved collection.

OMB Control Number: 2127–0635

Affected Public: Businesses that modify vehicles, after first retail sale, so that the vehicle may be used by persons with disabilities.

Requested Expiration Date of Approval: Three years from the date of approval.

Form Number: None.

Summary of the Collection of Information: Rental companies would be added to the group of entities who, if they avail themselves of the exemptions in 49 CFR subpart C, are required to keep a record, for each applicable vehicle, listing which standards, or portions thereof, are affected by the modification, and to provide a copy to the owner (renter) of the vehicle modified (see 49 CFR 595.7 (b) and (e) as published below). This SNPRM does not propose to extend the registration requirement for modifiers to rental companies, so that aspect of the collection is not proposed to be modified.

Description of the Need for the Information and Use of the Information: This SNPRM proposes to extend to rental companies the requirement that modifiers provide each customer whose vehicle modification involves the use of the make inoperative exemptions with a list of the exemptions used to modify that vehicle. (Practically speaking, there would only be the one exemption discussed in this SNPRM, for knee bolster air bags.) The simplest form of this document is an annotated invoice or rental agreement. No specific, separate, or special forms are required. A copy of this document must also be retained for five years. This document will be used by the consumer (or renter, in the case of rental vehicles) to understand the modifications made to his/her vehicle and their effect on vehicle safety. It may be used by NHTSA in the event of an inquiry about the safety of the modified vehicles or compliance with the requirements that might be adopted.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information): NHTSA estimates that rental companies would temporarily modify approximately 4000 vehicles per year [14] for persons with disabilities under the exemption proposed in this SNPRM, all of which are proposed to be subject to the notification requirement.

Estimate of the Total Annual Reporting and Recordkeeping Burden Resulting from the Collection of Information: The burden for the record required by proposed 49 CFR 595.8 for those vehicles will be an additional 1,333 hours per year nationwide. NHTSA anticipates that the least costly way for a rental company to comply with this portion of the new rule would be to annotate the vehicle modification invoice to describe the exemption, if any, involved with each item on the invoice. The cost of preparing the invoice is not a portion of our burden calculation, as that preparation would be done in the normal course of business. The time needed to annotate the invoice, we estimate, is 20 minutes. This burden does not include the gathering of the information required for the calculation. That information would be gathered in the normal course of the vehicle modification.

The labor costs associated with this additional burden are estimated to be $25.29 per hour for ''Automotive Service Technicians and Mechanics,'' Occupation code 49–3023.[15] This is based on the assumption that the person making the modification to the vehicle will be annotating the invoice, rather than a rental clerk assisting a customer. Therefore, the estimated total labor costs associated with this additional burden are $33,712 ($25.29 per hour wage × 1,333 hours = $33,711.57).

There will be no additional material cost associated with compliance with this requirement since no additional materials need be used above those used to prepare the invoice in the normal course of business. We are assuming it is normal and customary in the course of rental car business to prepare an invoice, to provide a copy of the invoice to the vehicle owner, and to keep a copy of the invoice for five years after the vehicle is rented.

Comments Are Invited On:

1. Will the document referenced in proposed 49 CFR 595.8 need to be prepared for approximately 4000 temporarily modified vehicles per year?

2. Will the annotation of each invoice as to which exemptions were used take an average of 20 minutes? If the exemption were only for the knee bolster air bag, would a time less than 20 minutes be needed?

3. Is it normal in the course of the car rental business, to provide a copy of the invoice to the vehicle owner, and to keep a copy of the invoice for five years after the vehicle is delivered to the owner in finished form?

Please submit any comments, identified by the docket number in the heading of this document, by the methods described in the **ADDRESSES** section of this document to NHTSA and OMB.

Plain Language

Executive Order 12866 requires each Agency to write all rules in plain language. Application of the principles of plain language includes consideration of the following questions:

- Have we organized the material to suit the public's needs?
- Are the requirements in the rule clearly stated?
- Does the rule contain technical language or jargon that isn't clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rule easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rule easier to understand?

If you have any responses to these questions, please include them in your comments on this proposal.

Regulation Identifier Number (RIN)

The Department of Transportation assigns a regulation identifier number (RIN) to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. You may use the RIN contained in the heading at the beginning of this document to find this action in the Unified Agenda.

[14] This information is based upon an estimate provided by Enterprise regarding the number of vehicle modifications it anticipates making.

[15] *See* May 2019 National Occupational Employment and Wage Estimates by ownership, Federal, state, and local government including the U.S. Postal Service, available at *https://www.bls.gov/oes/current/999001.htm#49-0000* (accessed December 22, 2020).

VI. Public Participation

How long do I have to submit comments?

We are providing a 60-day comment period.

How do I prepare and submit comments?

- Your comments must be written in English.
- To ensure that your comments are correctly filed in the Docket, please include the Docket Number shown at the beginning of this document in your comments.
- Your comments must not be more than 15 pages long. (49 CFR 553.21). We established this limit to encourage you to write your primary comments in a concise fashion. However, you may attach necessary additional documents to your comments. There is no limit on the length of the attachments.
- If you are submitting comments electronically as a PDF (Adobe) File, NHTSA asks that the documents be submitted using the Optical Character Recognition (OCR) process, thus allowing NHTSA to search and copy certain portions of your submissions. Comments may be submitted to the docket electronically by logging onto the Docket Management System website at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- You may also submit two copies of your comments, including the attachments, to Docket Management at the address given above under **ADDRESSES**.

Please note that pursuant to the Data Quality Act, in order for substantive data to be relied upon and used by the Agency, it must meet the information quality standards set forth in the OMB and DOT Data Quality Act guidelines. Accordingly, we encourage you to consult the guidelines in preparing your comments. OMB's guidelines may be accessed at *http://www.whitehouse.gov/omb/fedreg/reproducible.html.* DOT's guidelines may be accessed at *http://www.bts.gov/programs/statistical_policy_and_research/data_quality_guidelines.*

How can I be sure that my comments were received?

If you wish Docket Management to notify you upon its receipt of your comments, enclose a self-addressed, stamped postcard in the envelope containing your comments. Upon receiving your comments, Docket Management will return the postcard by mail.

How do I submit confidential business information?

If you wish to submit any information under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Chief Counsel, NHTSA, at the address given above under **FOR FURTHER INFORMATION CONTACT**. In addition, you should submit two copies, from which you have deleted the claimed confidential business information, to Docket Management at the address given above under **ADDRESSES**. When you send a comment containing information claimed to be confidential business information, you should include a cover letter setting forth the information specified in our confidential business information regulation. (49 CFR part 512). To facilitate social distancing during COVID–19, NHTSA is temporarily accepting confidential business information electronically. Please see *https://www.nhtsa.gov/coronavirus/submission-confidential-business-information* for details.

Will the Agency consider late comments?

We will consider all comments that Docket Management receives before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, we will also consider comments that Docket Management receives after that date. If Docket Management receives a comment too late for us to consider in developing the follow on final rule, we will consider that comment as an informal suggestion for future rulemaking action.

How can I read the comments submitted by other people?

You may read the comments received by Docket Management at the address given above under **ADDRESSES**. The hours of the Docket are indicated above in the same location. You may also see the comments on the internet. To read the comments on the internet, go to *http://www.regulations.gov.* Follow the online instructions for accessing the dockets.

Please note that, even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically check the Docket for new material.

List of Subjects in 49 CFR Part 595

Motor vehicle safety, Motor vehicles.

In consideration of the foregoing, NHTSA proposes to amend 49 CFR part 595 to read as follows:

PART 595—MAKE INOPERATIVE EXEMPTIONS

■ 1. The authority citation for Part 595 would be revised to read as follows:

Authority: 49 U.S.C. 322, 30111, 30115, 30117, 30122 and 30166; delegation of authority at 49 CFR 1.95.

■ 2. Revise § 595.3 to read as follows:

§ 595.3 Applicability.

This part applies to dealers, motor vehicle repair businesses, and rental companies.

■ 3. Amend § 595.4 by adding in alphabetical order, the definitions ''covered rental vehicle'' and ''rental company,'' to read as follows:

§ 595.4 Definitions.

* * * * *

The term *covered rental vehicle* is defined as it is in 49 U.S.C. 30102(a).

* * * * *

The term *rental company* is defined as it is in 49 U.S.C. 30102(a).

■ 4. Amend § 595.7 by adding paragraph (c)(19) to read as follows:

§ 595.7 Requirements for vehicle modifications to accommodate people with disabilities.

* * * * *

(c) * * *

(19) S5.5.1, S5.5.2, S6.2.1, and S6.2.2 of 49 CFR 571.111, in any case in which a personal mobility device transporter is temporarily installed on a vehicle by way of a trailer hitch to carry a personal mobility device (*e.g.,* a wheelchair, powered wheelchair, or powered scooter) used by the driver or a passenger with a disability.

* * * * *

■ 5. Add § 595.8 to read as follows:

§ 595.8 Modifications by rental companies.

(a) A rental company that modifies a motor vehicle temporarily in order to rent a covered rental vehicle to a person with a disability to operate, or ride as a passenger in, the motor vehicle is exempted from the ''make inoperative'' prohibition in 49 U.S.C. 30122 to the extent that those modifications make inoperative any part of a device or element of design installed on or in the motor vehicle in compliance with the Federal motor vehicle safety standards or portions thereof specified in paragraph (d) of this section. Modifications that would make inoperative devices or elements of design installed in compliance with any other Federal motor vehicle safety

standards, or portions thereof, are not covered by this exemption.

(b) The exemption described in paragraph (a) extends only for the period during which the covered rental vehicle is rented to a person with a disability and a reasonable period before and after the rental agreement in order to perform and reverse the modification described in paragraph (d) of this section.

(c) Any rental company that temporarily modifies a motor vehicle to enable a person with a disability to operate, or ride as a passenger in, the motor vehicle in such a manner as to make inoperative any part of a device or element of design installed on or in the motor vehicle in compliance with a Federal motor vehicle safety standard or portion thereof specified in paragraph (d) of this section must affix to the motor vehicle a label of the type and in the manner described in paragraph (e) of this section and must provide and retain a document of the type and in the manner described in paragraph (f) of this section.

(d)(1) 49 CFR 571.208, in the case of the disablement of a knee bolster air bag to allow the installation of hand controls.

(2) [Reserved]

(e) The label required by paragraph (c) of this section shall:

(1) Be affixed within the passenger compartment of the vehicle.;

(2) Be affixed in a location visible to the driver in a manner that does not obstruct the driver's view while operating the vehicle;

(3) Contain the statement ''WARNING—To accommodate installation of hand controls, this rental vehicle has had its knee bolster air bags temporarily disabled,'' and,

(4) Be removed when the modifications described in paragraph (d) are reversed.

(f) The document required by paragraph (c) of this section shall:

(1) Be provided in original or photocopied paper form, or in electronic form to the renter of the covered rental vehicle at the time of execution of the rental agreement;

(2) Contain the name and physical address of the rental company making the modifications;

(3) Be kept in original or photocopied paper form, or retained electronically, by the rental company for a period of not less than five years after the conclusion of the rental agreement for which the modification is made;

(4) Be clearly identifiable as to the vehicle that has been modified; and

(5) Identify the devices or elements of design installed on or in a motor vehicle in compliance with a Federal motor vehicle safety standard made inoperative by the rental company.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95.

James C. Owens,

Deputy Administrator.

[FR Doc. 2020–28648 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–59–P

Notices

Federal Register
Vol. 85, No. 248
Monday, December 28, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc No. AMS–FGIS–20–0077]

Certification of Alabama, Virginia, Washington, and Wisconsin To Provide Official Services at Export Port Locations Under a Delegation; Cancellation of South Carolina's Delegation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: The Agricultural Marketing Service (AMS) is announcing the certification of the Alabama Department of Agriculture and Industries (ADAI); Virginia Department of Agriculture and Consumer Services (VDACS); Washington State Department of Agriculture (WSDA); and the Wisconsin Department of Agriculture, Trade and Consumer Protection (WDATCP) to provide official inspection services at export port locations, under delegated authority of the United States Grain Standards Act (USGSA), as amended. AMS is also announcing the cancellation of the South Carolina Department of Agriculture's (SCDA) delegation.

DATES: Effective January 27, 2021.

FOR FURTHER INFORMATION CONTACT: Sophie Parker, Deputy Director, Quality Assurance and Compliance Division, Federal Grain Inspection Service, AMS, USDA; phone: (202) 720–9170; or email *FGISQACD@usda.gov.* If you would like to view the comments, please contact us at *FGISQACD@usda.gov* (7 CFR 1.27(c)).

SUPPLEMENTARY INFORMATION: The USGSA, at Section 7(e) (7 U.S.C. 79(e)), requires the Secretary of Agriculture (Secretary) to certify, every five years, that each State agency with a delegation of authority is meeting the criteria described for carrying out inspections on behalf of the Secretary. This certification process includes: (1) Publishing, in the **Federal Register**, a notice of intent to certify a State agency and provide a 30-day period for public comment; (2) evaluating the public comments received; and (3) conducting an investigation to determine whether the State agency is qualified. Findings must be based on public comments received and investigation conducted. Once concluded, USDA must publish a **Federal Register** notice announcing whether the certification has been granted, describing the basis on which the Secretary made the decision.

In the April 17, 2017; April 5, 2018; July 3, 2017; August 24, 2016; and April 17, 2017, editions of the **Federal Register** (82 FR 18101; 83 FR 14622; 82 FR 30819; 81 FR 57886; and 82 FR 18099), the Federal Grain Inspection Service (FGIS), requested comments separately on the quality of services provided by the delegated State agencies ADAI, VDACS, WSDA, WDATCP, and SCDA, respectively. Comments for each State agency were due 30 days from the respective publication dates.

FGIS received one comment in support of ADAI, VDACS, WDATCP, and SCDA maintaining their statuses as delegated State agencies under the USGSA. FGIS also received one comment supporting WSDA maintaining its status as a delegated State agency under the USGSA with certain contingences. This comment's proposed contingencies included: A prohibition on political influence over inspection decisions, requiring expedited service from FGIS when a delegated State agency is unable to perform services, improving processes for substitution of FGIS inspections, and improving the delegation documents. FGIS has updated the delegations in a manner that FGIS believes addresses many of the concerns this comment has raised, including providing how FGIS would assume inspection responsibility when a delegated State agency is unable to provide service, adopting uniform and time-limited delegation documents, and clarifying the relative responsibilities of FGIS and the delegated State agencies.

In compliance with the USGSA section 7, AMS conducted additional research to confirm whether ADAI, VDACS, WDATCP, or WSDA was under any investigation by the Department of Justice or Government Accountability Office that could disqualify them from being delegated authority under the USGSA. There were no findings to disqualify these agencies from consideration. AMS also assessed whether any negative legal opinions or decisions had been rendered against the agencies by the States' Attorneys General; nothing was found to disqualify the State agencies from the delegation process.

Compliance reviews were conducted to assess the performance of WDATCP, VDACS, ADAI and WSDA. For WDATCP, the review was a follow-up for a review conducted the year prior, during which performance concerns were uncovered; by the time the second review was conducted, these concerns had been resolved. The VDACS, ADAI and WSDA all performed well during their compliance reviews. AMS found all four State agencies compliant with the requirements.

AMS did not conduct the same level of evaluation for SCDA. In reviewing eligibility criteria against the State of South Carolina's current infrastructure, AMS acknowledges that the State of South Carolina no longer has any operable, bulk-grain export port facilities. Accordingly, AMS is not certifying the extension of SCDA's delegation. By way of this notice, SCDA's delegation is canceled. If any grain export port facility were to open in the future within the State of South Carolina, SCDA would have the opportunity to become delegated again.

With respect to ADAI, VDACS, WSDA, and WDATCP, after reviewing the comments and delegation criteria in section 7(e) of the USGSA (7 U.S.C. 79(e)), AMS has determined that ADAI, VDACS, WSDA, and WDATCP are qualified to provide official services in the geographic areas specified in the **Federal Register** on April 17, 2017; April 5, 2018; July 3, 2017; and August 24, 2016, respectively. As a result, AMS is certifying their delegation to provide official services at export port locations.

Interested persons may obtain official services by contacting these State agencies at the following telephone numbers:

State agency	Headquarters location and telephone
Alabama	Montgomery, AL, (334) 240–7231.
Virginia	Richmond, VA, (804) 786–3501.
Washington	Olympia, WA, (360) 902–1888.
Wisconsin	Madison, WI, (608) 224–4922.

Authority: 7 U.S.C. 71–87k.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–28499 Filed 12–23–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Economic Development Administration

Notice of Petitions by Firms for Determination of Eligibility To Apply for Trade Adjustment Assistance

AGENCY: Economic Development Administration, U.S. Department of Commerce.

ACTION: Notice and opportunity for public comment.

SUMMARY: The Economic Development Administration (EDA) has received petitions for certification of eligibility to apply for Trade Adjustment Assistance from the firms listed below. Accordingly, EDA has initiated investigations to determine whether increased imports into the United States of articles like or directly competitive with those produced by each of the firms contributed importantly to the total or partial separation of the firms' workers, or threat thereof, and to a decrease in sales or production of each petitioning firm.

SUPPLEMENTARY INFORMATION:

LIST OF PETITIONS RECEIVED BY EDA FOR CERTIFICATION OF ELIGIBILITY TO APPLY FOR TRADE ADJUSTMENT ASSISTANCE

[12/11/2020 through 12/18/2020]

Firm name	Firm address	Date accepted for investigation	Product(s)
Prime Photonics, LC	1116 South Main Street, Blacksburg, VA 24060.	12/14/2020	The firm manufactures optical sensors and measuring instruments.
Rand Manufacturing Network, Inc.	840 Tanglewood Drive, Wheeling, IL 60090.	12/17/2020	The firm manufactures plastic washers and miscellaneous plastic parts.

Any party having a substantial interest in these proceedings may request a public hearing on the matter. A written request for a hearing must be submitted to the Trade Adjustment Assistance Division, Room 71030, Economic Development Administration, U.S. Department of Commerce, Washington, DC 20230, no later than ten (10) calendar days following publication of this notice. These petitions are received pursuant to section 251 of the Trade Act of 1974, as amended.

Please follow the requirements set forth in EDA's regulations at 13 CFR 315.9 for procedures to request a public hearing. The Catalog of Federal Domestic Assistance official number and title for the program under which these petitions are submitted is 11.313, Trade Adjustment Assistance for Firms.

Bryan Borlik,

Director.

[FR Doc. 2020–28574 Filed 12–23–20; 8:45 am]

BILLING CODE 3510–WH–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–469–818]

Ripe Olives From Spain: Preliminary Results of Countervailing Duty Administrative Review; 2017–2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the countervailing duty (CVD) order on ripe olives from Spain. Commerce preliminarily determines that exporters/producers of ripe olives from Spain received countervailable subsidies during the period of review, November 28, 2017 through December 31, 2018. Interested parties are invited to comment on these preliminary results.

DATES: Applicable December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg, Dusten Hom, or William Langley, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1785, (202) 482–5075, (202) 482–3861, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 7, 2019, Commerce published the notice of initiation of an administrative review of the CVD order on ripe olives from Spain.[1] On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[2] On May 26, 2020, Commerce extended the deadline for the preliminary results of this review by 120 days.[3] On July 21, 2020, Commerce tolled deadlines for preliminary and final results in administrative reviews by an additional 60 days.[4] Accordingly, the deadline for the preliminary results of this review was postponed to December 18, 2020.

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5] A list of topics

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 53411 (October 7, 2019).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments due to COVID–19,'' dated April 24, 2020.

[3] *See* Memorandum, ''Ripe Olives from Spain: Extension of Deadline for Preliminary Results of 2017–2018 Countervailing Duty Administrative Review,'' dated May 26, 2020.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2017–2018 Countervailing Duty Administrative Review of Ripe Olives from Spain,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

discussed in the Preliminary Decision Memorandum is included as the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Order

The products covered by the order are ripe olives from Spain. For a complete description of the scope of this administrative review, *see* the Preliminary Decision Memorandum.[6]

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[7] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Commerce notes that, in making these findings, it relied, in part, on facts otherwise available pursuant to section 776(a) of the Act, as well as adverse facts available pursuant to section 776(b) of the Act. For further information, *see* ''Use of Facts Otherwise Available'' in the Preliminary Decision Memorandum.

Preliminary Results of Review

We preliminarily determine the following net countervailable subsidy rates for the period November 28, 2017 through December 31, 2018:

Company	Subsidy rate (percent)
Alimentary Group DCoop S.Coop. And	21.12
Agro Sevilla Aceitunas S.Coop. And	6.47
Angel Camacho Alimentación, S.L[8]	5.23

[8] As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with Angel Camacho Alimentación, S.L.: Grupo Angel Camacho Alimentacíon, Cuarterola S.L., and Cucanoche S.L.

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. We intend to issue instructions to CBP 15 days after publication of the final results of this review.

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown above for the respective companies listed above with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. For all non-reviewed firms, CBP will continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure and Public Comment

Commerce intends to disclose its calculations and analysis performed in reaching the preliminary results within seven days of publication of these preliminary results.[9] Commerce also intends to issue post-preliminary analysis memoranda subsequent to the publication of this notice. Commerce will notify the parties to this proceeding of the deadlines for the submission of case and rebuttal briefs after the issuance of the last post-preliminary analysis memorandum.[10] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs.[11] Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. All briefs must be filed electronically using ACCESS.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice. Hearing requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues addressed at the hearing will be limited to those raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.

Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their comments, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1) unless this deadline is extended.

Notification to Interested Parties

These preliminary results and notice are issued and published in accordance with sections 751(a) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4)

Dated: December 18, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Subsidies Valuation Information
V. Use of Facts Otherwise Available
VI. Analysis of Programs
VII. Recommendation

[FR Doc. 2020–28589 Filed 12–23–20; 8:45 am]

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[6] *See* Memorandum, ''Ripe Olives from Spain: Decision Memorandum for Preliminary Results of Countervailing Duty Administrative Review; 2017–2018,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[7] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[9] *See* 19 CFR 351.224(b).

[10] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements); *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020); and *Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020) (*Temporary Rule*).

[11] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–837]

Certain Cut-to-Length Carbon-Quality Steel Plate From the Republic of Korea: Final Results of Countervailing Duty Administrative Review; Calendar Year 2018

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that Hyundai Steel Co. (Hyundai Steel) and certain other producers/exporters of certain cut-to-length plate from the Republic of Korea (Korea) received countervailable subsidies that are above *de minimis* and that Dongkuk Steel Mill Co., Ltd. (DSM) received a *de minimis* net subsidy rate during the period of review (POR) January 1, 2018 through December 31, 2018.

DATES: Applicable December 28, 2020.

FOR FURTHER INFORMATION CONTACT: John Conniff (for Hyundai Steel) or Jolanta Lawska (for DSM), AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1009 or (202) 482–8362, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 6, 2020, Commerce published the *Preliminary Results* of this administrative review.[1] On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days.[2] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days.[3] Additionally, on August 6, 2020, Commerce issued a post-preliminary analysis memorandum.[4] On August 19, 2020, we received timely filed case briefs from Nucor Corporation (the petitioner), the Government of Korea (GOK), DSM, and Hyundai Steel. On September 2, 2020, the GOK, Hyundai Steel and DSM submitted timely filed rebuttal briefs. On September 25, 2020, Commerce extended the deadline for issuing the final results of this review by 29 days.[5] On November 2, 2020, Commerce further extended the final results of this review by 28 days to December 18, 2020.[6] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[7]

Scope of the Order

The merchandise covered by the order is certain hot-rolled carbon-quality steel plate. The merchandise subject to the order is currently classifiable in the HTSUS under subheadings: 7208.40.3030, 7208.40.3060, 7208.51.0030, 7208.51.0045, 7208.51.0060, 7208.52.0000, 7208.53.0000, 7208.90.0000, 7210.70.3000, 7210.90.9000, 7211.13.0000, 7211.14.0030, 7211.14.0045, 7211.90.0000, 7212.40.1000, 7212.40.5000, 7212.50.0000, 7225.40.3050, 7225.40.7000, 7225.50.6000, 7225.99.0090, 7226.91.5000, 7226.91.7000, 7226.91.8000, 7226.99.0000.

Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise covered by the order is dispositive.[8]

Analysis of Comments Received

All issues raised in interested parties' case briefs are addressed in the Issues and Decision Memorandum. The issues are identified in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/index.html.* The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

Based on the comments received from interested parties and record information, we have made changes to the net subsidy rates calculated for the mandatory respondents. For a discussion of these issues, *see* the Issues and Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we find that there is a subsidy, *i.e.,* a financial contribution from a government or public entity that gives rise to a benefit to the recipient, and that the subsidy is specific.[9] For a full description of the methodology underlying our conclusions, *see* the Issues and Decision Memorandum.

Rate for Non-Selected Companies Under Review

The statute and Commerce's regulations do not directly address the countervailing duty rates to be applied to companies not selected for individual examination where Commerce limited its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation. Section 777A(e)(2) of the Act provides that ''the individual countervailable subsidy rates determined under subparagraph (A) shall be used to determine the all-others rate under section 705(c)(5) {of the Act}.'' Section 705(c)(5)(A) of the Act states that for companies not investigated, in general, we will determine an all-others rate by using the weighted-average countervailable subsidy rates established for each of the companies individually investigated, excluding zero and *de minimis* rates or any rates based solely on the facts available.

We determine that Hyundai Steel received countervailable subsidies that

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[1] *See Certain Cut-to-Length Carbon-Quality Steel Plate from the Republic of Korea: Preliminary Results of Countervailing Duty Administrative Review; Calendar Year 2018,* 85 FR 13136 (March 6, 2020) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[3] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[4] *See* Memorandum, ''Countervailing Duty Administrative Review: Certain Cut-to-Length Carbon-Quality Steel Plate from the Republic of Korea: Post-Preliminary Analysis Memorandum,'' dated August 6, 2020.

[5] *See* Memorandum, ''Extension of Deadline for Final Results of Countervailing Duty Administrative Review,'' dated September 25, 2020.

[6] *See* Memorandum, ''Extension of Deadline for Final Results of Countervailing Duty Administrative Review,'' dated November 2, 2020.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Countervailing Duty Administrative Review: Cut-to-Length Carbon-Quality Steel Plate from the Republic of Korea; 2018,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[8] For a complete description of the scope of the order, *see* the Issues and Decision Memorandum.

[9] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

are above *de minimis.* Therefore, in these final results, we are applying the net subsidy rate calculated for Hyundai Steel to BDP International and Sung Jin Steel Co., Ltd.

Final Results of Administrative Review

In accordance with section 751(a)(1)(A) of the Act and 19 CFR 351.221(b)(5), we determine that the following total estimated net countervailable subsidy rates exist for the period January 1, 2018 through December 31, 2018:

Company	Subsidy rate *ad valorem* %
Dongkuk Steel Mill Co., Ltd ..	* 0.28
Hyundai Steel Company	0.50
BDP International	0.50
Sung Jin Steel Co., Ltd	0.50

* (*de minimis*).

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

In accordance with 19 CFR 351.212(b)(2), Commerce intends to issue appropriate instructions to U.S. Customs and Border Protection (CBP) 15 days after publication of these final results to liquidate shipments of subject merchandise. Because we have calculated a *de minimis* countervailable subsidy rate for DSM, we will instruct CBP to liquidate the appropriate entries without regard to countervailing duties in accordance with 19 CFR 351.212. We will instruct CBP to liquidate shipments of subject merchandise produced and/or exported by Hyundai Steel and the above listed companies, entered or withdrawn from warehouse for consumption from January 1, 2018 through December 31, 2018, at the *ad valorem* rates listed above for each respective company.

Cash Deposit Instructions

In accordance with section 751(a)(2)(C) of the Act, we intend to instruct CBP to collect cash deposits of estimated countervailing duties, in the amounts shown above, with the exception of DSM, on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review. Because the countervailable subsidy rate for DSM is *de minimis,* Commerce will instruct CBP to collect cash deposits at a rate of zero for DSM for all shipments of the subject merchandise that are entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most-recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: December 18, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Period of Review
V. Subsidies Valuation Information
VI. Analysis of Programs
VII. Analysis of Comments
Dongkuk Steel Mill Co., Ltd. (DSM)
Comment 1: Whether Commerce's Findings that the Demand Response Resources (DRR) Program Constitutes a Countervailable Subsidy is in Accordance with the Requirements of the Statute or the World Trade Organization (WTO) Agreement on Subsidies and Countervailing Measures (SCM Agreement)
Comment 2: Whether the ''Energy Savings System'' (ESS) Discount Program Is Not a Subsidy Relating to Subject Merchandise
Comment 3: Commerce Incorrectly Calculated the Benefit from the KEXIM Import Financing Used by DSM
Comment 4: Whether Commerce Incorrectly Calculated the Benefit from the R&D Project for the Development of Earthquake-Proof Reinforced Steel Bars (ITIPA R&D)
Comment 5: Commerce Incorrectly Described Unaffiliated Trading Companies as Affiliates of DSM in the Preliminary Issues and Decision Memorandum
Hyundai Steel Company (Hyundai Steel)
Comment 6: Commerce Erred in its Preliminary Finding that the Reduction for Sewerage Fees Program for Hyundai Steel
Comment 7: Commerce should continue to determine that the Upstream Electricity Subsidy Program is not Countervailable
Comment 8: Whether the GOK Provided Carbon Emission Credits for Less Than Adequate Remuneration (LTAR) to Hyundai Steel
Recommendation

[FR Doc. 2020–28591 Filed 12–23–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–469–817]

Ripe Olives From Spain: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that producers or exporters subject to this administrative review made sales of subject merchandise at less than normal value during the period of review (POR), January 26, 2018 through July 31, 2019. We invite interested parties to comment on these preliminary results.

DATES: Applicable December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun or Dmitry Vladimirov, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230; telephone (202) 482–5760 or (202) 482–0665, respectively.

SUPPLEMENTARY INFORMATION:

Background

On October 7, 2019, Commerce initiated the administrative review of the antidumping duty order on ripe olives (olives) from Spain.[1] On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days,

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 53411 (October 7, 2019).

thereby extending the deadline for these preliminary results until June 22, 2020.[2] On June 2, 2020, Commerce extended the time limit for these preliminary results to October 19, 2020, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act).[3] On July 21, 2020, Commerce tolled all deadlines in administrative reviews by an additional 60 days, thereby extending the deadline for these preliminary results until December 18, 2020.[4]

Scope of the Order

The merchandise subject to the order are ripe olives. For a complete description of the scope of this administrative review, see the Preliminary Decision Memorandum.[5]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Act. Export price and constructed export price are calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/index.html.* A list of the topics discussed in the Preliminary Decision Memorandum is attached as an Appendix to this notice.

Preliminary Results of Review

We preliminarily determine that the following weighted-average dumping margins exist for the period January 26, 2018 through July 31, 2019.

Producer/Exporter	Weighted-average dumping margin (Percent)
Agro Sevilla Aceitunas S.COOP Andalusia	16.51
Angel Camacho Alimentacion S.L.	22.31
Alimentary Group Dcoop S. Coop. And.	7.66

Disclosure and Public Comment

We intend to disclose the calculations performed to parties in this administrative review within five days after public announcement of the preliminary results in accordance with 19 CFR 351.224(b).

Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs no later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[6] Commerce has modified certain of its requirements for serving documents containing business proprietary information until further notice.[7] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[8]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. Requests should contain: (1) The party's name, address and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. An electronically filed hearing request must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[9]

Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of the final results, Commerce shall determine and U.S. Customs and Border Protection (CBP) shall assess antidumping duties on all appropriate entries. If the weighted-average dumping margin for either Agro Sevilla Aceitunas S.COOP Andalusia, Angel Camacho Alimentacion S.L., or Alimentary Group Dcoop S. Coop. And., is not zero or *de minimis* in the final results of this review, we will calculate, for each company, an importer-specific assessment rate on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1).[10] If any of these companies' weighted-average dumping margin is zero or *de minimis* in the final results of review, or if an importer-specific assessment rate for one of these companies is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regards to antidumping duties.[11] For entries of subject merchandise during the POR produced by any of these companies for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries.[12]

We intend to issue liquidation instructions to CBP fifteen days after publication of the final results of this review. The final results of this administrative review shall be the basis for the assessment of antidumping duties on entries of merchandise under review and for future cash deposits of estimated antidumping duties, where applicable.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

[3] *See* Memorandum, ''Ripe Olives from Spain: Extension of Deadline for Preliminary Results of 2018–2019 Antidumping Duty Administrative Review,'' dated June 2, 2020.

[4] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews,'' dated July 21, 2020.

[5] *See* Memorandum, ''Ripe Olives from Spain: Decision Memorandum for Preliminary Results of Antidumping Duty Administrative Review; 2018–2019,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect).'')

[7] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[8] *See* 19 CFR 351.303 (for general filing requirements).

[9] *See* 19 CFR 351.310(c).

[10] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[11] *Id.* at 8102–03; *see also* 19 CFR 351.106(c)(2).

[12] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

publication in the **Federal Register** of the notice of final results of administrative review for all shipments of olives from Spain entered, or withdrawn from warehouse, for consumption on or after the date of publication as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for companies subject to this review will be equal to the company-specific weighted-average dumping margin established in the final results of the review; (2) for merchandise exported by a company not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published in the completed segment for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the producer is, the cash deposit rate will be the rate established in the completed segment for the most recent period for the producer of the merchandise; (4) the cash deposit rate for all other producers or exporters will be the all-others rate established in the less-than-fair-value investigation for this proceeding, 19.98 percent.[13] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221.

Dated: December 18, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Requests for Withdrawal of Administrative Review
V. Discussion of the Methodology
VI. Currency Conversion
VII. Recommendation

[13] *See Ripe Olives from Spain: Antidumping Duty Order,* 83 FR 37465 (August 1, 2018).

[FR Doc. 2020–28590 Filed 12–23–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–475–819]

Certain Pasta from Italy; Rescission of Antidumping Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on certain pasta from Italy for the period of review (POR) January 1, 2019, through December 31, 2019, based on the timely withdrawal of the requests for review.

DATES: Applicable December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Konrad Ptaszynski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482- 6187.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2020, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the CVD order on certain pasta from Italy for the period January 1, 2019 through December 31, 2019.[1] By July 31, 2020, Commerce received timely requests for an administrative review from Armonie D'Italia S.r.l. (Armonie), Pastificio Fratelli De Luca S.r.l. (Fratelli), Pastificio C.A.M.S. S.r.l (CAMS), and Industria Alimentare Colavita, S.p.A (Colavita), in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b). [2] Commerce received no other requests for administrative review.

On September 3, 2020, pursuant to these requests, and in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice in the **Federal Register** initiating an administrative review of the CVD order on certain pasta from Italy.[3] On November 30, 2020, Colavita withdrew its request for an administrative review.[4] On December 2, 2020, CAMS, Armonie, and Fratelli withdrew their requests for an administrative review.[5]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party or parties that requested a review withdraws the request within 90 days of the publication date of the notice of initiation of the requested review. Armonie, CAMS, Colavita, and Fratelli withdrew their requests within 90 days of the publication date of the notice of initiation. No other parties requested an administrative review of the order. Therefore, in accordance with 19 CFR 351.213(d)(1), we are rescinding the administrative review of the CVD order on certain pasta from Italy covering January 1, 2019, through December 31, 2019, in its entirety.

Assessment

Commerce intends to instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries of pasta from Italy during the POR. Countervailing duties shall be assessed at rates equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after the date of publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Orders

This notice also serves as a reminder to all parties subject to administrative protective order (APO) of their

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 39531 (July 1, 2020).

[2] *See* Armonie's Letter, ''Certain Dry Pasta from Italy; C–475–819; Request for Administrative Review,'' dated July 28, 2020; Fratelli's Letter, ''Certain Dry Pasta from Italy; C–475–819; Request for Administrative Review,'' dated July 28, 2020; CAMS' Letter, ''Certain Dry Pasta from Italy; C–475–819; Request for Administrative Review,'' dated July 28, 2020; and Colavita's Letter, ''Certain Dry Pasta from Italy; C–475–819; Request for Administrative Review,'' dated July 31, 2020.

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 54983 (September 3, 2020).

[4] *See* Colavita's Letter, ''Certain Pasta from Italy: Withdrawal of Request for CVD Administrative Review of Indalco S.p.A,'' dated November 30, 2020.

[5] *See* CAMS' Letter, ''Certain Dry Pasta from Italy; C–475–819; Withdraw Request for Administrative Review,'' dated December 2, 2020; Armonie's Letter ''Certain Dry Pasta from Italy; C–475–819; Withdraw Request for Administrative Review''; Fratelli's Letter ''Certain Dry Pasta from Italy; C–475–819; Withdraw Request for Administrative Review''.

responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: December 18, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–28594 Filed 12–23–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–552–801]

Certain Frozen Fish Fillets From the Socialist Republic of Vietnam: Preliminary Results of the Antidumping Duty Administrative Review, Preliminary Determination of no Shipments, and Partial Rescission of the Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that certain producers and exporters of frozen fish fillets (fish fillets) from the Socialist Republic of Vietnam (Vietnam) made sales of subject merchandise at prices below normal value (NV) during the period of review (POR) August 1, 2018 through July 31, 2019. We also preliminarily determine that two companies are eligible for separate rate status, 27 companies did not establish eligibility for a separate rate and are part of the Vietnam-wide entity, and 21 companies had no shipments during the POR. Finally, we are rescinding this review with respect to 16 companies. We invite interested parties to comment on these preliminary results.

DATES: Applicable December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington DC 20230; telephone: (202) 482–2243.

SUPPLEMENTARY INFORMATION:

Background

On October 7, 2019, Commerce published in the **Federal Register** the notice of initiation of an administrative review of the antidumping duty (AD) order on fish fillets from Vietnam with respect to 76 companies.[1] We selected the largest exporters, Bien Dong Seafood Co., Ltd. (Bien Dong) and Vinh Hoan Corporation (Vinh Hoan),[2] as mandatory respondents.[3] Following the withdrawal of all review requests for Bien Dong,[4] Commerce selected Seafood Joint Stock Company No.4 Branch Dongtam Fisheries Processing Company (DOTASEAFOOD) as an additional mandatory respondent on January 22, 2020.[5]

Scope of the Order

The products covered by this order are fish fillets from Vietnam. For a full description of the scope of the order, *see* the Preliminary Decision Memorandum.[6]

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested a review withdraws the request within 90 days of the date of publication of the notice of initiation. As noted above, all interested parties timely withdrew their requests for review for 16 companies. Accordingly, Commerce is rescinding this review with respect to these 16 entities, in accordance with 19 CFR 351.213(d)(1).[7] The review will continue with respect to the other firms for which a review was requested and initiated.

Preliminary Determination of No Shipments

Based on an analysis of information from U.S. Customs and Border Protection (CBP) and the letters filed by 20 companies certifying no shipments, Commerce preliminarily determines that these companies had no shipments during the POR.[8] In addition, with regard to an additional company, HVG,[9] information on the record establishes that HVG had no shipments during the POR. For additional information regarding this finding, *see* the Preliminary Decision Memorandum.

Consistent with our assessment practice in non-market economy (NME) administrative reviews, Commerce is not rescinding this review for these 21 companies,[10] but intends to complete the review and issue appropriate instructions to CBP based on the final results of the review.[11]

Separate Rates

Commerce preliminarily determines that information placed on the record by mandatory respondent, Vinh Hoan, and separate rate applicant, Nam Viet Corporation (NAVICO), demonstrates that these companies are entitled to separate rate status. The remaining 27 companies subject to this review have not established eligibility for a separate rate, and are, therefore, considered to be part of the Vietnam-wide entity for these

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 84 FR 53411 (October 7, 2019).

[2] Vinh Hoan, Van Duc Food Export Joint Stock Company, and Van Duc Tien Giang Food Export Company have previously been treated as a single entity. *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Notice of Preliminary Results and Partial Rescission of the Sixth Antidumping Duty Administrative Review and Sixth New Shipper Review,* 75 FR 56062 (September 15, 2010), unchanged in *Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of the Sixth Antidumping Duty Administrative Review and Sixth New Shipper Review,* 76 FR 15941 (March 22, 2011). We refer to the companies, collectively, as Vinh Hoan.

[3] *See* Memorandum, ''Selection of Respondents for Individual Review,'' dated December 13, 2019.

[4] For a detailed history of the events following initiation of this review, *see* Memorandum, ''Preliminary Results of Antidumping Duty Administrative Review: Certain Frozen Fish Fillets from the Socialist Republic of Vietnam; 2018–2019,'' dated concurrently with this notice (Preliminary Decision Memorandum).

[5] *See* Memorandum, ''Selection of Replacement Respondent for Individual Review,'' dated January 22, 2020.

[6] *See* Preliminary Decision Memorandum.

[7] *See* Appendix II for a list of companies for which we are rescinding this review.

[8] *See* Preliminary Decision Memorandum for a complete list of companies with no shipments during the POR.

[9] The collapsed entity includes: An Giang Fisheries Import and Export Joint Stock Company; Asia Pangasius Company Limited; Europe Joint Stock Company; Hung Vuong Ben Tre Seafood Processing Company Limited; Hung Vuong Joint Stock Company (aka Hung Vuong Corporation); Hung Vuong Mascato Company Limited; Hung Vuong—Sa Dec Co. Ltd.; and Hung Vuong—Vinh Long Co., Ltd. (collectively, HVG). *See Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Preliminary Results of the Antidumping Duty Administrative Review, Preliminary Determination of No Shipments and Partial Rescission of the Antidumping Duty Administrative Review; 2016–2017,* 83 FR 46479 (September 13, 2018), and accompanying Preliminary Decision Memorandum (PDM) at 4, unchanged in *Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results, and Final Results of No Shipments of the Antidumping Duty Administrative Review; 2016–2017,* 84 FR 18007 (April 20, 2019).

[10] As noted above, HVG is a single entity consisting of eight companies.

[11] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011) and the ''Assessment Rates'' section, below.

preliminary results.[12] For additional information, *see* the Preliminary Decision Memorandum.

Vietnam-Wide Entity

The Vietnam-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the Vietnam-wide entity, the entity is not under review, and the entity's rate is not subject to change.[13]

Other than the companies discussed above—*i.e.,* those that received separate rate status, those with no shipments during the POR, or those for which all review requests were timely rescinded—Commerce considers all other companies for which a review was requested to be part of the Vietnam-wide entity. For additional information, *see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with sections 751(a)(1)(B) and 751(a)(2) of the Act. We have calculated constructed export prices in accordance with section 772 of the Act. Because Vietnam is an NME country within the meaning of section 771(18) of the Act, NV has been calculated in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.[14]

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margins exist for the period August 1, 2018 through July 31, 2019:

Exporter/producer	Weighted-average dumping margin (dollars per kilogram)
Vinh Hoan Corporation/Van Duc Food Export Joint Stock Company/Van Duc Tien Giang Food Export Company	$0.09
Review-Specific Rate Applicable to the Following Company:[15]	
Nam Viet Corporation	$0.09

Disclosure and Public Comment

Commerce intends to disclose to interested parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than 30 days after the date of publication of these preliminary results, unless the Secretary alters the time limit. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline for case briefs.[16] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Case and rebuttal briefs should be filed using ACCESS.[17] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information.[18]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and a list of the issues to be discussed. If a request for a hearing is made, Commerce will announce the date and time of the hearing. Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of our analysis of all issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[19] Commerce intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review.

If Vinh Hoan's weighted average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, Commerce will calculate importer-specific or customer-specific assessment rates for Vinh Hoan, in accordance with 19 CFR 351.212(b)(1). Specifically, Commerce intends to calculate an importer-specific per-unit assessment rate by dividing the amount of dumping for reviewed sales to the importer or customer by the total sales quantity associated with those transactions. Where either a respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[20]

For any respondent that was not selected for individual examination in this administrative review, but which qualified for a separate rate, the assessment rate will be equal to the weighted-average dumping margin assigned to Vinh Hoan in the final results of this review.

For entries that were not reported in the U.S. sales databases submitted by Vinh Hoan, Commerce will instruct CBP to liquidate such entries at the Vietnam-wide rate.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for all shipments of fish fillets

[12] *See* Preliminary Decision Memorandum for a complete list of companies not eligible for a separate rate. We note that this includes DOTASEAFOOD, a mandatory respondent that failed to respond to Commerce's request for information.

[13] *Id.*

[14] A list of topics discussed in the Preliminary Decision Memorandum is included at Appendix I of this notice.

[15] This rate is based on the rate calculated for Vinh Hoan.

[16] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[17] *See* 19 CFR 351.303.

[18] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

[19] *See* 19 CFR 351.212(b).

[20] *See* 19 CFR 351.106(c)(2).

from Vietnam entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) For the companies listed above that have a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review (except, if the rate is *de minimis,* then no cash deposit rate will be required); (2) for previously-examined Vietnamese and non-Vietnamese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific cash deposit rate; (3) for all Vietnam exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the Vietnam-wide entity (*i.e.,* $2.39 per kilogram); and (4) for all non-Vietnamese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the Vietnam exporter that supplied that non-Vietnam exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing the preliminary results of this review in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: December 15, 2020

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Partial Rescission of Review
V. Preliminary Determination of No Shipments
VI. Discussion of the Methodology
VII. Recommendation

Appendix II

Companies for Which We Are Rescinding the Review

1. An Giang Agriculture and Food Import-Export Joint Stock Company (also known as Afiex, An Giang Agriculture and Foods Import-Export Joint Stock Company, An Giang Agriculture and Food Import-Export Company, An Giang Agriculture and Foods Import and Export Company, or An Giang Agriculture and Foods Import-Export Company)
2. An My Fish Joint Stock Company (aka Anmyfish or Anmyfishco)
3. An Phu Seafood Corporation (aka ASEAFOOD or An Phu Seafood Corp.)
4. Asia Commerce Fisheries Joint Stock Company (aka Acomfish JSC or Acomfish)
5. Bien Dong Hau Giang Seafood Joint Stock Company (aka Bien Dong HG or Bien Dong Hau Giang Seafood Joint Stock Co.)
6. Bien Dong Seafood Company Ltd. (aka Bien Dong, Bien Dong Seafood, Bien Dong Seafood Co., Ltd., Biendong Seafood Co., Ltd., or Biendong Seafood Limited Liabilty Company)
7. Binh An Seafood Joint Stock Company (aka Binh An or Binh An Seafood Joint Stock Co.)
8. Da Nang Seaproducts Import-Export Corporation (aka Da Nang or Da Nang Seaproducts Import/Export Corp.)
9. GODACO Seafood Joint Stock Company (aka GODACO, GODACO Seafood J.S.C., GODACO Seafood, or GODACO_ SEAFOOD)
10. Hiep Thanh Seafood Joint Stock Company (aka Hiep Thanh or Hiep Thanh Seafood Joint Stock Co.)
11. International Development & Investment Corporation (aka IDI or International Development and Investment Corporation
12. Ngoc Ha Co. Ltd. Food Processing and Trading (aka Ngoc Ha or Ngoc Ha Co., Ltd. Foods Processing and Trading)
13. Saigon-Mekong Fishery Co., Ltd. (aka SAMEFICO or Saigon Mekong Fishery Co., Ltd.)
14. Sunrise Corporation
15. TG Fishery Holdings Corporation (aka TG)
16. To Chau Joint Stock Company (aka TOCHAU, TOCHAU JSC, or TOCHAU Joint Stock Company

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–898; C–557–822]

Utility Scale Wind Towers from India and Malaysia: Postponement of Preliminary Determinations in the Countervailing Duty Investigations

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable: December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Melissa Kinter at (202) 482–1413 (India) and Nathan James at (202) 482–5305 (Malaysia), AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On November 9, 2020, the Department of Commerce (Commerce) initiated the countervailing duty (CVD) investigations of imports of utility scale wind towers from India and Malaysia.[1] Currently, the preliminary determinations are due no later than January 13, 2021.

Postponement of Preliminary Determinations

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a CVD investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner makes a timely request for a postponement; or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination. Under 19 CFR 351.205(e), the petitioner must submit a request for postponement 25 days or more before the scheduled date of the preliminary determination and must state the reasons for the request. Commerce will grant the request unless it finds compelling reasons to deny it.

On December 4, 2020, the Wind Tower Trade Coalition (the petitioner) submitted timely requests that Commerce postpone the preliminary CVD determinations.[2] The petitioner stated that it requests postponement because additional time is needed to collect the necessary information for

[1] *See Utility Scale Wind Towers from India and Malaysia: Initiation of Countervailing Duty Investigations,* 85 FR 73019 (November 16, 2020).

[2] *See* Petitioner's Letters, ''Utility Scale Wind Towers from India: Request for Extension of Preliminary Determination Deadline,'' dated December 4, 2020 (India Postponement Request); and ''Utility Scale Wind Towers from Malaysia: Request for Extension of Preliminary Determination Deadline,'' dated December 4, 2020 (Malaysia Postponement Request).

determining the most accurate possible CVD subsidy rates.[3]

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determinations, and Commerce finds no compelling reason to deny the requests. Therefore, in accordance with section 703(c)(1)(A) of the Act, Commerce is postponing the deadline for the preliminary determinations to no later than 130 days after the date on which these investigations were initiated, *i.e.,* March 19, 2021. Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determinations of these investigations will continue to be 75 days after the date of the preliminary determinations.

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: December 17, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–28595 Filed 12–23–20; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–844]

Certain Lined Paper Products From India: Rescission of Countervailing Duty Administrative Review; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on certain lined paper products (lined paper) from India for the period of review January 1, 2019, through December 31, 2019.

DATES: Applicable: December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Jolanta Lawska, Office III, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–8362.

SUPPLEMENTARY INFORMATION:

Background

On September 1, 2020, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the countervailing duty order [1] on lined paper from India for the period January 1, 2019, through December 31, 2019.[2] On September 30, 2020, ITC Limited—Education and Stationery Products Business (ITC Limited), M/s.Bhaskar Paper Products (Bhaskar), Dinakar Process Private Limited (Dinakar), and JC Stationery (P) Ltd. (JC Stationery) filed a timely request for an administrative review of the *Order* with respect to products exported by ITC Limited and manufactured by ITC Limited and its converters Bhaskar, Dinakar, and JC Stationery.[3] On that same day, PP Bafna Ventures Private Limited (Bafna), filed a timely request of the *Order* with respect to itself.[4] No other interested party submitted a request for review. On October 30, 2020, Commerce published in the **Federal Register** a notice of initiation of this administrative review.[5] On November 10, 2020, Bafna timely withdrew its request for an administrative review.[6] Subsequently, on November 20, 2020, ITC Limited, Bhaskar, Dinakar, and JC Stationery timely withdrew their request for review.[7]

Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the party that requested the review withdraws its request within 90 days of the date of publication of the notice of initiation of the requested review. As noted above, Bafna, and ITC Limited, Bhaskar, Dinakar, and JC Stationary, withdrew their requests within the 90-day deadline, and no other party requested an administrative review of the *Order*. Therefore, we are rescinding, in its entirety, the administrative review of the *Order* for the period January 1, 2019, through December 31, 2019.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess countervailing duties on all appropriate entries of lined paper from India. Countervailing duties shall be assessed at rates equal to the cash deposit rate of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 15 days after publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under an APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Tariff Act of 1930, as amended, and 19 CFR 351.213(d)(4).

Dated: December 18, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

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[3] *See* India Postponement Request at 2; and Malaysia Postponement Request at 2.

[1] *See Amended Final Determination of Sales at Less Than Fair Value: Certain Lined Paper Products from the People's Republic of China; Notice of Antidumping Duty Orders: Certain Lined Paper Products from India, Indonesia and the People's Republic of China; and Notice of Countervailing Duty Orders: Certain Lined Paper Products from India and Indonesia,* 71 FR 56949 (September 28, 2006) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 54349, 54350 (September 1, 2020).

[3] *See* ITC Limited, Bhaskar, Dinakar, and JC Stationery's Letter, ''Lined Paper Products from India, C–533–844 Request for Administrative Review,'' dated September 30, 2020.

[4] *See* Bafna's Letter, ''Certain Lined Paper Products from India: Request for Administrative Review of Countervailing Duty of PP Bafna Ventured Private Limited,'' dated September 30, 2020.

[5] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 68840, 68845 (October 30, 2020).

[6] *See* Bafna's Letter, ''Certain Lined Paper Products from India: Withdrawal of Request for Administrative Review of Countervailing Duty of PP Bafna Ventures Private Limited (PP Bafna),'' dated November 10, 2020.

[7] *See* ITC Limited, Bhaskar, Dinakar, and JC Stationary's Letter, ''Lined Paper Products from India, C–533–844 Withdrawal of Request for Administrative Review,'' dated November 20, 2020.

DEPARTMENT OF COMMERCE

Minority Business Development Agency

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Asian American Pacific Islander Commission Survey

AGENCY: Minority Business Development Agency (MBDA), Commerce.

ACTION: Notice and request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The Asian American Pacific Islander (AAPI) Commission (Commission) will conduct a survey of AAPI business owners to determine the impact of the COVID–19 pandemic on business operations and the AAPI community. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before February 26, 2021.

ADDRESSES: Interested persons are invited to submit written comments to the MBDA PRA Clearance Liaison at *PRAcomments@doc.gov.* Please reference OMB Control Number 0648-0618 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Tina Wei Smith, Executive Director, White House Initiative on Asian American and Pacific Islanders (WHIAAPI), 1401 Constitution Avenue NW, Washington, DC 20230, (202) 482–1375, or *whiaapi@doc.gov*.

SUPPLEMENTARY INFORMATION:

I. Abstract

The President, through Executive Order 13872 (May 13, 2019), re-established the President's Advisory Commission on Asian Americans and Pacific Islanders (AAPI Advisory Commission or Commission) to advise the President, through the Secretary of Commerce and the Secretary of Transportation, as Co-Chairs of the Initiative. The AAPI Advisory Commission provides advice to the President on executive branch efforts to broaden access of AAPI communities, families, and businesses to economic resources and opportunities that empower AAPIs to improve the quality of their lives, raise the standard of living of their communities and families, and more fully participate in the U.S. economy. Additionally, the Commission works to advance relevant evidence-based research, data collection, and analysis for AAPI populations, subpopulations, and businesses.

As part of the research agenda to advise the President, a contractor hired by the Commission intends to conduct telephone interviews with an estimated 10,000 persons to obtain a sample size of 1000 AAPI business owners regarding the economic impact of the COVID–19 pandemic on AAPI businesses and determine the economic and social impact of COVID–19 on AAPI business owners as individuals, members of families, and of the AAPI community.

Methodology: On behalf of the AAPI Commission, a contractor will select a random sample of registered voters, modeled as potential Business Owners and Asians, from the National voter file using Registration Based Sampling (RBS), targeting the age group aligned with the most recent Census American Community Survey data and 50 percent women. This methodology will avoid extreme usage of post-survey ''weighting'' to ensure the reliability of survey results.

II. Method of Collection

Information will be collected via telephone interviews.

III. Data

OMB Control Number: New collection.

Form Number(s): None.

Type of Review: Regular submission.

Affected Public: Individuals or households; Business or other for-profit organizations; Not-for-profit institutions.

Estimated Number of Respondents: 10,000.

Estimated Time Per Response: 1 minute to 15 minutes, depending upon respondent.

Estimated Total Annual Burden Hours: 250.

Estimated Total Annual Cost to Public: 0.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–28546 Filed 12–23–20; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA710]

Fisheries of the Northeastern United States; Northeast Skate Complex Fishery; Supplemental Notice of Intent To Prepare an Environmental Impact Statement and Scoping Process

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

ACTION: Supplemental notice of intent to prepare an environmental impact statement; public scoping meetings; request for comments.

SUMMARY: The New England Fishery Management Council is preparing an environmental impact statement for Amendment 5 to the Northeast Skate Complex Fishery Management Plan. Amendment 5 considers implementing a limited access program in the skate

bait and/or wing fishery, as well as measures that may prevent the triggering of incidental skate possession limits, improve the precision and accuracy of catch data, and better define skate fishery participants. This notice alerts the public of a supplemental scoping period and the opportunity for public participation in that process.

DATES: Written scoping comments must be received on or before 5 p.m., local time, Friday, February 12, 2021. Two supplemental public scoping webinar meetings will be held during this comment period on January 21, 2021 and February 8, 2021. More information about the webinars is at: *https://www.nefmc.org/library/amendment-5-3.*

ADDRESSES: Written scoping comments on Amendment 5 may be sent by any of the following methods:

- Email to the following address: *comments@nefmc.org;*
- Mail to Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950; or
- Fax to (978) 465–3116.

Please indicate ''Skate Amendment 5 Supplemental Scoping Comment'' on your correspondence. Requests for copies of the supplemental Amendment 5 scoping document and other information should be directed to Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950, telephone (978) 465–0492. The supplemental scoping document is accessible electronically via the internet at *https://www.nefmc.org/library/amendment-5-3.*

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council, (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Background

The New England Fishery Management Council (Council), working through its public participatory committee and meeting processes, anticipates the development of an amendment that may require an environmental impact statement (EIS) to meet applicable criteria in the Council on Environmental Quality (CEQ) regulations and guidance for implementing the National Environmental Policy Act (NEPA). In the development of Amendment 5 to the Northeast Skate Complex Fishery Management Plan (FMP), the Council has been considering limited access to the skate bait and/or wing fishery. NEPA reviews initiated prior to the effective date of the 2020 CEQ regulations may be conducted using the 1978 version of the regulations. The effective date of the 2020 CEQ NEPA regulations was September 14, 2020. The NEPA process for this action began with the initial scoping period and first notice of intent (NOI) (82 FR 825, January 4, 2017) in early 2017. Therefore, the development of this amendment will continue under the 1978 NEPA regulations.

The Northeast Skate Complex comprises seven species (barndoor, clearnose, little, rosette, smooth, thorny, and winter skate), managed as a single unit along the east coast from Maine to Cape Hatteras, North Carolina. The skate bait fishery primarily targets little skate, with a small catch component of winter skate. The wing fishery primarily targets winter skate.

The Council first conducted scoping for Amendment 5 in early 2017 (82 FR 825, January 4, 2017) to address concerns that increasingly strict regulations in other fisheries, particularly in the Northeast Multispecies (groundfish) fishery, might cause these fishermen to switch fishing effort onto skates. An increase in effort in the skate fishery could cause the fishery to attain its quota in a shorter time, trigger reduced skate trip limits, or have other negative economic impacts on current participants. The Council has been exploring the creation of a limited access skate permit as a potential solution to these concerns. In September 2020, the Council expanded the scope of this action by approving a problem statement, goals, and types of measures to consider in Amendment 5. In addition to limited access, the Council may consider measures such as creating an intermediate trigger for incidental limits, creating different landing limits for segments of the wing fishery, revising monitoring and reporting requirements, restricting switching between state and Federal fishing for the wing and/or bait fishery, modifying gear to reduce bycatch, making the Federal skate permit a year-round permit for the wing and/or bait fishery, or other measures related to the problem statement and intended to achieve the Amendment's goals. These measures could help improve the accuracy of fishery data and the long-term sustainable management of the skate fishery. Through the development of Amendment 5, the Council may also consider updates to the goal and objectives of the FMP, which are unchanged since the FMP was adopted in 2003. Following the supplemental scoping period, the Council, with input from the public, will develop a range of alternatives to address the problem statement and goals of this action. The supplemental scoping document has more information on Amendment 5 and the topics being considered during this supplementary scoping period (see **ADDRESSES**).

Public Comment

All persons interested in the management of the Northeast Skate Complex for either the wing and/or bait fishery are invited to comment on the scope and significance of issues to be analyzed by submitting written comments (see **ADDRESSES**) and/or by participating in either of the two supplemental scoping webinar meetings for this amendment (see **DATES**).

After the supplemental scoping period, there will be additional opportunities for public comment throughout the development of a range of alternatives for Amendment 5, and, if necessary, a draft EIS to analyze their impacts. In addition to scoping comments, the public will have the opportunity to comment on the alternatives being considered by the Council through public meetings on any proposed action.

Special Accommodations

The webinar meetings are accessible to people with physical disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies (see **ADDRESSES**) at least five days prior to the meeting dates.

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

Dated: December 18, 2020.

Jennifer M. Wallace,

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

[FR Doc. 2020–28479 Filed 12–23–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Fishermen's Contingency Fund

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995

(PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before February 26, 2021.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *Adrienne.thomas@noaa.gov.* Please reference OMB Control Number 0648–0082 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Elaine Saiz, Chief, Financial Services Division, NOAA National Marine Fisheries Service, (301) 427–8725 or *elaine.saiz@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

United States (U.S.) commercial fishermen may file claims for compensation for losses of, or damage to, fishing gear or vessels, plus 50 percent of resulting economic losses, attributable to oil and gas activities on the U.S. Outer Continental Shelf. To obtain compensation, applicants must comply with requirements set forth in 50 CFR part 296.

The requirements include a ''report'' within 15 days of the date the vessel first returns to port after the casualty incident to gain a presumption of eligible causation, and an ''application'' within 90 days of when the applicant first became aware of the loss and/or damage.

The report is NOAA Form 88–166 and it requests identifying information such as: Respondent's name; address; social security number; and casualty location. The information in the report is usually completed by NOAA during a telephone call with the respondent.

The application is NOAA Form 88–164 and it requires the respondent to provide information on the property and economic losses and/or damages including type of damage; purchase date and price of lost/damaged gear; and income from recent fishing trips. It also includes an affidavit by which the applicant attests to the truthfulness of the claim.

II. Method of Collection

Respondents may telephone NOAA and provide the information for the report verbally or submit a paper or electronic report. Respondents have a choice of either electronic or paper forms for the application.

III. Data

OMB Control Number: 0648–0082.

Form Number: NOAA Forms 88–164, 88–166.

Type of Review: Extension of a current information collection.

Affected Public: Individuals or households; business or other for-profit organizations.

Estimated Number of Respondents: 20.

Estimated Time per Response: 15 minutes for a report and 7 hours, 45 minutes for an application.

Estimated Total Annual Burden Hours: 160.

Estimated Total Annual Cost to Public: $500 in recordkeeping/filing costs.

Respondent's Obligation: Required to Obtain or Retain Benefits.

Legal Authority: Title IV of the Outer Continental Shelf Lands Act Amendments of 1978 (43 U.S.C. 1841) authorizes the Fishermen's Contingency Fund (Fund or FCF) program to compensate U.S. commercial fishermen for losses of, or damages to, fishing gear or vessels, plus 50% of resulting gross economic loss, attributable to oil and gas activities on the OCS. Program requirements are set forth in 50 CFR part 296.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department, including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2020–28549 Filed 12–23–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA745]

North Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The North Pacific Fishery Management Council (Council) Community Engagement Committee will meet via web conference on January 12, 2021.

DATES: The meeting will be held on Tuesday, January 12, 2021, from 9 a.m. to 3 p.m., Alaska Time.

ADDRESSES: The meeting will be a web conference. Join online through the link at *https://meetings.npfmc.org/Meeting/Details/1847.*

Council address: North Pacific Fishery Management Council, 1007 W 3rd Ave., Anchorage, AK 99501–2252; telephone: (907) 271–2809. Instructions for attending the meeting via video conference are given under **SUPPLEMENTARY INFORMATION**, below.

FOR FURTHER INFORMATION CONTACT: Steve MacLean, Council staff; phone: (907) 271–2809; email: *steve.maclean@noaa.gov.* For technical support please contact our admin Council staff, email: *npfmc.admin@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Agenda

Tuesday, January 12, 2021

The Community Engagement Committee will meet to review and

finalize the report for the Council. The report will present a prioritized list of recommendations that the Council may consider implementing to improve Council engagement with rural and Alaska Native communities. The agenda is subject to change, and the latest version will be posted at *https://meetings.npfmc.org/Meeting/Details/1847* prior to the meeting, along with meeting materials.

Connection Information

You can attend the meeting online using a computer, tablet, or smart phone; or by phone only. Connection information will be posted online at: *https://meetings.npfmc.org/Meeting/Details/1847.*

Public Comment

Public comment letters will be accepted and should be submitted electronically to *https://meetings.npfmc.org/Meeting/Details/1847.*

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

Dated: December 21, 2020.

Rey Israel Marquez,

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

[FR Doc. 2020–28554 Filed 12–23–20; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from the Procurement List.

SUMMARY: This action adds service(s) to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes service(s) from the Procurement List previously furnished by such agencies.

DATES: *Date added to and deleted from the Procurement List:* January 27, 2021.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On 9/11/2020 and 10/16/2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the service(s) and impact of the additions on the current or most recent contractors, the Committee has determined that the service(s) listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service(s) to the Government.

2. The action will result in authorizing small entities to furnish the service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the service(s) proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service(s) are added to the Procurement List:

Service(s)

Service Type: Janitorial Service
Mandatory for: U.S. Department of Energy, Hanford Site and Richland North Areas, Richland, WA
Designated Source of Supply: Nobis Enterprises, Inc., Marietta, GA
Contracting Activity: ENERGY, DEPARTMENT OF, RICHLAND OPERATIONS OFFICE
Service Type: Custodial Service
Mandatory for: US Air Force, JBSA Lackland, Lackland Training Annex, Kelly Annex, San Antonio, TX
Designated Source of Supply: HHI Services Inc., San Antonio, TX
Contracting Activity: DEPT OF THE AIR FORCE, FA3016 502 CONS CL JBSA

Deletions

On 11/20/2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the service(s) to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the service(s) deleted from the Procurement List.

End of Certification

Accordingly, the following service(s) are deleted from the Procurement List:

Service(s)

Service Type: Document Destruction
Mandatory for: Internal Revenue Service: 40 West Baseline, Suite 211, Tempe, AZ
Mandatory for: Internal Revenue Service: 1244 Speer Blvd., Denver, CO
Mandatory for: Internal Revenue Service: 56 and 58 Inverness Drive E, Englewood, CO
Mandatory for: Internal Revenue Service: 4750 West Oak Boulevard, Las Vegas, NV
Mandatory for: Internal Revenue Service: 210 E. Earl Drive, Phoenix, AZ
Mandatory for: Internal Revenue Service: 50 South 200 East, Salt Lake City, UT
Mandatory for: Internal Revenue Service: 8671 Wolff Ct, Westminster, CO
Designated Source of Supply: Northwest Center, Seattle, WA
Contracting Activity: INTERNAL REVENUE SERVICE, DEPT OF TREAS/INTERNAL REVENUE SERVICE

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2020–28598 Filed 12–23–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

Office of the Department of the Air Force

Record of Decision for the Final Environmental Impact Statement Edwards Air Force Base Solar Project

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of availability.

SUMMARY: On November 23, 2020, the United States Air Force (USAF) signed the Record of Decision for the Final Environmental Impact Statement for the

Edwards Air Force Base (AFB) Solar Project.

ADDRESSES: Mr. Mike Ackerman, AFCEC/CZN, Bldg 1, 2261 Hughes Ave (STE 155), JBSA-Lackland, TX 78236–9853, (210) 925–2741; *michael.ackerman.2@us.af.mil.*

SUPPLEMENTARY INFORMATION: The USAF has decided to lease up to 4,000 acres of undeveloped, non-excess land at Edwards AFB to a developer for the construction, operation, and maintenance of a solar photovoltaic renewable energy project.

The Air Force's decision, documented in the Record of Decision, was based on analysis provided in the Final Environmental Impact Statement, and includes inputs from the public and regulatory agencies. The Final Environmental Impact Statement was made available to the public on January 24, 2020 through a Notice of Availability in the **Federal Register** (Volume 85, Number 16, Page 4320) with a review period that ended on February 24, 2020.

Authority: This Notice of Availability is published pursuant to the regulations (40 CFR part 1506.6) implementing the provisions of the National Environmental Policy Act (42 U.S.C. 4321, *et seq.*) and the Air Force's Environmental Impact Analysis Process (32 CFR parts 989.21(b) and 989.24(b)(7)).

Adriane S. Paris,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2020–28572 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent To Grant an Exclusive Patent License

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act, and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant an exclusive patent license to Inquis Medical Inc., a small business having a place of business at 1735 East Bayshore Rd, Suite 4, Redwood City, CA 94063.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to Chastity D. S. Whitaker, Ph.D., Air Force Materiel Command Law Office, AFMCLO/JAZ, 2240 B Street, Area B, Building 11, Wright-Patterson AFB, OH 45433–7109; Facsimile: (937) 255–9318; or Email: *afmclo.jaz.tech@us.af.mil.* Include Docket No. A59–201208A–PL in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Chastity D. S. Whitaker, Ph.D., Air Force Materiel Command Law Office, AFMCLO/JAZ, 2240 B Street, Area B, Building 11, Wright-Patterson AFB, OH 45433–7109; Telephone: (937) 904–5787; Facsimile: (937) 255–9318; or Email: *afmclo.jaz.tech@us.af.mil.*

SUPPLEMENTARY INFORMATION:

Abstract of patent application(s):

A negative pressure surgical apparatus. The apparatus includes a mask configured to cover a portion of the face of a patient and including a first port and an instrument port. The first port is configured to draw negative pressure from between the mask and the face of the patient. The instrument port is configured to receive a medical instrument therethrough and form a seal therewith. The instrument port is positioned on the mask so as to permit surgery at a surgical site.

Intellectual Property

—U.S. Application Serial No. 16/985,829, filed on August 5, 2020, and entitled *Negative pressure oronasal apparatus.*

The Department of the Air Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Adriane Paris,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2020–28577 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 20–58]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 20–58 with attached Policy Justification.

Dated: December 18, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

DEC 0 1 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 20-58 concerning the Army's proposed Letter(s) of Offer and Acceptance to the Kingdom of Saudi Arabia for defense articles and services estimated to cost $350 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Regional Balance (Classified document provided under separate cover)

Transmittal No. 20–58

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Kingdom of Saudi Arabia

(ii) *Total Estimated Value*:

Major Defense Equipment*	$ 0 million
Other	$350 million
Total	$350 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE):
None

Non-MDE:
U.S. Security Assistance Office (SAO) support services to include technical assistance and advisory support to the Kingdom of Saudi Arabia's Ministry of Defense (MOD) for an additional five years, through the U.S. Military Training Mission to Saudi Arabia (USMTM) located in Riyadh, Saudi Arabia. SAO support services provided includes: Pay and allowances for U.S. Military, U.S. Government, and Foreign National staff members; USMTM communications support costs; local contracting costs; construction and renovation costs of housing area; transportation costs; U.S. Mail services support costs; dependent education (grades K through 12); administrative costs;

temporary duty costs for USMTM personnel; Value Added Taxes (VAT) assessed by Saudi Arabia; future transition costs to move USMTM to a proposed new housing location in Saudi Arabia; and other related elements of logistical and program support.

(iv) *Military Department*: Army (SR–B–ABY)

(v) *Prior Related Cases, if any*: SR–B–ABV, SR–B–ABW, SR–B–ABX

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: None

(viii) *Date Report Delivered to Congress*: December 1, 2020

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Saudi Arabia—Security Assistance Office (SAO) Support Services, U.S. Training Mission to Saudi Arabia (USMTM)

The Kingdom of Saudi Arabia has requested U.S. Security Assistance Office (SAO) support services to include technical assistance and advisory support to the Kingdom of Saudi Arabia's Ministry of Defense (MOD) for an additional five years, through the U.S. Military Training Mission to Saudi Arabia (USMTM) located in Riyadh, Saudi Arabia. SAO support services provided includes: Pay and allowances for U.S. Military, U.S. Government, and Foreign National staff members; USMTM communications support costs; local contracting costs; construction and renovation costs of housing area; transportation costs; U.S. Mail services support costs; dependent education (grades K through 12); administrative costs; temporary duty costs for USMTM personnel; Value Added Taxes (VAT) assessed by Saudi Arabia; future transition costs to move USMTM to a proposed new housing location in Saudi Arabia; and other related elements of logistical and program support. The total estimated cost is $350 million.

This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a friendly country that is a force for political stability and economic progress in the Middle East.

This proposed sale will continue to improve Saudi Arabia's capability to meet current and future threats by utilizing USMTM's continued efforts to train, advise, and assist the Saudi Arabian Armed Forces to build defense capacity and capability through military exercises and professional military education. USMTM conducts non-combat, institutional advising that assists the MOD in developing, training, and sustaining a capable deterrent to regional threats.

The proposed sale of this support and services will not alter the basic military balance in the region.

There is no prime contractor associated with this proposed sale. There are no known offset agreements in connection with this potential sale.

Implementation of this proposed sale will continue to require the permanent assignment of approximately 330 U.S. Military, U.S. Government, and Foreign National USMTM staff members to Saudi Arabia. Additional Training Advisory Field Teams (TAFT) and Support teams will travel to the country on a temporary basis as required.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2020–28500 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 21–04]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 21–04 with attached Policy Justification.

Dated: December 18, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

December 1, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 21-04 concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Canada for defense articles and services estimated to cost $275 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification

BILLING CODE 5001–06–C

Transmittal No. 21–04

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of Canada

(ii) *Total Estimated Value*:

Major Defense Equipment *	$ 0 million
Other	$275 million
Total	$275 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase*:

Major Defense Equipment (MDE):

None

Non-MDE:

C-17 sustainment support to include aircraft hardware and software modification and support; software delivery and support; ground handling equipment; component, parts and accessories; GPS receivers; alternative mission equipment; publications and technical documentation; contractor logistics support and Globemaster III Sustainment Program (G3) participation; other U.S. Government and contractor engineering, technical, and logistical support services; and related elements of program and logistical support.

(iv) *Military Department*: Air Force (CN-D-QCV)

(v) *Prior Related Cases, if any*: CN-D-QCR, CN-D-QZZ

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: None

(viii) *Date Report Delivered to Congress*: December 1, 2020

*As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Canada – C-17 Sustainment

The Government of Canada has requested to buy C-17 sustainment support to include aircraft hardware and software modification and support; software delivery and support; ground handling equipment; component, parts and accessories; GPS receivers; alternative mission equipment; publications and technical documentation; contractor logistics support and Globemaster III Sustainment Program (G3) participation; other U.S. Government and contractor engineering, technical, and logistical support services; and related elements of program and logistical support. The total estimated program cost is $275 million.

This proposed sale will support the foreign policy and national security objectives of the United States by helping to improve the military capability of Canada, a NATO ally that is an important force for ensuring political stability and economic progress, and a contributor to military, peacekeeping and humanitarian operations around the world.

The proposed sale will improve Canada's capability to meet current and future threats by sustaining their strategic air lift capability, which allows Canada to maintain sovereignty and homeland defense, increase interoperability with the United States and other partners, and deter potential adversaries. Canada already operates the C-17 and will have no difficulty absorbing the additional sustainment or upgrades into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be The Boeing Company, Chicago, IL. There are no known offset agreements in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Canada.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

[FR Doc. 2020–28507 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2020–OS–0103]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Office of the Under Secretary of Defense for Personnel and Readiness announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by February 26, 2021.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number, and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to DANTES, 6490 Saufley Field Rd, Pensacola, Florida 32509, Candice Rice, 850–452–1901.

SUPPLEMENTARY INFORMATION: *Title; Associated Form; and OMB Number:* Application for Department of Defense (DoD) Voluntary Education Partnership Memorandum of Understanding (MOU); DD Form 3115; OMB Control Number 0704–XXXX.

Needs and Uses: The information collection requirement is necessary to enhance the DoD's ability to improve Service member and veteran education experiences, and ensure there is applicable and relevant information, as well as streamlined-tools to aid them in selecting an education institution that best meets their respective needs. The data culled from this information collection will standardize data/information provided to Service members and veterans to help them understand the total cost of educational programs. This includes providing meaningful information and data to students about the financial costs, refund policies, and attendance at the institution so military students can make informed decisions on where to attend school, provide information on academic and student support services specific to the educational institutions' programs, inform service member and veteran students about available tools to aid them in selecting an education institution, be certified to participate in federal student aid programs through the Department of Education under Title IV, be accredited by a national or regional accrediting body recognized by the ED, and be state-approved for the use of veterans' education benefits (Post 9/11–GI Bill).

Affected Public: Individuals or Households.

Annual Burden Hours: 262.

Number of Respondents: 2,616.

Responses per Respondent: 1.

Annual Responses: 2,616.

Average Burden per Response: 6 minutes.

Frequency: Annually.

Dated: December 11, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–28482 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 21–07]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 21–07 with attached Policy Justification and Sensitivity of Technology.

Dated: December 18, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

December 15, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 21-07 concerning the Air Force's proposed Letter(s) of Offer and Acceptance to the Government of Italy for defense articles and services estimated to cost $500 million. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 5001-06-C

Transmittal No. 21-07

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser*: Government of Italy

(ii) *Total Estimated Value*:

Major Defense Equipment *	$ 10 million
Other	$490 million
Total	$500 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* The Government of Italy has requested to buy articles and services to support the integration of two (2) Airborne Intelligence, Surveillance, Reconnaissance, and Electronic Warfare (AISREW) mission systems onto two (2) Italian Ministry of Defense provided G550 aircraft consisting of:

Major Defense Equipment (MDE):

Four (4) Multifunctional Information Distribution Systems – Joint Tactical Radio System (MIDS JTRS) (2 installed, 2 spares)

Three (3) Embedded/GPS/INS (EGI) with GPS Security Devices, Airborne (2 installed, 1 spare)

Four (4) RIO™ Communications Intelligence Systems (2 installed, 2 spares)

Non-MDE:

Also included are Missile Warning Sensors, AN/ALE-47 Countermeasure Dispenser Sets

(CMDS), MX-20HD Electro-Optical and Infra-Red systems, Osprey 50 AESA Radars, AISREW ISR equipment, Secure Communications equipment, Identification Friend or Foe Systems, aircraft modification and integration, ground systems for data processing and crew training, ground support equipment, publications and technical data, U.S. Government and contractor engineering, technical and logistics support services, flight test and certification, and other related elements of logistical and program support.

(iv) *Military Department*: Air Force (IT-D-BAA)

(v) *Prior Related Cases, if any*: None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid*: None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold*: See Attached Annex

(viii) *Date Report Delivered to Congress*: December 15, 2020

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Italy — Gulfstream G550 Aircraft with Airborne Intelligence, Surveillance, Reconnaissance, and Electronic Warfare (AISREW) Mission Systems

The Government of Italy has requested to buy articles and services to support the integration of two (2) Airborne Intelligence, Surveillance, Reconnaissance, and Electronic Warfare (AISREW) mission systems onto two (2) Italian Ministry of Defense provided G550 aircraft consisting of: four (4) Multifunctional Information Distribution Systems — Joint Tactical Radio System (MIDS JTRS) (2 installed, 2 spares); three (3) Embedded/GPS/INS (EGI) with GPS security devices, airborne (2 installed, 1 spare); and four (4) RIO™ Communications Intelligence Systems (2 installed, 2 spares). Also included are Missile Warning Sensors, AN/ALE-47 Countermeasure Dispenser Sets (CMDS), MX-20HD Electro-Optical and Infra-Red systems, Osprey 50 AESA Radars, AISREW ISR equipment, Secure Communications equipment, Identification Friend or Foe Systems, aircraft modification and integration, ground systems for data processing and crew training, ground support equipment, publications and technical data, U.S. Government and contractor engineering, technical and logistics support services, flight test and certification, and other related elements of logistical and program support. The total estimated program cost is $500 million.

This proposed sale will support U.S. foreign policy and national security by helping to improve the security of a NATO ally, which is an important partner for political stability and economic progress in Europe.

The proposed sale supports and complements the ongoing efforts of Italy to modernize its airborne Intelligence, Surveillance, Reconnaissance, and Electronic Warfare capability and increases interoperability between the U.S. Air Force and the Italian Air Force (ITAF). Italy will have no difficulty absorbing these articles into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be L3Harris, Greenville, TX. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will require the assignment of up to six (6) additional U.S. contractor representatives to Italy for a duration of one (1) year to support equipment familiarization.

There will be no adverse impact on U.S. defense readiness resulting from this proposed sale.

Transmittal No. 21-07

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. Missile Warning Sensor (MWS) units are mounted on the aircraft exterior to provide omni-directional protection. The MWS warns of threat missile approach by detecting radiation associated with the rocket motor. The Infrared Missile Warning System (IRMWS) is a small, lightweight, passive, electro-optic, threat-warning device used to detect surface-to-air missiles fired at helicopters and low-flying fixed-wing aircraft and automatically provides counter-measures, as well as audio and visual warning messages to the aircrew.

2. Multifunctional Information Distribution System-Joint Tactical Radio System (MIDS JTRS) is an advanced Link-16 command, control, communications, and intelligence (C3I) system incorporating high capacity, jam-resistant, digital communication links for exchange of near real-time tactical information, including both data and voice, among air, ground, and sea elements.

3. The AN/ALE-47 Countermeasure Dispenser Set (CMDS) provides an integrated threat-adaptive, computer controlled capability for dispensing chaff, flares, and active radio frequency expendables. The system is internally mounted and may be operated as a stand-alone system or may be integrated with other on-board Electronic Warfare (EW) and avionics systems. The AN/ALE-47 uses threat data received over the aircraft interfaces to assess the threat situation and determine a response. Expendable routines tailored to the immediate aircraft and threat environment may be dispensed using one of four operational modes.

4. The Embedded GPS-INS (EGI) is a sensor that combines GPS and inertial sensor inputs to provide accurate location information for navigation and targeting, and can be loaded with crypto-variable keys.

5. Wescam MX-20HD is a gyro-stabilized, multi-spectral, multi-field of view Electro-Optical/Infrared (EO/IR) system. The systems provide surveillance laser illumination and laser designation through use of an externally mounted turret sensor unit and internally mounted master control. Sensor video imagery is displayed in the aircraft real time and may be recorded for subsequent ground analysis.

6. The Osprey family of surveillance radars provides second generation Active Electronically Scanned Array (AESA) surveillance capability as the primary sensor on airborne assets. The Osprey radars are at a high technology readiness level and are in production for fixed and rotary wing applications. This Osprey configuration employs a side-looking radar. Osprey radars provide a genuine multi-domain capability, with high performance sea surveillance, notably against difficult targets, land surveillance with wide swath, very high resolution ground mapping, small and low speed ground target indication, high performance air to air surveillance, tracking and intercept.

7. The AISREW mission systems, to include the RIO™ Communications Intelligence Systems, provide near-real-time information to tactical forces, combatant commanders and national-level authorities across the spectrum of conflict. The mission system can forward gather information in a variety of formats via secured communications systems. Most hardware used in this system is generic and commercially available. However, if any of the specialized hardware or publications are lost, the information could provide insight into many critical U.S. capabilities. Information gained could be used to develop countermeasures as

well as offensive and defensive counter-tactics.

8. The highest level of classification of information included in this potential sale is SECRET.

9. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

10. A determination has been made that Italy can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

11. All defense articles and services listed in this transmittal have been authorized for release and export to Italy.

[FR Doc. 2020–28519 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2020–OS–0097]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary of Defense (OSD), Department of Defense (DoD).

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the DoD proposes to establish a new system of records covering all DoD components titled, ''Defense Training Records'' DoD 0005. This system of records describes the DoD's collection, use, and maintenance of records about training delivered to DoD Service Members, civilian personnel, and other DoD-affiliated individuals. The training data includes enrollment and participation information, information pertaining to class schedules, programs, and instructors, training trends and needs, testing and examination materials, and assessments of training efficacy. Additionally, the DoD is issuing a Notice of Proposed Rulemaking, which proposes to exempt this system of records from certain provisions of the Privacy Act, elsewhere in today's issue of the **Federal Register**.

DATES: This new system of records is effective upon publication; however, comments on the Routine Uses will be accepted on or before January 27, 2021. The Routine Uses are effective at the close of the comment period.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: https://www.regulations.gov.*

Follow the instructions for submitting comments.

* *Mail:* The DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Lyn Kirby, Defense Privacy, Civil Liberties, and Transparency Division, Directorate for Oversight and Compliance, Department of Defense, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700; *OSD.DPCLTD@mail.mil;* (703) 571–0070.

SUPPLEMENTARY INFORMATION: The Defense Training Records system of records is being established as a DoD-wide Privacy Act system of records for use by all DoD offices and components. A DoD-wide system of records notice (SORN) supports multiple DoD paper or electronic recordkeeping systems operated by more than one DoD component and maintain the same kind of information about individuals for the same purpose. Establishment of DoD-wide SORNs helps the DoD standardize the rules governing the collection, maintenance, use, and sharing of personal information in key areas across the enterprise. DoD-wide SORNs also reduce duplicative and overlapping SORNs published by separate DoD components. The creation of this DoD-wide SORNs is expected to make locating relevant SORNs easier for DoD personnel and the public, and create efficiencies in the operation of the DoD privacy program.

This system of records describes training records created and maintained by all component parts of DoD, wherever they are maintained. The system consists of both electronic and paper records and will be used by DoD components and offices to maintain records about training provided to DoD-affiliated individuals, including Military Service members, civilian employees, dependents and family members, contractors, and other individuals enrolled in courses administered by the DoD. These records may include information pertaining to class schedules, enrollment, participation, programs, and instructors; training trends and needs; testing and examination materials; and assessments of training efficacy. The collection and maintenance of this information will assist the DoD in meeting its obligations under law, regulation, and policy to provide training on various subjects to ensure that the agency mission can be successfully accomplished. Records pertaining to diploma or degree-conferring institutions, such as the military academies (United States Military Academy, United States Naval Academy, United States Air Force Academy, United States Marine Academy), the DoD Education Activity Schools, Uniformed Service University of the Health Sciences, and the National Defense University, are not part of this system of records.

Additionally, the DoD is issuing a Notice of Proposed Rulemaking to exempt this system of records from certain provisions of the Privacy Act elsewhere in today's issue of the **Federal Register**.

The DoD notices for systems of records subject to the Privacy Act of 1974, as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at the Defense Privacy, Civil Liberties, and Transparency Division website at *https://dpcld.defense.gov.*

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, DoD has provided a report of this system of records to the OMB and to Congress.

Dated: November 25, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

SYSTEM NAME AND NUMBER:

Defense Training Records, DoD 0005.

SECURITY CLASSIFICATION:

Classified and unclassified.

SYSTEM LOCATION:

Department of Defense (Department or DoD), located at 1000 Defense Pentagon, Washington, DC 20301–1000, and other Department installations, offices, or mission locations, at which electronic or paper training records may be

maintained. Information may also be stored within a government-certified cloud, implemented and overseen by the Department's Chief Information Officer (CIO), 6000 Defense Pentagon, Washington, DC 20301–6000.

SYSTEM MANAGER(S):

The system managers are as follows:

A. Program Manager, Advanced Distributed Learning Initiative, Office of the Assistant Secretary of Defense for Readiness, 4000 Defense Pentagon, Washington, DC 20301–4000, *whs-mc-alex.esd.mbx.osd-js-foia-requester-service-center@mail.mil.*

B. Commander, Air Education and Training Command (AETC), Joint Base San Antonio-Randolph, TX, (703) 693–2735.

C. Commander, U.S. Army Training Support Center (USATSC), 1900 Jackson Lane, Fort Eustis, VA 23604–5166, (571) 515–0306.

D. Executive Director, Naval Education and Training Command (NETC), Learning and Development, 250 Dallas Street, Pensacola, FL 32508, *donfoia-pa@navy.mil.*

E. Commanding General, United States Marine Corps, Training and Education Command (TECOM), 1019 Elliot Road, Quantico, VA 22134–5010, (703) 614–4008.

For Combatant Commands, or other Defense Agencies, the system manager can be found at: *www.FOIA.gov* under the DoD component with oversight of the records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. Chapter 41, Training; 5 CFR part 410, Office of Personnel Management-Training; E.O. 11348, Providing for the Further Training of Government Employees, as amended by E.O. 12107, Relating to the Civil Service Commission and Labor-Management in the Federal Service; 10 U.S.C. 113, Secretary of Defense; 10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; 10 U.S.C. 1746 Defense Acquisition University; 10 U.S.C.1747, Acquisition Fellowship Program; DoD Instruction 1215.08 Senior Reserve Officers Training Corp Programs; DoD Directive 1322.18, Military Training; DoD Directive 1322.08E, Voluntary Education Programs for Military Personnel; DoD Instruction 1322.26, Distributed Learning; DoD Instruction 1322.25, Voluntary Education Program; DoD Instruction 1322.9, Job Training, Employment Skills Training, Apprenticeships, and Internships (JTEST–AI) for Eligible Service Members; DoD Instruction 1430.16, Growing Civilian Leaders; DoD Instruction 5132.13, Staffing of Security Cooperation Organizations (SCOs) and the Selection and Training of Security Cooperation Personnel; DoD Instruction 1215.21, Reserve Component (RC) Use of Electronic-based Distributed Learning; Directive-Type Memorandums 13–004, Operation of the DoD Financial Management Certification Program Methods for Training; and DoD Instruction 1015.2, Military Morale, Welfare and Recreation (MWR), DoD Instruction 1300.26, Operation of the DoD Financial Management Certification Program; and E.O. 9397.

PURPOSE(S) OF THE SYSTEM:

a. To support DoD training as may be required by law and policy, as well as for mission, professional development, and employment purposes.

b. To track individual training and professional development, including enrollment, participation and completion information; and class schedules, programs, and instructors.

c. To track training and professional development trends and needs, testing and examination materials, credentialing, promotional decisions, career development planning, and assessments of professional competencies and training efficacy.

d. To determine eligibility for enrollment/attendance, and facilitate post-training job referrals and placement.

e. To monitor and track the expenditure of training and related travel funds, and training-related contract management.

f. To facilitate the compilation of statistical information about training.

g. To fulfill regulatory requirements to report civilian employee training to the Office of Personnel Management.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

DoD-affiliated individuals enrolled in training sponsored or administered by DoD, including: Military Service members (active duty, Guard/Reserve, cadets and midshipmen, Public Health Services, and the Coast Guard personnel when operating as a Military Service with the Navy), DoD civilian employees (including non-appropriated fund employees and DoD Outside the Contiguous United States hires, also known as local national employees), dependents and family members of the above, contractors, personnel of other government agencies, and other individuals affiliated with the DoD.

CATEGORIES OF RECORDS IN THE SYSTEM:

a. Personal information, such as name, Social Security number (SSN), DoD ID Number, or other DoD assigned student or educational ID number, date and place of birth, gender, citizenship, driver's license, photograph, email address(es), personal and duty phone numbers, emergency contact information, race and ethnic origin, religious preference collected to support the placement of chaplain at appropriate locations.

b. Employment information, such as employment status, duty position, service component, branch, personnel classification, security clearance, grade/rank/series, military status, military occupational specialty, official orders, unit of assignment, occupation, and other organizational affiliation information.

c. Select Personal Health Information, such as medical profiles, physical examinations, psychological test record for special assignment eligibility, and disability information collected to consider or provide accommodations to students during training.

d. Course and training data, such as nomination forms, instructor lists, examination and course completion status, professional development, worksheets, training waivers, student identification number, course descriptions and schedules, enrollment and participation information, graduation dates, examination and testing materials, grades and student evaluations, aptitudes and personal qualities, course and instructor critiques, date graduated or eliminated with reasons for elimination, and information pertaining to training trends, needs, and assessments.

e. Equipment issued to trainees and other training participants, and other reports pertaining to training, such as credit hours accumulated, assignment history, curricula, and individual goals.

f. Professional development information, to include, mentor agreements, evaluations and performance documentations, career development planning, background and biographical information, civilian and military education information, and certifications.

g. Educational information, such as degree, major/minor, grade point average, institution name, academic status, and transcripts.

h. Financial information, such as payment records, and travel and other expenditures related to the training.

NOTE: Records pertaining to diploma and degree-conferring institutions, such as the military academies (United States Military Academy, United States Naval Academy, United States Air Force Academy, United States Marine Academy); the DoD Education Activity Schools, Uniformed Service

University of the Health Sciences, and the National Defense University, are not part of this system of records

RECORD SOURCE CATEGORIES:

a. Individuals applying for or undergoing training, mentors, supervisors, instructors, and facilitators.

b. Academic institutions and/or other organizations supporting the development or delivery of DoD training, including training offered to select DoD personnel by the Intelligence Community.

c. All DoD databases flowing into or accessed through the following integrated data systems, environments, applications, and tools: the Defense Civilian Human Resources Management System (DCHRMS), Military Personnel (MILPERS), Department of Defense Voluntary Education System (DODVES), Defense Enrollment Eligibility Reporting System (DEERS), Army Training Requirement and Resources System (ATRRS), Total Workforce Management System (TWMS), Career Acquisition Personnel & Position Management Information System (CAPPMIS), Defense Civilian Personnel Data System (DPCPDS), Acquisition Career Management System (ACMS), Joint Personnel Adjudication System (JPAS), Medical Protection System (MEDPROS), and Management Information System (MIS II).

d. Other DoD learning management systems, the data from which data is migrated into the DoD Enterprise Learning Modernization System.

e. Other federal government learning and student management systems, such as the Department of Education Postsecondary Education Participants System (PEPS), and State Departments of Education and their grant recipients.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, all or a portion of the records or information contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

a. To contractors, grantees, experts, consultants, students, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the federal government when necessary to accomplish an agency function related to this system of records.

b. To the appropriate Federal, State, local, territorial, tribal, foreign, or international law enforcement authority or other appropriate entity where a record, either alone or in conjunction with other information, indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature.

c. To any component of the Department of Justice for the purpose of representing the DoD, or its components, officers, employees, or members in pending or potential litigation to which the record is pertinent.

d. In an appropriate proceeding before a court, grand jury, or administrative or adjudicative body or official, when the DoD or other Agency representing the DoD determines that the records are relevant and necessary to the proceeding; or in an appropriate proceeding before an administrative or adjudicative body when the adjudicator determines the records to be relevant to the proceeding.

e. To the National Archives and Records Administration for the purpose of records management inspections conducted under the authority of 44 U.S.C. 2904 and 2906.

f. To a Member of Congress or staff acting upon the Member's behalf when the Member or staff requests the information on behalf of, and at the request of, the individual who is the subject of the record.

g. To appropriate agencies, entities, and persons when (1) the DoD suspects or confirms a breach of the system of records; (2) the DoD determines as a result of the suspected or confirmed breach there is a risk of harm to individuals, the DoD (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the DoD's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

h. To another Federal agency or Federal entity, when the DoD determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

i. To such recipients and under such circumstances and procedures as are mandated by Federal statute or treaty.

j. To the Office of Personnel Management to satisfy requirements to submit civilian employee training data in accordance with 5 CFR part 410.

k. To a Federal, State, tribal, local or foreign government agency or professional licensing authority in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance or status of a license, grant, or other benefit by the requesting entity, to the extent that the information is relevant and necessary to the requesting entity's decision on the matter.

l. To educational institutions or training facilities for purposes of enrollment and verification of employee attendance and performance.

m. To the Equal Employment Opportunity Commission, Merit Systems Protection Board, Office of the Special Counsel, Federal Labor Relations Authority, or Office of Personnel Management or to arbitrators and other parties responsible for processing any personnel actions or conducting administrative hearings or appeals, or if needed in the performance of authorized duties.

n. To the Department of Justice or a consumer reporting agency for further action on a delinquent debt when circumstances warrant.

o. To employers to the extent necessary to obtain information pertinent to the individual's fitness and qualifications for training and to provide training status.

p. To the United States Coast Guard Voluntary Education Program Office for the purpose of education counseling, financial management, and funds disbursement.

q. To a public or professional licensing organization when such information indicates, either by itself or in combination with other information, a violation or potential violation of professional standards, or reflects on the moral, educational, or professional qualifications of an individual who is licensed or who is seeking to become licensed.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records may be stored electronically or on paper in secure facilities in a locked drawer behind a locked door. The records may be stored on magnetic disc, tape, and digital media.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by name, agency, birth date, SSN, DoD ID

number, or other DoD assigned student or educational ID number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

a. Non-mission employee training program records are maintained and disposed in accordance with National Archives and Records Administration General Records Schedule 2.6.

b. Mission-related training records are maintained and disposed in accordance with National Archives and Records Administration Schedules. The Military Departments, Joint Chiefs of Staff and OSD all retain in accordance with their individual Records and Information Management retention schedules.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

DoD components safeguard records in this system of records according to applicable rules, policies, and procedures, including all applicable DoD automated systems security and access policies. DoD policies require the use of controls to minimize the risk of compromise of personally identifiable information (PII) in paper and electronic form and to enforce access by those with a need to know and with appropriate clearances. Additionally, the DoD has established security audit and accountability policies and procedures which support the safeguarding of PII and detection of potential PII incidents. The DoD routinely employs safeguards such as the following to information systems and paper recordkeeping systems: Multifactor log-in authentication including CAC authentication and password; SIPR token as required; physical and technological access controls governing access to data; network encryption to protect data transmitted over the network; disk encryption securing disks storing data; key management services to safeguard encryption keys; masking of sensitive data as practicable; mandatory information assurance and privacy training for individuals who will have access; identification, marking, and safeguarding of PII; physical access safeguards including multifactor identification physical access controls, detection and electronic alert systems for access to servers and other network infrastructure; and electronic intrusion detection systems in DoD facilities.

RECORD ACCESS PROCEDURES:

Individuals seeking access to their records should address written inquiries to the DoD office with oversight of the records. The public may identify the appropriate DoD office through the following website: *www.FOIA.gov.* Signed written requests should contain the name and number of this system of records notice along with the full name, identifier (*i.e.,* DoD ID Number or Defense Benefits Number), date of birth, current address, and telephone number of the individual. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the appropriate format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

CONTESTING RECORD PROCEDURES:

The DoD rules for accessing records, contesting contents, and appealing initial agency determinations are contained in 32 CFR part 310, or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the appropriate system managers(s). Signed written requests should contain the full name, identifier (*i.e.,* DoD ID Number or DoD Benefits Number), date of birth, and current address and telephone number of the individual. In addition, the requester must provide either a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the appropriate format:

If executed outside the United States: ''I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature).''

If executed within the United States, its territories, possessions, or commonwealths: ''I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature).''

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

The DoD has exempted records maintained in this system from 5 U.S.C. 552a(c)(3) and (d) of the Privacy Act, pursuant to 5 U.S.C. 552a(k)(1) and (k)(6). In addition, when exempt records received from other systems of records become part of this system, the DoD also claims the same exemptions for those records that are claimed for the original primary systems of records from which they originated and claims any additional exemptions set forth here. An exemption rule for this system has been promulgated in accordance with the requirements of 5 U.S.C. 553(b)(1), (2), and (3), and (c), and published in 32 CFR part 310.

HISTORY:

None.

[FR Doc. 2020–26548 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 21–03]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The Department of Defense is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Karma Job at *karma.d.job.civ@mail.mil* or (703) 697–8976.

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 21–03 with attached Policy Justification and Sensitivity of Technology.

Dated: December 18, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 5001–06–P

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, SUITE 101
ARLINGTON, VA 22202-5408

NOV 0 9 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Madam Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 21-03 concerning the Air Force's and the Navy's proposed Letter(s) of Offer and Acceptance to the Government of the United Arab Emirates for defense articles and services estimated to cost $10.0 billion. After this letter is delivered to your office, we plan to issue a news release to notify the public of this proposed sale.

Sincerely,

Heidi H. Grant
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified document provided under separate cover)

BILLING CODE 5001–06–C

Transmittal No. 21-03

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of the United Arab Emirates

(ii) *Total Estimated Value:*

Major Defense Equipment *	$6.4 billion
Other	$3.6 billion
Total	$10.0 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* Weapons are for Multi-Platform Aircraft with Up-To Quantities:

Major Defense Equipment (MDE):
Eight hundred two (802) AIM-120C8 Advanced Medium Range Air-to-Air Missiles (AMRAAM)
Sixteen (16) AIM-120C8 AMRAAM Guidance Sections Spares
Two thousand four (2,004) MK-82 500LB General Purpose (GP) Bombs
Seventy-two (72) MK-82 Inert 500LB GP Bombs
One thousand (1,000) MK-84 2,000LB GP Bombs
One thousand two (1,002) MK-83

1,000LB GP Bombs
Two thousand five hundred (2,500) Small Diameter Bomb Increment 1 (SDB-1), GBU-39/B, with CNU-659/E Container
Eight (8) GBU-39 SDB-1 Guided Test Vehicles
Two thousand (2,000) KMU-572 Joint Direct Attack Munition (JDAM) Tail Kit for 500LB Bombs
One thousand (1,000) KMU-556 JDAM Tail Kit for 2,000LB Bombs
One thousand (1,000) KMU-559 JDAM Tail Kit for 1,000LB Bombs
Four thousand (4,000) FMU-139 Fuze Systems
Six hundred fifty (650) AGM-154C Joint Stand Off Weapons (JSOWs)
Fifty (50) AGM-154E Joint Stand Off Weapons – Extended Range (JSOW-ER)
One hundred fifty (150) AGM-88E Advanced Anti-Radiation Guided Missile (AARGM) Tactical Missiles
Six (6) CATM-88 AARGM CATMs

Non-MDE:

Also included are six (6) AGM-154C JSOW-C Captive Air Training Missiles (CATMs); six (6) AGM-154E JSOW-ER CATMs; ARD 446-1B and ARD 863-1A1W Impulse Cartridges; JSOW-C Dummy Air Training Missiles (DATM); JSOW-C Captive Flight Vehicles (CFVs); JSOW-ER DATMs; JSOW-ER CFVs; PGU-23/U training ammunition, encryption devices and keying equipment for test missiles (not for export); Laser Illuminated Target Detector, DSU-38A/B; software delivery and support; AIM-120C Captive Air Training Missiles (CATM) and Airborne Instrumented Units (AIU) Telemetry Sections; missile containers; munitions components; aircraft test and integration support; containers; mission planning; munitions security, storage and training; facility design, construction and quality standards; weapon operational flight program software development; transportation; tools and test equipment; support equipment; spare and repair parts; weapons and aircraft integration support and test equipment; publications and technical documentation; personnel training and training equipment, devices and software; U.S. Government and contractor engineering, technical and logistics support services; site surveys; and other related elements of logistics and program support.

(iv) *Military Department:* Air Force (AE-D-YAF, AE-D-QAM); Navy (AE-P-ABN, AE-P-ABO, AE-P-ABP, AE-P-ABQ)

(v) *Prior Related Cases, if any:* AE-D-YAB, AE-D-YAC, AE-D-AAD, AE-D-AAE, AE-D-AAF, and AE-P-ABE

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* November 09, 2020

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

United Arab Emirates—Munitions, Sustainment and Support

The Government of the United Arab Emirates (UAE) has requested to buy eight hundred two (802) AIM-120C8 Advanced Medium Range Air-to-Air Missiles (AMRAAM); sixteen (16) AIM-120C8 AMRAAM guidance sections spares; two thousand four (2,004) MK-82 500LB General Purpose (GP) Bombs; seventy-two (72) MK-82 Inert 500LB GP Bombs; one thousand (1,000) MK-84 2,000LB GP Bombs; one thousand two (1,002) MK-83 1,000LB GP Bombs; two thousand five hundred (2,500) Small Diameter Bomb Increment 1 (SDB-1), GBU-39/B, with CNU-659/E Container; eight (8) GBU-39 SDB-1 Guided Test Vehicles; two thousand (2,000) KMU-572 Joint Direct Attack Munition (JDAM) Tail Kit for 500LB Bombs; one thousand (1,000) KMU-556 JDAM Tail Kit for 2,000LB Bombs; one thousand (1,000) KMU-559 JDAM Tail Kit for 1,000LB Bombs; four thousand (4,000) FMU-139 Fuze systems; six hundred fifty (650) AGM-154C Joint Stand Off Weapons (JSOWs); fifty (50) AGM-154E Joint Stand Off Weapons - Extended Range (JSOW-ER); one hundred fifty (150) AGM-88E Advanced Anti-Radiation Guided Missile (AARGM) Tactical Missiles; six (6) CATM-88 AARGM CATMs. Also included are six (6) JSOW-C AGM-154C Captive Air Training Missiles (CATMs); six (6) JSOW-ER AGM-154E CATMs; ARD 446-1B and ARD 863-1A1W Impulse Cartridges; JSOW-C Dummy Air Training Missiles (DATM); JSOW-C Captive Flight Vehicles (CFVs); JSOW-ER DATMs; JSOW-ER CFVs; PGU-23/U training ammunition, encryption devices and keying equipment for test missiles (not for export); Laser Illuminated Target Detector, DSU-38A/B; software delivery and support; AIM-120C Captive Air Training Missiles (CATM) and Airborne Instrumented Units (AIU) Telemetry Sections; missile containers; munitions components; aircraft test and integration support; containers; mission planning; munitions security, storage and training; facility design, construction and quality standards; weapon operational flight program software development; transportation; tools and test equipment; support equipment; spare and repair parts; weapons and aircraft integration support and test equipment; publications and technical documentation; personnel training and training equipment, devices and software; U.S. Government and contractor engineering, technical and logistics support services; site surveys; and other related elements of logistics and program support. The total estimated cost is $10.0 billion.

This proposed sale will support the foreign policy and national security of the United States by helping to improve the security of an important regional partner. The UAE has been, and continues to be, a vital U.S. partner for political stability and economic progress in the Middle East.

The proposed sale will improve the UAE's capability to meet current and future threats by providing enhanced capabilities to various aircraft platforms in effective defense of air, land, and sea. The proposed sale of the missiles/munitions and support will increase interoperability with the U.S. and align the UAE Air Force's capabilities with existing regional baselines. Further, the UAE continues to provide host-nation support of vital U.S. forces stationed in the UAE and plays a vital role in supporting U.S. regional interests. The UAE will have no difficulty absorbing these weapons into its armed forces.

The proposed sale of this equipment and support represents a significant increase in capability and will alter the regional military balance.

The principal contractors will be Raytheon, Tucson, AZ; and Northrop Grumman Information Systems, Ridgecrest, CA. If requested, F-16 integration will be completed via Direct Commercial Sale (DCS) between Lockheed Martin and the purchaser. The munitions will be sourced through procurement and the contractor determined during contract negotiations. There are no known offset agreements proposed in connection with this potential sale. However, the purchaser typically requests offsets. Any offset agreements will be defined in negotiations between the purchaser and the contractor(s).

Implementation of this proposed sale will require annual trips to the UAE involving U.S. Government and contractor representatives for technical reviews, support, and oversight.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 21-03

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

Annex

Item No. vii

(vii) Sensitivity of Technology:

1. The AIM-120C-7/C-8 Advanced Medium Range Air-to-Air Missile (AMRAAM) is a supersonic, air launched, aerial intercept, guided missile featuring digital technology and micro-miniature solid-state electronics. The potential sale will include AMRAAM Guidance Sections. AMRAAM capabilities include look-down/shoot-down, multiple launches against multiple targets, resistance to electronic countermeasures, and interception of high- and low-flying and maneuvering targets. The AIM-120C-8 is a form, fit, function refresh of the AIM-120C-7 and is the next generation to be produced.

2. The AMRAAM NDI-Airborne Instrumented Unit (AIU) telemetry set replaces the missile's warhead, thus allowing for secured telemetered test shots. The NDI-AIU telemetry set is non-exportable and will remain under the control of the U.S. Government or U.S. Defense Contractor.

3. The MK-82 General Purpose (GP) bomb is a 500 pound, free-fall, unguided, low-drag weapon. The MK-82 is designed for soft, fragment-sensitive targets and is not intended for hard targets or penetrations. The explosive filling is usually tritonal, though other compositions have sometimes been used.

4. MK-82 Inert General Purpose (GP) bomb is a 500 pound, free-fall, unguided, low-drag inert weapon used for integration testing. There is no explosive fill.

5. The MK-83 General Purpose (GP) bomb is a 1,000 pound, free-fall, unguided, low-drag weapon. The MK-83 is designed for soft, fragment-sensitive targets and is not intended for hard targets or penetrations. The explosive filling is usually tritonal, though other compositions have sometimes been used.

6. The MK-84 General Purpose (GP) bomb is a 2,000 pound, free-fall, unguided, low-drag weapon. The MK-84 is designed for soft, fragment sensitive targets and is not intended for hard targets or penetrations. The explosive filling is usually tritonal, though other compositions have sometimes been used.

7. The GBU-39 Small Diameter Bomb Increment 1 (SDB-1) is a 250-pound, GPS-aided inertial navigation system, small autonomous, day or night, adverse weather, conventional, air-to-ground precision glide weapon able to strike fixed and stationary re-locatable non-hardened targets from standoff ranges. It is intended to provide aircraft with an ability to carry a high number of bombs. Aircraft are able to carry four SDBs in place of one 2,000-pound bomb.

8. The Joint Direct Attack Munitions (JDAM) is a guidance set which converts existing unguided bombs (MK-82, MK-83, MK-84, BLU-109, BLU-110, BLU-111, BLU-117, BLU-126 (Navy) or BLU-129 warhead) into an accurate, adverse weather ''smart'' munition. The Guidance Set consists of a Tail Kit, which contains the Inertial Navigation System (INS) and a Global Positioning System (GPS), a set of Aerosurfaces and an umbilical cover, which allows the JDAM to improve the accuracy of unguided, General Purpose bombs. The JDAM weapon can be delivered from modest standoff ranges at high or low altitudes against a variety of land and surface targets during the day or night. JDAM is capable of receiving target coordinates via preplanned mission data from the delivery aircraft, by onboard aircraft sensors (i.e., FLIR, Radar, etc.) during captive carry, or from a third-party source via manual or automated aircrew cockpit entry. The Guidance Set, when combined with a warhead and appropriate fuze, forms a JDAM Guided Bomb Unit (GBU).

a. (U) The KMU-572F/B is the tailkit for a GBU-38 500LB JDAM.

b. (U) The KMU-559B/B is the tailkit for a GBU-32 1000LB JDAM.

c. (U) The KMU-556B/B is the tailkit for a GBU-31 2000LB JDAM.

9. The Laser JDAM (GBU-54) converts existing unguided free-fall bombs into precision-guided ''smart'' munitions by adding a new tail section containing Inertial Navigation System (INS) guidance/Global Positioning System (GPS) guidance and adds a semi-active laser seeker. This allows the weapon to strike targets moving at up to 70 mph. The LJDAM weapon consists of a DSU-38 sensor, a JDAM guidance set installed on the bomb body, and a fuze. The DSU-38 consists of a laser spot tracker (same size and shape as a DSU-33 proximity fuze), a cable connecting the DSU-38 to the basic JDAM guidance set, a cable cover, cable cover tie-down straps, modified tail kit door and wiring harness, and associated modified JDAM software that incorporates navigation and guidance flight software to support both LJDAM and standard JDAM missions.

10. The Joint Programmable Fuze (JPF) FMU-139 is a multi-delay, multi-arm and proximity sensor compatible with general purpose blast, frag and hardened-target penetrator weapons. The JPF settings are cockpit selectable in flight when used numerous precision-guided weapons. It can interface with the following weapons: GBU-31, GBU-32, GBU-38, and GBU-54.

11. The AGM-154 JSOW is used by the U.S. Navy, U.S. Marine Corps, and U.S. Air Force, and allows aircraft to attack well-defended targets in day, night, and adverse weather conditions. The AGM-154C carries a BROACH warhead. The BROACH warhead incorporates an advanced multi stage warhead. The JSOW uses the GPS Precise Positioning System (PPS), which provides for a more accurate capability than the commercial version of GPS.

12. The JSOW-C utilizes GPS/INS guidance and an uncooled imaging infrared seeker for terminal guidance, Autonomous Acquisition, and provides a precision targeting, 500-pound-class tandem warhead that is the U.S. Navy's primary standoff weapon against hardened targets.

13. The AGM-154E JSOW-ER adds an engine, and supporting components, to the JSOW C Airframe. The JSOW-ER uses the 300-pound Maverick Warhead due to its smaller size, thereby creating room for fuel, but maintains the same penetration capability as the JSOW C.

14. The AGM-88E Advanced Anti-Radiation Guided Missile (AARGM) weapon system is an air-to-ground missile intended for Suppression of Enemy Air Defenses (SEAD) and Destruction of Enemy Air Defenses (DEAD) missions. The AARGM provides suppression or destruction of enemy RADAR and denies the enemy the use of air defense systems, thereby improving the survivability of tactical aircraft.

15. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

16. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

17. A determination has been made that the UAE can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security

objectives outlined in the Policy Justification.

18. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of the United Arab Emirates.

[FR Doc. 2020–28495 Filed 12–23–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

President's Advisory 1776 Commission

AGENCY: Office of Communications and Outreach, U.S. Department of Education.

ACTION: Announcement of an open meeting.

SUMMARY: This notice sets forth the agenda, time, and instructions for public participation in the January 5, 2020, meeting of the President's Advisory 1776 Commission (''The 1776 Commission'') and provides information to members of the public regarding the meeting. Notice of this meeting is required under Section 10(a)(2) of the Federal Advisory Committee Act (FACA). This notice is being published less than 15 days from the meeting date due to the exceptional and immediate need to establish a strategic plan for The 1776 Commission to respond to recent attacks on the American founding and identify the nation's core principles for further enjoyment of liberty and striving ''to form a more perfect Union.''

DATES: The meeting of The 1776 Commission will be held on Tuesday, January 5, 2021, from 1:00 p.m. to 3:00 p.m. Eastern Standard Time at the Eisenhower Executive Office Building, 1650 Pennsylvania Avenue NW, Washington, DC 20502. Members of the public can attend virtually.

FOR FURTHER INFORMATION CONTACT: Adam Honeysett, Designated Federal Official, Office of Communications and Outreach, U.S. Department of Education, 400 Maryland Avenue SW, Room 7W220, Washington, DC 20202, telephone: (202) 401–3003 or email: *Adam.Honeysett@ed.gov.*

SUPPLEMENTARY INFORMATION: The 1776 Commission's Statutory Authority and Function: The 1776 Commission is established under Executive Order 13958 (November 2, 2020). The 1776 Commission's duties are to advise the President regarding how to better enable a rising generation to understand the history and principles of the founding of the United States in 1776 and to strive to form a more perfect Union by: (i) Producing a report, within 1 year of the date of Executive Order 13958, which shall be publicly disseminated, regarding the core principles of the American founding and how these principles may be understood to further enjoyment of ''the blessings of liberty'' and to promote our striving ''to form a more perfect Union;'' (ii) offering recommendations regarding the Federal Government's plans to celebrate the 250th anniversary of American Independence and coordinating with relevant external stakeholders on the United States Semiquincentennial Commission's plans; (iii) facilitating the development and implementation of a ''Presidential 1776 Award'' to recognize student knowledge of the American founding, including knowledge about the Founders, the Declaration of Independence, the Constitutional Convention, and the great soldiers and battles of the American Revolutionary War; (iv) advising executive departments and agencies with regard to their efforts to ensure patriotic education—meaning the presentation of the history of the American founding and foundational principles, the examination of how the United States has grown closer to those principles throughout its history, and the explanation of why commitment to America's aspirations is beneficial and justified—and provide such education to the public at national parks, battlefields, monuments, museums, installations, landmarks, cemeteries, and other places important to the American Revolution and the American founding, as appropriate and consistent with applicable law; (v) advising agencies on prioritizing the American founding in Federal grants and initiatives, including those described in section 4 of Executive Order 13958, as appropriate and consistent with applicable law; and (vi) facilitating and promoting other activities to support public knowledge and patriotic education on the American Revolution and the American founding, as appropriate and consistent with applicable law.

Meeting Agenda:

The agenda for The 1776 Commission meeting is the establishment of a strategic plan to meet its duties under its charter.

Instructions for Accessing the Meeting:

Members of the public can access the meeting by registering to obtain dial-in instructions by emailing Adam Honeysett at *Adam.Honeysett@ed.gov.* Due to technical constraints, registration is limited to 200 participants and will be available on a first-come, first-served basis:

Access to Records of the Meeting: The Department will post the official report of the meeting on the Department's website within 90 days after the meeting. In addition, pursuant to the FACA, the public may request to inspect records of the meeting at 400 Maryland Avenue SW, Washington, DC, by emailing *Adam.Honeysett@ed.gov* or by phoning (202) 401–3003 to schedule an appointment.

Public Comment:

Members of the public may submit written statements regarding the work of The 1776 Commission via *Adam.Honeysett@ed.gov* (please use the subject line ''January 2021 1776 Commission Meeting Public Comment'') or by letter to Adam Honeysett, Office of Communication and Outreach, U.S. Department of Education, 400 Maryland Avenue SW, 7W220, Washington, DC 20202, by Monday, January 4, 2021.

Reasonable Accommodations: The meeting platform and access code are accessible to individuals with disabilities. If you will need an auxiliary aid or service for the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice not later than Monday, January 4, 2020. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**,in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You also may access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: Executive Order 13958 (November 2, 2020)

Elizabeth Hill,

Delegated to perform the duties of the Assistant Secretary, Communications Director, Office of Communications and Outreach.

[FR Doc. 2020–28607 Filed 12–23–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0158]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Implementation Evaluation of the Title III National Professional Development Program

AGENCY: Institute of Educational Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before January 27, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Tracy Rimdzius, 202–245–7283.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Implementation Evaluation of the Title III National Professional Development Program.

OMB Control Number: 1850–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 883.

Total Estimated Number of Annual Burden Hours: 594.

Abstract: The data collection described in this submission includes activities for an implementation evaluation of the National Professional Development (NPD) program, authorized by Title III of the Elementary and Secondary Education Act (ESEA), which aims to help educational personnel working with English learners (ELs) meet high professional standards and to improve classroom instruction for ELs. The evaluation is designed to provide a systematic and up-to-date look at the implementation of NPD-supported activities among the programs' 91 current grantees as well as a representative sample of pre-service and in-service educators who participated in NPD-supported activities. The surveys will collect information on NPD grantees' goals, strategies used to meet those goals, changes made to teacher education programs, and challenges and successes in promoting educator capacity to serve ELs.

Dated: December 21, 2020.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–28551 Filed 12–23–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Talent Search Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2021 for the Talent Search Program, Assistance Listing Number 84.044A. This notice relates to the approved information collection under OMB control number 1840–0818.

DATES:

Applications Available: December 28, 2020.

Deadline for Transmittal of Applications: February 26, 2021.

Deadline for Intergovernmental Review: April 27, 2021.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768), and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf*.

FOR FURTHER INFORMATION CONTACT: Antoinette Clark Edwards, U.S. Department of Education, 400 Maryland Avenue SW, Room 2C223, Washington, DC 20202–4260. Telephone: (202) 453–7121. Email: *Antoinette.Edwards@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: The purpose of the Talent Search Program is to identify qualified individuals from disadvantaged backgrounds with potential for education at the postsecondary level and encourage them to complete secondary school and undertake postsecondary education. Talent Search projects publicize the availability of, and facilitate the application for, student financial assistance for persons who seek to pursue postsecondary education, and encourage persons who have not completed programs at the secondary or postsecondary level to enter or reenter and complete these programs.

Priorities: This notice contains three competitive preference priorities.

Competitive Preference Priorities 1 and 2 are from the Secretary's Final Supplemental Priorities and Definitions for Discretionary Grant Programs (Supplemental Priorities), published in the **Federal Register** on March 2, 2018 (83 FR 9096). Competitive Preference Priority 3 is from the Secretary's Final Administrative Priorities for Discretionary Grant Programs (Administrative Priorities) published in the **Federal Register** on March 9, 2020 (85 FR 13640).

Note: Applicants must include, in the one-page abstract submitted with the application, a statement indicating which, if any, of the competitive preference priorities are addressed. If the applicant has addressed the competitive preference priorities, this information must also be listed on the Talent Search Program Profile Form.

Competitive Preference Priorities: For FY 2021 and any subsequent year in which we make awards from the list of unfunded applications from this competition, these priorities are competitive preference priorities. Under 34 CFR 75.105(c)(2)(i), we award up to an additional six points to an application, depending on how well the application meets one or more of these priorities.

These priorities are:

Competitive Preference Priority 1—Fostering Knowledge and Promoting the Development of Skills that Prepare Students to be Informed, Thoughtful, and Productive Individuals and Citizens (up to 2 points).

Projects that are designed to support instruction in time management, job seeking, personal organization, public and interpersonal communication, or other practical skills needed for successful career outcomes.

Competitive Preference Priority 2—Promoting Science, Technology, Engineering, or Math (STEM) Education, with a particular focus on Computer Science (up to 2 points).

Projects designed to improve student achievement or other educational outcomes in one or more of the following areas: Science, technology, engineering, math, or computer science (as defined in this notice). These projects must address the following priority area: Increasing access to STEM coursework, including computer science, and hands-on learning opportunities, such as through expanded course offerings, dual-enrollment, high-quality online coursework, or other innovative delivery mechanisms.

Competitive Preference Priority 3—Applications that Demonstrate a Rationale (up to 2 points).

Under this priority, an applicant proposes a project that demonstrates a rationale (as defined in 34 CFR 77.1).

Definitions: The definitions below are from the Supplemental Priorities and 34 CFR 77.1(c).

Computer science means the study of computers and algorithmic processes and includes the study of computing principles and theories, computational thinking, computer hardware, software design, coding, analytics, and computer applications.

Computer science often includes computer programming or coding as a tool to create software, including applications, games, websites, and tools to manage or manipulate data; or development and management of computer hardware and the other electronics related to sharing, securing, and using digital information.

In addition to coding, the expanding field of computer science emphasizes computational thinking and interdisciplinary problem-solving to equip students with the skills and abilities necessary to apply computation in our digital world.

Computer science does not include using a computer for everyday activities, such as browsing the internet; use of tools like word processing, spreadsheets, or presentation software; or using computers in the study and exploration of unrelated subjects.

Demonstrates a rationale means a key project component included in the project's logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.,* the active ''ingredients'' that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Note: In developing logic models, applicants may want to use resources such as the Regional Educational Laboratory Program's (REL Pacific) Education Logic Model Application, available at *https://ies.ed.gov/ncee/edlabs/regions/pacific/elm.asp,* to help design their logic models. Other sources include: *https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014025.pdf, https://ies.ed.gov/ncee/edlabs/regions/pacific/pdf/REL_2014007.pdf,* and *https://ies.ed.gov/ncee/edlabs/regions/northeast/pdf/REL_2015057.pdf.*

Program Authority: 20 U.S.C. 1070a-11 and 1070a-12.

Note: Projects must be awarded and operated in a manner consistent with the nondiscrimination requirements contained in the U.S. Constitution and the Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75 (except for §§ 75.215 through 75.221), 77, 79, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended in 2 CFR part 3474. (d) The regulations for this program in 34 CFR part 643. (e) The Supplemental Priorities. (f) The Administrative Priorities.

Note: The regulations in 34 CFR part 79 apply to all applicants except federally recognized Indian Tribes.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.

Estimated Available Funds: The Administration has requested $950,000,000 for the Federal TRIO Programs for FY 2021, of which we intend to use an estimated $171,000,000 for Talent Search awards. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Estimated Range of Awards: $267,995-$1,030,588.

Estimated Average Size of Awards: $391,715.

Maximum Award:

- For an applicant that is not currently receiving a Talent Search Program grant, the maximum award amount is $277,375. All projects must serve a minimum of 500 participants annually and have a per participant cost of no more than $555.
- For an applicant that is currently receiving a Talent Search Program grant, the maximum award amount is the greater of (a) $277,375 or (b) 100 percent of the applicant's base award amount for FY 2020. For example, an applicant that is eligible for, and requests, a $550,000 grant, must propose to serve at least 990 participants. All projects must serve a minimum of 500 participants annually and have a per participant cost of no more than $555.

Estimated Number of Awards: 473.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 60 months.

III. Eligibility Information

1. *Eligible Applicants:* (a) Institutions of higher education, (b) public or private agencies or organizations, including community-based organizations with experience in serving disadvantaged youth, (c) secondary schools, and (d) combinations of such institutions, agencies, and organizations, for planning, developing, or carrying out one or more of the services identified under this program.

Note: If you are a nonprofit organization, under 34 CFR 75.51, you may demonstrate your nonprofit status by providing: (1) Proof that the Internal Revenue Service currently recognizes the applicant as an organization to which contributions are tax deductible under section 501(c)(3) of the Internal Revenue Code; (2) a statement from a State taxing body or the State attorney general certifying that the organization is a nonprofit organization operating within the State and that no part of its net earnings may lawfully benefit any private shareholder or individual; (3) a certified copy of the applicant's certificate of incorporation or similar document if it clearly establishes the nonprofit status of the applicant; or (4) any item described above if that item applies to a State or national parent organization, together with a statement by the State or parent organization that the applicant is a local nonprofit affiliate.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses a training indirect cost rate. This limits indirect cost reimbursement to an entity's actual cost, as determined in its negotiated indirect cost rate agreement, or eight percent of a modified total direct cost base, whichever amount is less. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

c. *Administrative Cost Limitation:* This program does not include any program-specific limitation on administrative expenses. All administrative expenses must be reasonable and necessary and confirm to Cost Principles described in 2 CFR part 200 subpart E of the Uniform Guidance.

3. *Subgrantees:* A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Other:* An applicant may submit multiple applications if each separate application describes a project that will serve a different target area or different target schools. The term ''target area'' is defined as a geographic area served by a project, and the term ''target school'' is a school designated by the applicant as a focus of project services (34 CFR 643.7).

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *www.govinfo.gov/content/pkg/FR-2019-02-13/pdf/2019-02206.pdf,* which contain requirements and information on how to submit an application.

2. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

3. *Funding Restrictions:* We specify unallowable costs in 34 CFR 643.31. We reference additional regulations outlining funding restrictions in the *Applicable Regulation* section of this notice.

4. *Recommended Page Limit:* The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 65 pages and (2) use the following standards:

- A ''page'' is 8.5″ x 11″, on one side only, with 1'' margins at the top, bottom, and both sides.
- Double space (no more than three lines per vertical inch) all the text in the application narrative, including titles, headings, footnotes, quotations, references, captions, as well as all text in charts, tables, figures, and graphs.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications or the one-page abstract. However, the recommended page limit does apply to all of the application narrative.

We recommend that any application addressing the competitive preference priorities include no more than three additional pages each for Competitive Preference Priorities 1, 2 and 3, if addressed. Applications that do not follow the page limit and formatting recommendations will not be penalized.

V. Application Review Information

1. *Selection Criteria:* The following selection criteria for this program competition are from 34 CFR 643.21. We will award up to 100 points to an application under the selection criteria and up to 6 additional points to an application, depending on how well it meets the competitive preference priorities, for a total score of up to 106 points. The maximum number of points available for each criterion is indicated in parentheses.

(a) *Need for the project* (24 points). The Secretary evaluates the need for a Talent Search project in the proposed target area on the basis of the extent to which the application contains clear evidence of the following:

(1) A high number or high percentage of (i) low-income families residing in the target area; or (ii) students attending the target schools who are eligible for free or reduced priced lunch as described in sections 9(b)(1) and 17(c)(4) of the Richard B. Russell National School Lunch Act (4 points).

(2) Low rates of high school persistence among individuals in the target schools as evidenced by the annual student persistence rates in the proposed target schools for the most recent year for which data are available (2 points).

(3) Low rates of students in the target school or schools who graduate high school with a regular secondary school diploma in the standard number of years for the most recent year for which data are available (4 points).

(4) Low postsecondary enrollment and completion rates among individuals in the target area and schools as evidenced by—

(i) Low rates of enrollment in programs of postsecondary education by graduates of the target schools in the most recent year for which data are available; and

(ii) A high number or high percentage of individuals residing in the target area with education completion levels below the baccalaureate degree level (6 points).

(5) The extent to which the target secondary schools do not offer their students the courses or academic support to complete a rigorous secondary school program of study or

have low participation or low success by low-income or first generation students in such courses (2 points).

(6) Other indicators of need for a Talent Search project, including low academic achievement and low standardized test scores of students enrolled in the target schools, a high ratio of students to school counselors in the target schools, and the presence of unaddressed academic or socio-economic problems of eligible individuals, including foster care youth and homeless children and youth in the target schools or the target area (6 points).

(b) *Objectives* (8 points). The Secretary evaluates the quality of the applicant's objectives and proposed targets (percentages) in the following areas on the basis of the extent to which they are both ambitious, as related to the need data provided under paragraph (a) of this section, and attainable given the project's plan of operation, budget, and other resources:

(1) Secondary school persistence (2 points).

(2) Secondary school graduation (regular secondary school diploma) (2 points).

(3) Secondary school graduation (rigorous secondary school program of study) (1 point).

(4) Postsecondary education enrollment (2 points).

(5) Postsecondary degree attainment (1 point).

(c) *Plan of operation* (30 points). The Secretary evaluates the quality of the applicant's plan of operation on the basis of the following:

(1) The plan to inform the residents, schools, and community organizations in the target area of the purpose, objectives, and services of the project and the eligibility requirements for participation in the project (3 points).

(2) The plan to identify and select eligible project participants (3 points).

(3) The plan for providing the services delineated in 34 CFR 643.4 as appropriate based on the project's assessment of each participant's need for services (10 points).

(4) The plan to work in a coordinated, collaborative, and cost-effective manner as part of an overarching college access strategy with the target schools or school system and other programs for disadvantaged students to provide participants with access to and assistance in completing a rigorous secondary school program of study (6 points).

(5) The plan, including timelines, personnel, and other resources, to ensure the proper and efficient administration of the project, including the project's organizational structure; the time commitment of key project staff; and financial, personnel, and records management (6 points).

(6) The plan to follow former participants as they enter, continue in, and complete postsecondary education (2 points).

(d) *Applicant and community support* (16 points). The Secretary evaluates the applicant and community support for the proposed project on the basis of the extent to which the applicant has made provision for resources to supplement the grant and enhance the project's services, including—

(1) Facilities, equipment, supplies, personnel, and other resources committed by the applicant (8 points); and

(2) Resources secured through written commitments from community partners (8 points).

(i) An applicant that is an institution of higher education must include in its application commitments from the target schools and community organizations;

(ii) An applicant that is a secondary school must include in its application commitments from institutions of higher education, community organizations, and, as appropriate, other secondary schools and the school district; and

(iii) An applicant that is a community organization must include in its application commitments from the target schools and institutions of higher education.

(e) *Quality of personnel* (9 points). (1) The Secretary evaluates the quality of the personnel the applicant plans to use in the project on the basis of the following:

(i) The qualifications required of the project director (3 points).

(ii) The qualifications required of each of the other personnel to be used in the project (3 points).

(iii) The plan to employ personnel who have succeeded in overcoming the disadvantages of circumstances like those of the population of the target area (3 points).

(2) In evaluating the qualifications of a person, the Secretary considers his or her experience and training in fields related to the objectives of the project.

(f) *Budget* (5 points). The Secretary evaluates the extent to which the project budget is reasonable, cost-effective, and adequate to support the project.

(g) *Evaluation plan* (8 points). The Secretary evaluates the quality of the evaluation plan for the project on the basis of the extent to which the applicant's methods of evaluation—

(1) Are appropriate to the project's objectives;

(2) Provide for the applicant to determine, using specific and quantifiable measures, the success of the project in—

(i) Making progress toward achieving its objectives (a formative evaluation); and

(ii) Achieving its objectives at the end of the project period (a summative evaluation); and

(3) Provide for the disclosure of unanticipated project outcomes, using quantifiable measures if appropriate.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, the Secretary may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, and compliance with grant conditions. The Secretary may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, the Secretary also requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

For this competition, a panel of three non-Federal reviewers will review each application in accordance with the selection criteria, pursuant to 34 CFR 643.21. The individual scores assigned by the reviewers will be added and the sum divided by the number of reviewers to determine the peer reviewer score received in the review process. Additionally, in accordance with 34 CFR 643.22, the Secretary will award prior experience points to applicants that have conducted a Talent Search project during budget periods 2017–18, 2018–19, and 2019–20, based on their documented experience. Prior experience points, if any, will be added to the application's averaged reader score to determine the total score for each application.

Note: Tie-breaker: If there are insufficient funds for all applications with the same total scores, the Secretary will choose among the tied applications so as to serve geographical areas that have been underserved by the Talent Search Program.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.205, before awarding grants under this program the Department conducts a review of the risks posed by applicants. Under 2 CFR 3474.10, the Secretary may

impose specific conditions and, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.205(a)(2) we must make a judgement about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We may notify you informally, also.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy requirements in the application package and reference these and other requirements in the *Applicable Regulations* section in this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by the Secretary under 34 CFR 75.118. The Secretary may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html*.

5. *Performance Measures:* Under the Government Performance and Results Act of 1993 (GPRA), the success of the Talent Search Program will be measured by secondary school persistence and graduation rates of Talent Search participants, as well as postsecondary enrollment and completion rates. All Talent Search Program grantees will be required to submit an annual performance report documenting secondary school persistence, secondary school graduation, and postsecondary enrollment of their participants. Since students may take different amounts of time to complete their postsecondary education, multiple years of performance report data are needed to determine the postsecondary completion rates of Talent Search Program participants. The Department will aggregate the data provided in the annual performance reports from all grantees to determine the accomplishment level.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary considers, among other things: Whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; and, if the Secretary has established performance measurement requirements, the performance targets in the grantee's approved application. In making a continuation grant, the Secretary also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package in an accessible format.

The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov*. At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit

your search to documents published by the Department.

Robert L. King,

Assistant Secretary for Postsecondary Education.

[FR Doc. 2020–28583 Filed 12–23–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–486–000]

National Fuel Gas Supply Corporation; Notice of Request for Extension of Time

Take notice that on December 11, 2020, National Fuel Gas Supply Corporation (National Fuel) requested that the Federal Energy Regulatory Commission (Commission) grant an extension of time, until December 1, 2023, to continue using Well 7451 in the Beech Hill Storage Field (Beech Hill) as a withdrawal-only well in order to continue to collect and evaluate information it needs to further demonstrate and assess the reservoir connection between the Beech Hill Complex and the Shongo Pool.

The Commission authorized National Fuel to test Well 7451 and to assess the connection between the Beech Hill Complex and the Shongo Pool in its January 26, 2018 order, for a term not to exceed three years (January 2018 Order).[1] Ordering Paragraph (A) of the January 2018 Order requires National Fuel to notify the Commission within three years of the certificate being issued, if the certificate authorization needs to be abandoned.[2]

National Fuel states that it has not collected enough information about Well 7451 to make any final determinations as required by the Commission approved Containment Plan of the Beech Hill Storage Field.[3] National Fuel's reservoir models have projected different points at which the effect of any interconnection may be evident, the soonest point those models project the effect will be evident is when an additional withdrawal of 0.655 Bcf of gas from Well 7451 occurs. National Fuel expects it will take about two years or longer to reach a level of total withdrawal that will provide information needed to verify and update the reservoir models.

This notice establishes a 15-calendar day intervention and comment period deadline. Any person wishing to comment on National Fuel's request for an extension of time may do so. No reply comments or answers will be considered. If you wish to obtain legal status by becoming a party to the proceedings for this request, you should, on or before the comment date stated below, file a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10).[4]

As a matter of practice, the Commission itself generally acts on requests for extensions of time to complete construction for Natural Gas Act facilities when such requests are contested before order issuance. For those extension requests that are contested,[5] the Commission will aim to issue an order acting on the request within 45 days.[6] The Commission will address all arguments relating to whether the applicant has demonstrated there is good cause to grant the extension.[7] The Commission will not consider arguments that re-litigate the issuance of the certificate order, including whether the Commission properly found the project to be in the public convenience and necessity and whether the Commission's environmental analysis for the certificate complied with the National Environmental Policy Act.[8] At the time a pipeline requests an extension of time, orders on certificates of public convenience and necessity are final and the Commission will not re-litigate their issuance.[9] The OEP Director, or his or her designee, will act on all of those extension requests that are uncontested.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on January 4, 2021.

Dated: December 18, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28563 Filed 12–23–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1946–015.

Applicants: Broad River Energy LLC.

Description: Triennial Compliance Filing for the Southeast Region of Broad River Energy LLC.

Filed Date: 12/17/20.

Accession Number: 20201217–5235.

Comments Due: 5 p.m. ET 2/16/21.

Docket Numbers: ER12–1740–002.

Applicants: Rippey Wind Energy LLC.

Description: Compliance filing: Rippey Wind Energy LLC MBR Tariff Update to be effective 12/19/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5105.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER12–1740–003.

Applicants: Rippey Wind Energy LLC.

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[1] *National Fuel Gas Supply Corporation,* 162 FERC ¶ 62,063 (2018).

[2] *Id.,* at Ordering Paragraph A.

[3] See National Fuel Gas Supply Corporation, Beech Hill Containment and Management Plan, filed February 1, 2017 and Commission March 6, 2017 unpublished letter to National Fuel regarding the Beech Hill Containment and Management Plan.

[4] Only motions to intervene from entities that were party to the underlying proceeding will be accepted. *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 39 (2020).

[5] Contested proceedings are those where an intervenor disputes any material issue of the filing. 18 CFR 385.2201(c)(1) (2019).

[6] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

[7] *Id.* at P 40.

[8] Similarly, the Commission will not re-litigate the issuance of an NGA section 3 authorization, including whether a proposed project is not inconsistent with the public interest and whether the Commission's environmental analysis for the permit order complied with NEPA.

[9] *Algonquin Gas Transmission, LLC,* 170 FERC ¶ 61,144, at P 40 (2020).

Description: Notice of Non-Material Change in Status of Rippey Wind Energy LLC.

Filed Date: 12/18/20.

Accession Number: 20201218–5220.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER13–2100–006; ER13–434–008; ER16–1750–007; ER16–2601–005; ER17–2292–005; ER17–2381–004; ER19–1656–004; R20–2123–002; ER20–2768–002.

Applicants: Virginia Electric and Power Company, Dominion Energy Generation Marketing, Inc., Eastern Shore Solar LLC, Summit Farms Solar, LLC, Southampton Solar LLC, Scott-II Solar LLC, Wilkinson Solar LLC, Greensville County Solar Project, LLC, Hardin Solar Energy LLC.

Description: Notice of Non-Material Change in Status of the Dominion Energy PJM Companies.

Filed Date: 12/17/20.

Accession Number: 20201217–5251.

Comments Due: 5 p.m. ET 1/7/21.

Docket Numbers: ER15–734–001.

Applicants: Wolverine Power Supply Cooperative, Inc.

Description: Market-Based Triennial Review Filing: Market Power Update Triennial to be effective 12/19/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5129.

Comments Due: 5 p.m. ET 2/16/21.

Docket Numbers: ER16–2290–002.

Applicants: Spartan Renewable Energy, Inc.

Description: Market-Based Triennial Review Filing: Market Power Update Triennial to be effective 12/19/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5132.

Comments Due: 5 p.m. ET 2/16/21.

Docket Numbers: ER19–1904–002.

Applicants: Nevada Power Company

Description: Compliance filing: OATT Revision Attachment N 12.18.20 to be effective 5/22/2019.

Filed Date: 12/18/20.

Accession Number: 20201218–5181.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER20–1890–004.

Applicants: California Independent System Operator Corporation.

Description: Compliance filing: 2020–12–17 Limited Time Waiver Petition—Postpone Eff. Date to Feb 1, 2021 to be effective N/A.

Filed Date: 12/17/20.

Accession Number: 20201217–5140.

Comments Due: 5 p.m. ET 1/7/21.

Docket Numbers: ER20–2123–001.

Applicants: Hardin Solar Energy LLC.

Description: Compliance filing: Amended Market-Based Rate Tariff to be effective 2/16/2021.

Filed Date: 12/17/20.

Accession Number: 20201217–5179.

Comments Due: 5 p.m. ET 1/7/21.

Docket Numbers: ER20–2875–000.

Applicants: Southwest Power Pool, Inc.

Description: Report Filing: Refund Report in Response to Order issued in EL19–80–000 to be effective N/A.

Filed Date: 12/18/20.

Accession Number: 20201218–5060.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER20–2953–001.

Applicants: Lone Tree Wind, LLC.

Description: Compliance filing: Revised Rate Schedule FERC No. 1 to be effective 11/23/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5083.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–109–002.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Correction to Amendment to WMPA, SA No. 4768; Queue No. AC1–117 (consent) to be effective 8/4/2017.

Filed Date: 12/17/20.

Accession Number: 20201217–5079.

Comments Due: 5 p.m. ET 1/7/21.

Docket Numbers: ER21–284–001.

Applicants: Groton Station Fuel Cell, LLC.

Description: Tariff Amendment: Amendment to 1 to be effective 12/1/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5187.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–560–000.

Applicants: Georgia-Pacific Consumer Operations LLC, Palatka.

Description: Errata to Notice of Cancellation of MRB Tariff of Georgia-Pacific Consumer Operations LLC, Palatka.

Filed Date: 12/15/20.

Accession Number: 20201215–5179.

Comments Due: 5 p.m. ET 1/5/21.

Docket Numbers: ER21–678–000.

Applicants: Public Service Company of Colorado.

Description: § 205(d) Rate Filing: 2020–12–17 PSC–HLYCRS-Dist Wheeling-625–0.0.0 to be effective 1/1/2021.

Filed Date: 12/17/20.

Accession Number: 20201217–5222.

Comments Due: 5 p.m. ET 1/7/21.

Docket Numbers: ER21–679–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2020–12–17_MISO Spinning Reserves Filing to be effective 6/1/2021.

Filed Date: 12/17/20.

Accession Number: 20201217–5226.

Comments Due: 5 p.m. ET 1/7/21.

Docket Numbers: ER21–680–000.

Applicants: Gopher State Solar, LLC, Otter Tail Solar, LLC, Otter Tail Storage, LLC.

Description: Request for Prospective Tariff Waiver, et al. of Gopher State Solar, LLC, et al.

Filed Date: 12/17/20.

Accession Number: 20201217–5253.

Comments Due: 5 p.m. ET 12/28/20.

Docket Numbers: ER21–681–000.

Applicants: Midcontinent Independent System Operator, Inc., American Transmission Company LLC.

Description: § 205(d) Rate Filing: 2020–12–18_SA 3592 ATC-Wood County Solar E&P (J986) to be effective 1/1/2021.

Filed Date: 12/18/20.

Accession Number: 20201218–5107.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–682–000.

Applicants: Basin Electric Power Cooperative.

Description: § 205(d) Rate Filing: Submission of Revised Wholesale Power Contract FERC Rate Schedule No. 4 to be effective 1/1/2021.

Filed Date: 12/18/20.

Accession Number: 20201218–5146.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–683–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Correction to Original ISA, SA No. 5689; Queue No. AF1–193 (amend) to be effective 6/29/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5149.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–684–000.

Applicants: Wheelabrator South Broward Inc.

Description: Compliance filing: Request for Cat. 1 Seller Status in the SE Region and Revised MBR Tariff to be effective 12/19/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5190.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–685–000.

Applicants: Trieve, LLC.

Description: Baseline eTariff Filing: Application For Market Based Rate Authority to be effective 12/19/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5191.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–686–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: East Texas Cooperatives, Inc. State Rate Revisions to be effective 3/1/2021.

Filed Date: 12/18/20.

Accession Number: 20201218–5209.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–687–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: Revisions to Rate Schedule Nos. 328 and 329 to be effective 1/1/2021.

Filed Date: 12/18/20.

Accession Number: 20201218–5221.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–688–000.

Applicants: Duke Energy Carolinas, LLC.

Description: § 205(d) Rate Filing: Revisions to Cancelled Rate Schedule Nos. 327, 331, 334 to be effective 1/1/2018.

Filed Date: 12/18/20.

Accession Number: 20201218–5231.

Comments Due: 5 p.m. ET 1/8/21.

Docket Numbers: ER21–689–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: PJM submits New Jersey State Agreement Approach Study Agreement, SA No. to be effective 11/18/2020.

Filed Date: 12/18/20.

Accession Number: 20201218–5238.

Comments Due: 5 p.m. ET 1/8/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 18, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28562 Filed 12–23–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP21–317–000.

Applicants: Natural Gas Pipeline Company of America.

Description: § 4(d) Rate Filing: Removal of Expired Negotiated Rate Agreements Filing to be effective 1/18/2021.

Filed Date: 12/17/20.

Accession Number: 20201217–5000.

Comments Due: 5 p.m. ET 12/29/20.

Docket Numbers: RP21–318–000.

Applicants: Gulf South Pipeline Company, LLC.

Description: § 4(d) Rate Filing: Amendments to Neg Rate Agmts (Aethon 52454, 53154) to be effective 12/17/2020.

Filed Date: 12/17/20.

Accession Number: 20201217–5059.

Comments Due: 5 p.m. ET 12/29/20.

Docket Numbers: RP21–319–000.

Applicants: Sabine Pipe Line LLC.

Description: § 4(d) Rate Filing: Normal 7.25 and 7.26 to be effective 2/1/2021.

Filed Date: 12/17/20.

Accession Number: 20201217–5075.

Comments Due: 5 p.m. ET 12/29/20.

Docket Numbers: RP21–320–000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: § 4(d) Rate Filing: Non-Conforming—Southeastern Trail to be effective 1/1/2021.

Filed Date: 12/17/20.

Accession Number: 20201217–5171.

Comments Due: 5 p.m. ET 12/29/20

Docket Numbers: RP21–321–000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: § 4(d) Rate Filing: List of Non-Conforming Service Agreements (Southeastern Trail) to be effective 1/1/2021.

Filed Date: 12/17/20.

Accession Number: 20201217–5196.

Comments Due: 5 p.m. ET 12/29/20.

Docket Numbers: RP21–322–000.

Applicants: Stagecoach Pipeline & Storage Company LL.

Description: § 4(d) Rate Filing: Stagecoach Pipeline & Storage Company LLC—Filing of Non-Conforming Agreement to be effective 1/1/2021.

Filed Date: 12/17/20.

Accession Number: 20201217–5225.

Comments Due: 5 p.m. ET 12/29/20.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 18, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–28564 Filed 12–23–20; 8:45 am]

BILLING CODE 6717–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E.

Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than January 27, 2021.

A. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210–2204. Comments can also be sent electronically to *BOS.SRC.Applications.Comments@bos.frb.org*:

1. *Vineyard Bancorp, MHC, Edgartown, Massachusetts;* to become a mutual bank holding company by acquiring Martha's Vineyard Savings Bank, Edgartown, Massachusetts.

Board of Governors of the Federal Reserve System, December 21, 2020.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2020–28603 Filed 12–23–20; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue, NW, Washington DC 20551–0001, not later than January 12, 2021.

A. Federal Reserve Bank of Atlanta (Kathryn Haney, Assistant Vice President) 1000 Peachtree Street, NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *Donald B. Kelly and Louise N. Kelly, both of Monticello, Georgia; Donald Bruce Kelly, Jr., Melissa A. Kelly, Donald Bruce Kelly, III, and Taylor Anne Kelly, all of Bogart, Georgia; E. Clyde Kelly, III, Macon, Georgia; Jennifer Kelly, Smyrna, Georgia; and Keryn K. Arnett, Cumming, Georgia;* to retain voting shares of Monticello Bancshares, Inc., and thereby indirectly retain voting shares of Bank of Monticello, both of Monticello, Georgia.

Board of Governors of the Federal Reserve System, December 21, 2020.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2020–28604 Filed 12–23–20; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

[File No. 202 3065]

Steves Distributing, LLC; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 27, 2021

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''Steves Distributing, LLC; File No. 202 3065'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Keith Fentonmiller (202–326–2775), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained at *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 27, 2021. Write ''Steves Distributing, LLC; File No. 202 3065'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the public health emergency in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Steves Distributing, LLC; File No. 202 3065'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social

Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 27, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order with Steves Distributing, LLC, a limited liability company doing business as ''Steves Goods,'' and Steven Taylor Schultheis, individually and as an officer and owner of Steves Distributing, LLC (collectively, ''Respondents'').

The proposed consent order (''Order'') has been placed on the public record for 30 days so that interested persons may submit comments. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Order and the comments received, and will decide whether it should withdraw the Order or make it final.

This matter involves the Respondents' advertising of cannabidiol (''CBD'') and cannabigerol (''CBG''), cannabinoid compounds found in hemp and cannabis. The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) CBD and CBG products can effectively prevent, treat, or mitigate multiple diseases and other health conditions; and (2) studies or scientific research prove that CBD and CBG products effectively prevent, treat, or mitigate multiple diseases and other health conditions.

The Order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food the respondent sells, markets, promotes, or advertises.

Provision I requires randomized, double-blind, placebo-controlled clinical testing for the challenged claims or any disease treatment, mitigation, or cure claim for a Covered Product. The Order defines ''Covered Product'' as any dietary supplement, food, or drug including but not limited to CBD products or CBG products.

Provision II prohibits other misleading or unsubstantiated representations about the health benefits, performance, efficacy, safety, or side effects of any Covered Product or essentially equivalent product. It also covers prevention claims not specifically included in Provision I.

Provision III requires the preservation of certain records for any testing Respondents rely upon as competent and reliable scientific evidence. Provision IV addresses Respondents' false establishment claims and generally prohibits misrepresentations regarding the scientifically or clinically proven benefits of any product. Provision V provides a safe harbor for FDA-approved claims.

Provisions VI and VII contain monetary payment provisions.

Provisions VIII, IX, and X require Respondents to provide customer information to the Commission and to provide notice of the Order to customers, affiliates and other resellers. Provision XI requires an acknowledgement of receipt of the Order. It also requires the individual Respondents to deliver a copy of the Order to certain individuals in any business for which they are the majority owner or which they control directly or indirectly.

Provisions XII, XIII, and XIV provide the required reporting, recordkeeping, and compliance monitoring programs that must be put in place. Provision XV explains when the Order is final and effective.

The purpose of this analysis is to aid public comment on the Proposed Order. It is not intended to constitute an official interpretation of the complaint or Proposed Order, or to modify in any way the Proposed Order's terms.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Rohit Chopra [1]

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish—and unlawful—claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their

[1] *In the Matter of EasyButter, LLC et al.,* Comm'n File No. 2023047; *In the Matter of Reef Industries, Inc. et al.,* Comm'n File No. 2023064; *In the Mater of Steves Distributing, LLC et al.,* Comm'n File No. 2023065; *In the Matter of CBD Meds, Inc. et al.,* Comm'n File No. 2023080; *In the Matter of Epichouse, LLC et al.,* Comm'n File No. 2023094; *In the Matter of Bionatrol Health, LLC et al.,* Comm'n File No. 2023114.

medical spending, and undermine ''a competitor's ability to compete'' on honest attributes.[2]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID–19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[3] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries—so-called ''body brokers''—who collect kickbacks from this harmful practice.[4]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[5] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[6]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[7] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[8] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[9] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[10] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[11] and apprising firms of these findings—along with a warning that noncompliance can result in penalties—makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a ''high level of voluntary compliance achieved quickly and at a low cost.'' [12] Going forward, we should pursue this strategy.

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.[13]

Concurring Statement of Commissioner Christine S. Wilson

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the

[2] *In re Pfizer, Inc.,* 81 F.T.C. 23, 62 (1972).

[3] *See, e.g.,* Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic,* Wall Street J. (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic,* American Medical Association (last updated on Oct. 31, 2020), *https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.*

[4] For example, recent reporting describes the ''Florida Shuffle,'' where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America,* Vox (Mar. 2, 2020), *https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-bri-jayne. See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), *https://www.ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid* (calling on the FTC to do more to tackle this problem).

[5] Public Law 115–271 §§ 8021–8023 (codified in 15 U.S.C. 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

[6] Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), *https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.*

[7] Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), *https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.*

[8] In one of these matters, the respondents are paying nothing.

[9] 15 U.S.C. 45(m)(1)(b).

[10] *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256.* Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

[11] This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that ''[f]airness to the consumer, as well as fairness to competitors'' compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.,* 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that ''a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.'' *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.,* 155 F.T.C. 1, 6 (2013).

[12] Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an ''extremely effective and efficient way to enforce the law.'' Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), *https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.*

[13] My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication. The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters [1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that ''[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes.'' [6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

[FR Doc. 2020–28545 Filed 12–23–20; 8:45 am]

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[1] Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions,* Oct. 22, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims;* Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis,* Sept. 10, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused;* Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases,* Apr. 2, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.*

[2] Press Release, *FTC Order Stops the Marketer of* ''*Thrive*'' *Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID–19,* July 10, 2020, available at *https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.*

[3] *See, e.g.,* Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

[4] *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.*

[5] *See, e.g.,* Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC* v. *Avrom Boris Lasarow, et al.* (Feb. 2015), *https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health;* Statement of Commissioner Joshua D. Wright, *FTC* v. *Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), *https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin;* Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru;* Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part;* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC* v. *Springtech 77376, et al.* (July 2013), *https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12–49 (May 2012), available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.*

[6] *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

FEDERAL TRADE COMMISSION

[File No. 202 3047]

EasyButter, LLC; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 27, 2021.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''EasyButter, LLC; File No. 202 3047'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Gideon Sinasohn (404–656–1356), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade

Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 27, 2021. Write ''EasyButter, LLC; File No. 202 3047'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the public health emergency in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''EasyButter, LLC; File No. 202 3047'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 27, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order with EasyButter, LLC, (''EasyButter'') and Michael Solomon, individually and as an officer and owner of EasyButter, LLC. (''Respondents'').

The proposed consent order (''order'') has been placed on the public record for 30 days so that interested persons may submit comments. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves the Respondents' advertising of products containing cannabidiol (''CBD Products). The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that: (1) Their CBD Products prevent diabetes and treat acne, AIDS, autism, bipolar disorder, cancer, depression, epilepsy, PTSD, seizures, and substance abuse; (2) tests or studies prove that their CBD products treat autism; and (3) doctors recommend CBD over prescription medications for depression and PTSD.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food the Respondents sell, market, promote, or advertise, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product will: (1) Alleviate or cure seizures; or (2) cure, mitigate, or treat any disease, including but not limited to acne, AIDS, autism, bipolar disorder, cancer, depression, diabetes, epilepsy, post-traumatic stress disorder, and substance abuse, unless the representation is non-misleading, including that, at the time such representation is made, he possesses and relies upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, ''competent and reliable scientific evidence'' must consist of human clinical testing of the covered product or of an essentially equivalent product that is sufficient in quality and quantity, based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) Randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than

representations covered under Part I, about the health benefits, performance, efficacy, safety or side effects of any covered product, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, ''competent and reliable scientific evidence'' means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would generally require such human clinical testing to substantiate that the representation is true.

Part III requires that with regard to any human clinical test or study (''test'') upon which the Respondents rely to substantiate any claim covered by the order, the Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting: (1) That any covered product is scientifically proven to treat autism; (2) that doctors recommend any covered product over prescription medications for depression, and PTSD; (3) that the performance or benefits of any product are scientifically or clinically proven; or (4) the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research; are scientifically or clinically proven.

Part V provides Respondents a safe harbor for making claims approved by the Food and Drug Administration (''FDA''). Part VI requires Respondents to pay the Commission $36,254.37 within 8 days of the effective date of the order. Part VII requires Respondents to relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to the order.

Part VIII requires Respondents to send notices to consumers who purchased their CBD products informing them about the settlement. Part IX requires Respondents to submit an acknowledgement of receipt of the order, and for the individual Respondent to serve the order on certain individuals, including all officers or directors of any business the individual Respondent controls and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which a Respondent has delivered a copy of the order.

Part X requires Respondents to file compliance reports with the Commission, and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. Part XI contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. Part XII contains other requirements related to the Commission's monitoring of the Respondents' order compliance. Part XIII provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to aid public comment on the order. It is not intended to constitute an official interpretation of the complaint or order, or to modify in any way the order's terms.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Rohit Chopra [1]

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish—and unlawful—claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine ''a competitor's ability to compete'' on honest attributes.[2]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID–19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[3] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries—so-called ''body brokers''—who collect kickbacks from this harmful practice.[4]

[1] *In the Matter of EasyButter, LLC et al.,* Comm'n File No. 2023047; *In the Matter of Reef Industries, Inc. et al.,* Comm'n File No. 2023064; *In the Mater of Steves Distributing, LLC et al.,* Comm'n File No. 2023065; *In the Matter of CBD Meds, Inc. et al.,* Comm'n File No. 2023080; *In the Matter of Epichouse, LLC et al.,* Comm'n File No. 2023094; *In the Matter of Bionatrol Health, LLC et al.,* Comm'n File No. 2023114.

[2] *In re Pfizer, Inc.,* 81 F.T.C. 23, 62 (1972).

[3] *See, e.g.,* Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic,* Wall Street J. (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic,* American Medical Association (last updated on Oct. 31, 2020), *https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.*

[4] For example, recent reporting describes the ''Florida Shuffle,'' where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America,* Vox (Mar. 2, 2020), *https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-bri-jayne. See also* Letter from

Continued

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[5] The Commission is well positioned to help shut down these abuses, ensure they are not profitable, and hold predatory actors and their enablers to account.[6]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[7] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[8] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[9] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[10] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[11] and apprising firms of these findings—along with a warning that noncompliance can result in penalties—makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a ''high level of voluntary compliance achieved quickly and at a low cost.'' [12] Going forward, we should pursue this strategy.

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.[13]

Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), *https://www.ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid* (calling on the FTC to do more to tackle this problem).

[5] Public Law 115–271 §§ 8021–8023 (codified in 15 U.S.C. 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

[6] Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), *https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.*

[7] Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), *https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.*

[8] In one of these matters, the respondents are paying nothing.

[9] 15 U.S.C. 45(m)(1)(b).

[10] *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256.* Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

[11] This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that ''[f]airness to the consumer, as well as fairness to competitors'' compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.,* 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that ''a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.'' *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.,* 155 F.T.C. 1, 6 (2013).

[12] Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an ''extremely effective and efficient way to enforce the law.'' Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), *https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.*

[13] My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

Concurring Statement of Commissioner Christine S. Wilson

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication. The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters [1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases

[1] Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions,* Oct. 22, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims;* Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis,* Sept. 10, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused;* Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases,* Apr. 2, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.*

[2] Press Release, *FTC Order Stops the Marketer of* ''*Thrive*'' *Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID–19,* July 10, 2020, available at *https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.*

and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that ''[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes.'' [6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

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[3] *See, e.g.,* Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

[4] *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.*

[5] *See, e.g.,* Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC* v. *Avrom Boris Lasarow, et al.* (Feb. 2015), *https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health;* Statement of Commissioner Joshua D. Wright, *FTC* v. *Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), *https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin;* Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru;* Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part;* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC* v. *Springtech 77376, et al.* (July 2013), *https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12–49 (May 2012), available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.*

[6] *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

FEDERAL TRADE COMMISSION

[File No. 202 3114]

Bionatrol Health, LLC; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement; request for comment.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices. The attached Analysis to Aid Public Comment describes both the allegations in the complaint and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before January 27, 2021.

ADDRESSES: Interested parties may file comments online or on paper by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Please write ''Bionatrol Health, LLC, FTC File No. 202 3114'' on your comment, and file your comment online at *https://www.regulations.gov* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Keith Fentonmiller (202–326–2775), Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 15 U.S.C. 46(f), and FTC Rule 2.34, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC website at this web address: *https://www.ftc.gov/news-events/commission-actions.*

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 27, 2021. Write ''Bionatrol Health, LLC, FTC File No. 202 3114'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the *https://www.regulations.gov* website.

Because of the public health emergency in response to the COVID–19 pandemic and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Bionatrol Health, LLC; File No. 202 3114'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex D), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex D), Washington, DC 20024. If possible, submit your paper comment to the

Commission by courier or overnight service.

Because your comment will be placed on the publicly accessible website at *https://www.regulations.gov,* you are solely responsible for making sure your comment does not include any sensitive or confidential information. In particular, your comment should not include sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . is privileged or confidential''—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted on the *https://www.regulations.gov* website—as legally required by FTC Rule 4.9(b)—we cannot redact or remove your comment from that website, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website at *http://www.ftc.gov* to read this Notice and the news release describing the proposed settlement. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 27, 2021. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission (''FTC'' or ''Commission'') has accepted, subject to final approval, an agreement containing a consent order with Bionatrol Health, LLC (''Bionatrol''); Isle Revive, LLC also doing business as Isle Revive CBD (''Isle Revive''); Marcelo Torre, individually and as a manager of Bionatrol and Isle Revive; and Anthony McCabe, individually (collectively, ''Respondents'').

The proposed consent order (''order'') has been placed on the public record for 30 days so that interested persons may submit comments. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the order and the comments received, and will decide whether it should withdraw the order or make it final.

This matter involves Respondents' advertising for products containing cannabidiol (''CBD Products), including Bionatrol Full-Spectrum CBD Oil Extract. The complaint alleges that Respondents violated Sections 5(a) and 12 of the FTC Act by disseminating false and unsubstantiated advertisements claiming that their CBD Products, among other things: Are safe for all users; treat pain better than prescription medicine like OxyContin; prevent and treat age-related cognitive decline, chronic pain, including arthritis pain, heart disease, hypertension, and migraines; and are ''medically proven'' to (a) improve anxiety, insomnia, chronic pain, hypertension, and cardiovascular health; (b) treat depression and bipolar disorder; (c) reduce age-related cognitive decline; (d) improve memory recall; and (e) reduce arthritis pain, migraines, and headaches. The complaint further alleges that Respondents misrepresented the cost to purchase one bottle of their CBD Oil Extract and unfairly charged consumers' credit cards for the additional cost without their express informed consent.

The order includes injunctive relief that prohibits these alleged violations and fences in similar and related conduct. The product coverage would apply to any dietary supplement, drug, or food that Respondents sell or market, including CBD Products.

Part I prohibits Respondents from making any representation about the efficacy of any covered product, including that such product:

A. Treats, alleviates, or cures age-related cognitive decline;

B. prevents age-related cognitive decline; pain, including arthritis pain; hypertension; or migraines;

C. treats, alleviates, or cures any disease, including but not limited to bipolar disorder; pain, including arthritis pain; depression; heart disease; hypertension; and migraines;

D. replaces the need for prescription painkillers like oxycontin; or

E. is safe for all consumers, unless the representation is non-misleading, including that, at the time such representation is made, they possess and rely upon competent and reliable scientific evidence that substantiates that the representation is true.

For purposes of Part I, competent and reliable scientific evidence must consist of human clinical testing of the covered product, or of an essentially equivalent product, that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing must be: (1) Randomized, double-blind, and placebo-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing.

Part II prohibits Respondents from making any representation, other than representations covered under Part I, about the health benefits, performance, efficacy, safety, or side effects of any covered product, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of Part II, ''competent and reliable scientific evidence'' means tests, analyses, research, or studies that (1) have been conducted and evaluated in an objective manner by experts in the relevant disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and placebo-controlled human clinical testing of the covered product, or of an essentially equivalent product, when such experts would

generally require such human clinical testing to substantiate that the representation is true.

Part III requires that, with regard to any human clinical test or study (''test'') upon which Respondents rely to substantiate any claim covered by the order, Respondents must secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of a test.

Part IV prohibits Respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research or that any benefit of any covered product is scientifically or clinically proven. Part V prohibits Respondents from misrepresenting, among other things, any cost to the consumer to purchase, receive, use, or return the initial good or service; that a good or service is offered on a ''free,'' ''trial,'' ''sample,'' ''bonus,'' ''gift,'' ''no obligation,'' ''discounted'' basis, or words of similar import; and any material aspect of the nature or terms of a refund, cancellation, exchange, or repurchase policy for the good or service. Part VI prohibits Respondents from charging any consumer without obtaining the consumer's express informed consent to the charge and having created and maintained a record of such consent. Part VII provides Respondents a safe harbor for making claims approved by the Food and Drug Administration (''FDA'').

Parts VIII and IX require Respondents Bionatrol and Isle Revive to pay the Commission $20,000.00 and describes the procedures and legal rights related that payment.

Part X requires Respondents Bionatrol, Isle Revive, and Torre to send email notices to consumers who purchased Bionatrol Full-Spectrum CBD Oil Extract informing them about the settlement. Part XI requires Respondents to submit an acknowledgement of receipt of the order, to serve the order on certain individuals, including all officers or directors of any business Respondents control and employees having managerial responsibilities for conduct related to the subject matter of the order, and to obtain acknowledgements from each individual or entity to which Respondents have delivered a copy of the order.

Part XII requires Respondents to file compliance reports with the Commission and to notify the Commission of bankruptcy filings or changes in corporate structure that might affect compliance obligations. Part XIII contains recordkeeping requirements for accounting records, personnel records, consumer correspondence, advertising and marketing materials, and claim substantiation, as well as all records necessary to demonstrate compliance or non-compliance with the order. Part XIV contains other requirements related to the Commission's monitoring of Respondents' order compliance. Part XV provides the effective dates of the order, including that, with exceptions, the order will terminate in 20 years.

The purpose of this analysis is to aid public comment on the order. It is not intended to constitute an official interpretation of the complaint or order, or to modify in any way the order's terms.

By direction of the Commission.

April J. Tabor,

Acting Secretary.

Statement of Commissioner Rohit Chopra [1]

Summary

- When companies lie about the effectiveness of their treatments for serious conditions, this harms patients and diverts sales away from firms that tell the truth.
- Congress gave the FTC a new authority to crack down on abuses in the opioid treatment industry, but the agency has not prioritized this issue. This should change.
- The FTC can increase its effectiveness when it comes to health claims by shifting resources away from small businesses and by deploying the unused Penalty Offense Authority.

Today, the Federal Trade Commission is taking action against several outfits regarding their outlandish—and unlawful—claims about cannabidiol (CBD). While CBD is currently the subject of considerable scientific research, there is no evidence yet that CBD can treat or cure cancer, Alzheimer's, or other serious diseases. Baseless claims give patients false hope, improperly increase or divert their medical spending, and undermine ''a competitor's ability to compete'' on honest attributes.[2]

I support these actions and congratulate those who made them a reality. Going forward, however, the FTC will need to refocus its efforts on health claims by targeting abuses in the substance use disorder treatment industry, shifting attention toward large businesses, and making more effective use of the FTC's Penalty Offense Authority.

First, COVID–19 and the resulting economic and social distress are fueling new concerns about substance use disorders. In particular, there are signs that the pandemic is leading to greater dependence on opioids.[3] It is critical that the FTC take steps to prevent exploitation of patients seeking treatment for substance use disorders.

I am particularly concerned about abusive practices in the for-profit opioid treatment industry, and believe this should be a high priority. This industry has grown exponentially by profiting off those suffering from addiction. Many of these outfits use lead generators to steer Americans into high-cost, subpar treatment centers, and some even hire intermediaries—so-called ''body brokers''—who collect kickbacks from this harmful practice.[4]

More than two years ago, Congress passed the SUPPORT for Patients and Communities Act. Among other provisions, the Act authorized the Commission to seek civil penalties, restitution, damages, and other relief against outfits that engage in misconduct related to substance use disorder treatment.[5] The Commission is well positioned to help shut down these abuses, ensure they are not profitable,

[1] *In the Matter of EasyButter, LLC et al.,* Comm'n File No. 2023047; *In the Matter of Reef Industries, Inc. et al.,* Comm'n File No. 2023064; *In the Mater of Steves Distributing, LLC et al.,* Comm'n File No. 2023065; *In the Matter of CBD Meds, Inc. et al.,* Comm'n File No. 2023080; *In the Matter of Epichouse, LLC et al.,* Comm'n File No. 2023094; *In the Matter of Bionatrol Health, LLC et al.,* Comm'n File No. 2023114.

[2] *In re Pfizer, Inc.,* 81 F.T.C. 23, 62 (1972).

[3] *See, e.g.,* Jon Kamp & Arian Campo-Flores, *The Opioid Crisis, Already Serious, Has Intensified During Coronavirus Pandemic,* Wall Street J. (Sept. 8, 2020), *https://www.wsj.com/articles/the-opioid-crisis-already-serious-has-intensified-during-coronavirus-pandemic-11599557401; Issue brief: Reports of increases in opioid- and other drug-related overdose and other concerns during COVID pandemic,* AMERICAN MEDICAL ASSOCIATION (last updated on Oct. 31, 2020), *https://www.ama-assn.org/delivering-care/opioids/covid-19-may-be-worsening-opioid-crisis-states-can-take-action.*

[4] For example, recent reporting describes the ''Florida Shuffle,'' where treatment facilities pay brokers to recruit patients through 12-step meetings, conferences, hotlines, and online groups, leading to serious harm. *See* German Lopez, *She wanted addiction treatment. She ended up in the relapse capital of America,* VOX (Mar. 2, 2020), *https://www.vox.com/policy-and-politics/2020/3/2/21156327/florida-shuffle-drug-rehab-addiction-treatment-bri-jayne. See also* Letter from Commissioner Chopra to Congress on Deceptive Marketing Practices in the Opioid Addiction Treatment Industry (July 28, 2018), *https://www.ftc.gov/public-statements/2018/07/letter-commissioner-chopra-congress-deceptive-marketing-practices-opioid* (calling on the FTC to do more to tackle this problem).

[5] Public Law 115–271 §§ 8021–8023 (codified in 15 U.S.C. 45d). The Act also allows the Commission to prosecute deceptive marketing of opioid treatment products. Notably, a number of respondents in this sweep are alleged to have made claims that CBD could replace OxyContin.

and hold predatory actors and their enablers to account.[6]

Unfortunately, the Commission has brought zero cases under this new authority. While I have supported actions like this one that challenge baseless CBD claims, as well as previous actions charging that pain relief devices and similar products were sold deceptively,[7] I am concerned that we have largely ignored Congressional concerns about unlawful opioid treatment practices. I urge my fellow Commissioners to change course on our enforcement priorities, especially given our limited resources.

Second, the FTC should focus more of its enforcement efforts on larger firms rather than small businesses. Today's actions focus on very small players, some of which are defunct. While I appreciate that small businesses can also harm honest competitors and families, they are often judgment-proof, making it unlikely victims will see any relief.[8] I am confident that FTC staff can successfully challenge powerful, well-financed defendants that break the law.

Finally, the Commission should reduce the prevalence of unlawful health claims by triggering civil penalties under the FTC's Penalty Offense Authority.[9] Under the Penalty Offense Authority, firms that engage in conduct they know has been previously condemned by the Commission can face civil penalties, in addition to the relief that we typically seek.[10] For example, the Commission routinely issues warning letters to businesses regarding unsubstantiated health claims. Future warning letters can be more effective if they include penalty offense notifications.

The Commission has repeatedly found that objective claims require a reasonable basis,[11] and apprising firms of these findings—along with a warning that noncompliance can result in penalties—makes it significantly more likely they will come into compliance voluntarily. In fact, when the Commission employed this strategy four decades ago, it reportedly resulted in a ''high level of voluntary compliance achieved quickly and at a low cost.'' [12] Going forward, we should pursue this strategy.

I thank everyone who made today's actions possible, and look forward to future efforts that address emerging harms using the full range of our tools and authorities.[13]

Concurring Statement of Commissioner Christine S. Wilson

Today the Commission announces six settlements with marketers of cannabidiol (CBD) products resolving allegations that they made false, misleading, and/or unsubstantiated express disease claims for their products. I support these cases because accurate and complete information about products contributes to the efficient functioning of the market and facilitates informed consumer decision-making. In contrast, deceptive or false claims inhibit informed decision-making and may cause economic injury to consumers.

The Commission's complaints in these matters allege that the marketers claimed their products could treat, prevent, or cure diseases or serious medical conditions, including cancer, heart disease, Alzheimer's, diabetes, and Parkinson's disease, and that scientific research or clinical studies supported these claims. In fact, according to the Commission's complaints, the proposed respondents did not conduct scientific research on the efficacy of their products to treat these diseases or conditions. In addition, the complaints allege that some of the proposed respondents claimed that their products could be taken in lieu of prescription medication. The Commission has been working with the FDA, and on its own, to combat false and unsubstantiated claims for CBD products, including through warning letters [1] and a law enforcement action.[2] Here, where consumers may have foregone proven measures to address serious diseases and the marketers have made virtually no effort to possess and rely on scientific evidence to support their strong, express disease claims, as we allege in our complaint, I agree that law enforcement is appropriate.

The Commission's proposed consent orders in these matters require respondents to possess and rely on competent and reliable evidence, defined as randomized, double-blind, placebo-controlled human clinical trials to support disease and other serious health claims for these types of products in the future.[3] Although I support this requirement in these cases, for these types of claims, I caution that the Commission should impose this stringent substantiation requirement sparingly. Credible science supports the

[6] Given public reports regarding private equity rollups of smaller opioid treatment facilities, the Commission can also examine whether anticompetitive M&A strategies are leading to further patient harm. *See* Statement of Commissioner Rohit Chopra Regarding Private Equity Roll-ups and the Hart-Scott-Rodino Annual Report to Congress, Comm'n File No. P110014 (July 8, 2020), *https://www.ftc.gov/public-statements/2020/07/statement-commissioner-rohit-chopra-regarding-private-equity-roll-ups-hart.*

[7] Press Release, Fed. Trade Comm'n, Marketers of Pain Relief Device Settle FTC False Advertising Complaint (Mar. 4, 2020), *https://www.ftc.gov/news-events/press-releases/2020/03/marketers-pain-relief-device-settle-ftc-false-advertising.*

[8] In one of these matters, the respondents are paying nothing.

[9] 15 U.S.C. 45(m)(1)(b).

[10] *See* Rohit Chopra & Samuel A.A. Levine, The Case for Resurrecting the FTC Act's Penalty Offense Authority (Oct. 29, 2020), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3721256.* Particularly given challenges to the FTC's 13(b) authority, incorporating a penalty offense strategy can safeguard the Commission's ability to seek strong remedies against lawbreakers.

[11] This requirement was first established in the Commission's 1972 *Pfizer* decision, and it has been affirmed repeatedly. *Pfizer, Inc., supra* note 2 (finding that ''[f]airness to the consumer, as well as fairness to competitors'' compels the conclusion that affirmative claims require a reasonable basis); *In re Thompson Medical Co.,* 104 F.T.C. 648, 813 (1984) (collecting cases), aff'd, 791 F.2d 189 (D.C. Cir. 1986). Appended to *Thompson Medical* was the Commission's Policy Statement Regarding Advertising Substantiation, which states that ''a firm's failure to possess and rely upon a reasonable basis for objective claims constitutes an unfair and deceptive act or practice in violation of Section 5 of the Federal Trade Commission Act.'' *Id.* at 839. This standard continues to govern the Commission's approach to substantiation, as recently reaffirmed in the Commission's final order against POM Wonderful. *In re POM Wonderful LLC et al.,* 155 F.T.C. 1, 6 (2013).

[12] Commissioner Bailey made this observation in the context of opposing industry efforts to repeal this authority, an authority she described as an ''extremely effective and efficient way to enforce the law.'' Testimony of Commissioner Patricia P. Bailey Before the Subcomm. on Com., Tourism and Transp. of the Comm. on Energy and Com. of the H.R. Concerning the 1982 Reauthorization of the Fed. Trade Comm'n, at 11 (Apr. 1, 1982), *https://www.ftc.gov/system/files/documents/public_statements/693551/19820401_bailey_testimony_before_the_subcorrmittee_on_commerce_subcommittee_on_commerce_touri.pdf.*

[13] My colleague, Commissioner Christine S. Wilson, has issued a statement in this matter. I agree that the Commission should not prioritize close-call substantiation cases, especially those involving small businesses.

[1] Press Release, *FTC and FDA Warn Florida Company Marketing CBD Products about Claims Related to Treating Autism, ADHD, Parkinson's, Alzheimer's, and Other Medical Conditions,* Oct. 22, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/10/ftc-fda-warn-florida-company-marketing-cbd-productsabout-claims;* Press Release, *FTC Sends Warning Letters to Companies Advertising Their CBD-Infused Products as Treatmentsfor Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis,* Sept. 10, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbdinfused;* Press Release, *FTC Joins FDA in Sending Warning Letters to Companies Advertising and Selling Products Containing Cannabidiol (CBD) Claiming to Treat Alzheimer's, Cancer, and Other Diseases,* Apr. 2, 2019, available at *https://www.ftc.gov/news-events/press-releases/2019/04/ftc-joins-fda-sending-warning-letters-companiesadvertising.*

[2] Press Release, *FTC Order Stops the Marketer of ''Thrive'' Supplement from Making Baseless Claims It Can Treat, Prevent, or Reduce the Risks from COVID–19,* July 10, 2020, available at *https://www.ftc.gov/newsevents/press-releases/2020/07/ftc-order-stops-marketer-thrive-supplement-making-baseless-claims.*

[3] *See, e.g.,* Part I of Proposed Order, In the Matter of Bionatrol Health, LLC, et. al. (Dec. 2020).

use of CBD products to treat certain conditions—specifically, the FDA has approved a drug containing CBD as an active ingredient to treat rare, severe forms of epilepsy.[4] And I understand that many research studies are currently seeking to determine whether there are other scientifically valid and safe uses of this ingredient.

I agree with my predecessors who have stated that the Commission should be careful to avoid imposing an unduly high standard of substantiation that risks denying consumers truthful, useful information, may diminish incentives to conduct research, and could chill manufacturer incentives to introduce new products to the market.[5] And I agree with the observation of my colleague Commissioner Chopra in his statement that ''[b]aseless claims give patients false hope, improperly increase or divert their medical spending, and undermine 'a competitor's ability to compete' on honest attributes.'' [6] Although I support these cases, I hope that the Commission's actions here, which challenge wholly unsubstantiated disease claims, do not discourage research into the potential legitimate benefits of CBD and a wide array of other products. In addition, going forward, I urge the Commission to focus our scarce resources on marketers that make strong, express claims about diseases and serious health issues with little to no scientific support and engage in deceptive practices that cause substantial consumer injury.

[FR Doc. 2020–28544 Filed 12–23–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Formative Data Collections for ACF Program Support (OMB #0970–0531)

AGENCY: Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) proposes to revise the existing overarching generic clearance for Formative Data Collections for ACF Program Support (OMB #0970–0531) to increase the estimated number of respondents and, therefore, the overall burden estimate.

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: The goals of the generic information collections under this approval are to obtain information about program and grantee processes or needs, and to inform the following types of activities, among others:

- Delivery of targeted assistance and workflows related to program and grantee processes, and the development and refinement of recordkeeping and communication systems.
- Planning for provision of programmatic or evaluation-related training or technical assistance (T/TA).
- Obtaining grantee or other stakeholder input on the development of program performance measures.
- Use of rapid-cycle testing activities to strengthen programs in preparation for summative evaluations.

ACF uses a variety of techniques such as semi-structured discussions, focus groups, surveys, templates, open-ended requests, and telephone or in-person interviews, in order to reach these goals.

Following standard OMB requirements, OPRE will submit a change request for each individual data collection activity under this generic clearance. Each request will include the individual instrument(s), a justification specific to the individual information collection, and any supplementary documents. OMB should review requests within 10 days of submission.

Respondents: Example respondents include: Current or prospective service providers, training or T/TA providers, grantees, contractors, current and potential participants in ACF programs or similar comparison groups, experts in fields pertaining to ACF programs, key stakeholder groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, state or local government officials, or others involved in or prospectively involved in ACF programs.

Instrument	Estimated total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Semi-Structured Discussions and Focus Groups	5,000	1	2	10,000
Interviews	2,500	1	1	2,500
Questionnaires/Surveys	2,500	1.5	.5	1,875
Templates and Open-ended Requests	650	1	10	6,500

[4] *See* FDA Press Release, *FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy* (June 25, 2018), available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-comprised-active-ingredient-derived-marijuana-treat-rare-severe-forms.*

[5] *See, e.g.,* Statement of Commissioner Maureen K. Ohlhausen, *In the Matter of Health Discovery Corporation and FTC* v. *Avrom Boris Lasarow, et al.* (Feb. 2015), *https://www.ftc.gov/public-statements/2015/02/dissenting-statement-commissioner-maureen-k-ohlhausen-matter-health;* Statement of Commissioner Joshua D. Wright, *FTC* v. *Kevin Wright; HCG Platinum, LLC; and Right Way Nutrition, LLC* (Dec. 2014), *https://www.ftc.gov/public-statements/2014/12/statement-commissioner-joshua-d-wright-federal-trade-commission-v-kevin;* Statement of Commissioner Joshua D. Wright, *In the Matter of GeneLink, Inc., and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-joshua-d-wright-matter-genelink-inc-foru;* Statement of Commissioner Maureen K. Ohlhausen Dissenting in Part and Concurring in Part, *In the Matter of GeneLink, Inc. and foru International Corporation* (January 2014), *https://www.ftc.gov/public-statements/2014/01/statement-commissioner-maureen-k-ohlhausen-dissenting-part-concurring-part;* Dissenting Statement of Commissioner Maureen K. Ohlhausen, *FTC* v. *Springtech 77376, et al.* (July 2013), *https://www.ftc.gov/public-statements/2013/07/dissenting-statement-commissioner-maureen-k-ohlhausen; see also* J. Howard Beales, III and Timothy J. Muris, In Defense of the *Pfizer* Factors, George Mason Law & Economics Research Paper No. 12–49 (May 2012), available at: *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2087776.*

[6] *See* Statement of Commissioner Rohit Chopra Regarding the Cannabidiol (CBD) Enforcement Actions (Dec. 17, 2020).

Estimated Total Annual Burden Hours: 20,875.

Authority: Social Security Act, Sec 1110 [42 U.S.C. 1310].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–28576 Filed 12–23–20; 8:45 am]

BILLING CODE 4184–79–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1440]

Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Oncologic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on February 9, 2021, from 10 a.m. to 2 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1440. The docket will close on February 8, 2021. Submit either electronic or written comments on this public meeting by February 8, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 8, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 8, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before January 26, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is canceled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–1440 for ''Oncologic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: She-Chia Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, email: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously

announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss supplemental biologics license application (sBLA) 125514/s–089, for KEYTRUDA (pembrolizumab), submitted by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. The proposed indication (use) for this product is for the treatment of patients with high-risk, early-stage triple-negative breast cancer, in combination with chemotherapy as neoadjuvant treatment, then as a single agent as adjuvant treatment after surgery.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before January 26, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 12 noon and 1 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before January 15, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 19, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact She-Chia Chen (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: December 18, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28558 Filed 12–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2252]

Interim Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Interim Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (BsUFA)'' and an opportunity for public comment. The topics to be discussed are the interim assessment and public stakeholder views of the program to date.

DATES: The public meeting will be held on January 27, 2021, from 9:30 a.m. to 12:30 p.m. Eastern Time and will take place virtually by Adobe Connect only. Submit either electronic or written comments on this public meeting by March 29, 2021. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 29, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 29, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–N–2252 for ''Interim Assessment of the Program for Enhanced Review Transparency and Communication in the Biosimilar User Fee Act (BsUFA); Public Meeting; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Kimberly Taylor, Food and Drug Administration, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1152, Silver Spring, MD 20993, 240–402–5193, *Kimberly.taylor@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The BsUFA was originally enacted in 2012 as the Biosimilar User Fee Act under the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) for a period of 5 years. In 2017, the BsUFA was renewed for 5 more years under the FDA Reauthorization Act of 2017 (FDARA) (BsUFA II) (Pub. L. 115–52, Title IV)). The BsUFA's intent is to provide additional revenues so that FDA can hire staff, improve systems, and continue a well-managed biosimilar biological product review process to make biosimilar biological product therapies available to patients sooner. BsUFA II was authorized to continue the collection of user fees by FDA to facilitate and expedite the process for the review of biosimilar biological products in the United States.

Under BsUFA II, FDA committed to apply a new review model to original biosimilar biologics license application (BLA) reviews. That review model is identified in section II.B. of the BsUFA II Commitment Letter as the Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs (the Program). The Program provides opportunities for increased communication between FDA and applicants, including mid-cycle and late-cycle meetings. To accommodate the increased interaction during regulatory review, FDA's review clock begins after the 60-day administrative filing review period for applications reviewed under the Program. The goal of the Program is to promote the efficiency and effectiveness of the first-cycle review process and minimize the number of review cycles necessary for approval, ensuring that patients have timely access to safe, effective, and high quality biosimilar and interchangeable biological products.

An independent evaluator is assessing the Program to understand its effect on the review of BsUFA applications. In addition to publishing an interim assessment on FDA's website, a public meeting will be held on January 27, 2021, where the interim assessment will be discussed, and public stakeholders may present their views on the Program to date.

Additional information concerning the BsUFA—including the text of the law, the ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022'' (the BsUFA II Commitment Letter), ''Biosimilar Authorization Performance Goals and Procedures Fiscal Years 2013 through 2017'' (the BsUFA Commitment Letter), key **Federal Register** documents, BsUFA-related guidances, BsUFA user fee rates, performance reports, and financial reports—may be found at *https://www.fda.gov/industry/fda-user-fee-programs/biosimilar-user-fee-amendments.*

II. Topics for Discussion at the Public Meeting

FDA and an independent contractor will discuss the findings of the interim assessment, including anonymized and aggregated feedback from biosimilar BLA applicants and FDA review teams resulting from independent contractor interviews. FDA will discuss any issues identified to date, including any proposed plans to improve the likelihood of the Program's success. A panel of external stakeholders will also provide their perspective. To view the interim assessment report, please visit here: *https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufa-ii-assessment-program-enhanced-review-transparency-and-communication-biosimilar-user-fee-act.*

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: *https://www.eventbrite.com/e/public-meeting-on-the-interim-assessment-of-the-bsufa-ii-program-tickets-127577568943.* Please provide complete contact information for each attendee, including name, affiliation, and email.

Persons interested in attending this public meeting must register by January 26, 2021, at 11:59 p.m. Eastern Time. Registrants will receive confirmation once they have been accepted.

Requests for Oral Presentations: Those who register online by January 14, 2021, will receive a notification about an opportunity to participate in the public comment session of the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are

urged to consolidate or coordinate their comments and request time jointly. All requests to make a public comment during the meeting must be received by January 15, 2021, 11:59 p.m. Eastern Time. We will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by January 20, 2021. No commercial or promotional material will be permitted to be presented at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will be held via Adobe Connect. The link for this public meeting is *https://collaboration.fda.gov/bsufa012721.*

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available at *www.regulations.gov* in this docket.

Dated: December 21, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28602 Filed 12–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–0530]

Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the draft guidance entitled ''Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry,'' which was announced in the **Federal Register** of November 12, 2020. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the draft guidance published November 12, 2020 (85 FR 71920). Submit either electronic or written comments on the draft guidance by February 25, 2021, to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–D–0530 for ''Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

FOR FURTHER INFORMATION CONTACT: Carol D'lima, Office of Nutrition and Food Labeling, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of November 12, 2020 (85 FR 71920), we published a notice of availability for a draft guidance entitled

''Voluntary Disclosure of Sesame as an Allergen: Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request.'' This action opened a docket with a 60-day comment period to receive comments related to the voluntary disclosure of sesame as an allergen.

We have received a request for a 60-day extension of the comment period for the draft guidance. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful response to the draft guidance. In the interest of balancing the public health importance of sesame allergen labeling and granting additional time to submit comments before we finalize the draft guidance, we have concluded that it is reasonable to extend the comment period for 45 days, until February 25, 2021. We believe that this extension allows adequate time for interested persons to submit comments.

Dated: December 18, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28559 Filed 12–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–4303]

Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling.'' This guidance is being issued in accordance with the Food and Drug Administration Safety and Innovation Act (FDASIA), which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require that certain submissions under the FD&C Act and the Public Health Service Act (PHS Act) be submitted in electronic format, beginning no earlier than 24 months after issuance of final guidance on electronic format for submissions. The guidance describes how FDA plans to implement the requirements for the electronic submission of Risk Evaluation and Mitigation Strategies (REMS) documents in certain submissions under new drug applications (NDAs), abbreviated new drug applications (ANDAs), and certain biologics license applications (BLAs), beginning December 28, 2022. This guidance finalizes the draft guidance entitled ''Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling'' published September 5, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on December 28, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–D–4303 for ''Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

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

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Nancy Guan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–348–1549; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling.'' FDASIA amended the FD&C Act to require that certain submissions under the FD&C Act and the PHS Act be submitted in electronic format, beginning no earlier than 24 months after issuance of final guidance on electronic format for submissions. This guidance describes how FDA plans to implement the requirements for the electronic submission of REMS documents in certain submissions under NDAs, ANDAs, and certain BLAs, beginning December 28, 2022.

This guidance finalizes the draft guidance entitled ''Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling'' issued September 5, 2017 (82 FR 41968). FDA has considered all the public comments received on the draft guidance in finalizing this guidance. FDA made editorial changes to improve clarity and address comments as appropriate. FDA also amended language in Part III.C of the guidance to reflect the recent publication of exemption and waiver criteria for eCTD submissions in a separate guidance.

FDA guidances ordinarily contain standard language explaining that guidances should be viewed only as recommendations unless specific regulatory or statutory requirements are cited. FDA is not including this standard language in this guidance because this guidance contains binding provisions. In section 745A(a) of the FD&C Act, Congress granted explicit authorization to FDA to specify in guidance the format for the electronic submissions required under that section. Accordingly, this guidance explains such requirements under section 745A(a) of the FD&C Act, indicated by the use of the words *must* or *required,* and therefore is not subject to the usual restrictions in FDA's good guidance practice regulations, such as the requirement that guidances not establish legally enforceable responsibilities. See 21 CFR 10.115(d). This guidance represents the Agency's current thinking on ''Providing Regulatory Submissions in Electronic Format—Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling.''

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: December 21, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28560 Filed 12–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0008]

Advisory Committee; Cellular, Tissue and Gene Therapies Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Cellular, Tissue and Gene Therapies Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Cellular, Tissue and Gene Therapies Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 28, 2022, expiration date.

DATES: Authority for the Cellular, Tissue and Gene Therapies Advisory Committee will expire on October 28, 2022, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Prabhakara Atreya, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10993 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993–0002, 240–402–8006, *Prabhakara.Atreya@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102–3.65 and approval by the Department of Health and Human Services pursuant to 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the Cellular, Tissue and Gene Therapies Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products, which are intended for transplantation,

implantation, infusion, and transfer in the prevention and treatment of a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions. The Committee also considers the quality and relevance of FDA's research program, which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner.

The Committee shall consist of a core of 13 voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of cellular therapies, tissue transplantation, gene transfer therapies, and xenotransplantation (biostatistics, bioethics, hematology/oncology, human tissues and transplantation, reproductive medicine, general medicine, and various medical specialties, including surgery and oncology, immunology, virology, molecular biology, cell biology, developmental biology, tumor biology, biochemistry, rDNA technology, nuclear medicine, gene therapy, infectious diseases, and cellular kinetics). Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this Committee serve as Special Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting member who is identified with industry interests.

The Commissioner or designee shall have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members) or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

If functioning as a medical device panel, a non-voting representative of consumer interests and a non-voting representative of industry interests will be included in addition to the voting members.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/cellular-tissue-and-gene-therapies-advisory-committee/charter-cellular-tissue-and-gene-therapies-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: December 18, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28561 Filed 12–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Vaccine Injury Compensation Program; List of Petitions Received

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HRSA is publishing this notice of petitions received under the National Vaccine Injury Compensation Program (the Program), as required by Section 2112(b)(2) of the Public Health Service (PHS) Act, as amended. While the Secretary of HHS is named as the respondent in all proceedings brought by the filing of petitions for compensation under the Program, the United States Court of Federal Claims is charged by statute with responsibility for considering and acting upon the petitions.

FOR FURTHER INFORMATION CONTACT: For information about requirements for filing petitions, and the Program in general, contact Lisa L. Reyes, Clerk of Court, United States Court of Federal Claims, 717 Madison Place NW, Washington, DC 20005, (202) 357–6400. For information on HRSA's role in the Program, contact the Director, National Vaccine Injury Compensation Program, 5600 Fishers Lane, Room 08N146B, Rockville, Maryland 20857; (301) 443–6593, or visit our website at: *http://www.hrsa.gov/vaccinecompensation/index.html.*

SUPPLEMENTARY INFORMATION: The Program provides a system of no-fault compensation individuals who have been injured by specified childhood vaccines. Subtitle 2 of Title XXI of the PHS Act, 42 U.S.C. 300aa–10 *et seq.,* provides that those seeking compensation are to file a petition with the United States Court of Federal Claims and to serve a copy of the petition to the Secretary of HHS, who is named as the respondent in each proceeding. The Secretary has delegated this responsibility under the Program to HRSA. The Court is directed by statute to appoint special masters who take evidence, conduct hearings as appropriate, and make initial decisions as to eligibility for, and amount of, compensation.

A petition may be filed with respect to injuries, disabilities, illnesses, conditions, and deaths resulting from vaccines described in the Vaccine Injury Table (the Table) set forth at 42 CFR 100.3. This Table lists for each covered childhood vaccine the conditions that may lead to compensation and, for each condition, the time period for occurrence of the first symptom or manifestation of onset or of significant aggravation after vaccine administration. Compensation may also be awarded for conditions not listed in the Table and for conditions that are manifested outside the time periods specified in the Table, but only if the petitioner shows that the condition was caused by one of the listed vaccines.

Section 2112(b)(2) of the PHS Act, 42 U.S.C. 300aa–12(b)(2), requires that ''[w]ithin 30 days after the Secretary receives service of any petition filed under section 2111 the Secretary shall publish notice of such petition in the **Federal Register**.'' Set forth below is a list of petitions received by HRSA on November 1, 2020, through November 30, 2020. This list provides the name of petitioner, city and state of vaccination (if unknown then city and state of person or attorney filing claim), and case number. In cases where the Court has redacted the name of a petitioner

and/or the case number, the list reflects such redaction.

Section 2112(b)(2) also provides that the special master ''shall afford all interested persons an opportunity to submit relevant, written information'' relating to the following:

1. The existence of evidence ''that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition,'' and

2. Any allegation in a petition that the petitioner either:

a. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by'' one of the vaccines referred to in the Table, or

b. ''[S]ustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine'' referred to in the Table.

In accordance with Section 2112(b)(2), all interested persons may submit written information relevant to the issues described above in the case of the petitions listed below. Any person choosing to do so should file an original and three (3) copies of the information with the Clerk of the United States Court of Federal Claims at the address listed above (under the heading ''For Further Information Contact''), with a copy to HRSA addressed to Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, 5600 Fishers Lane, 08N146B, Rockville, Maryland 20857.

The Court's caption (Petitioner's Name v. Secretary of HHS) and the docket number assigned to the petition should be used as the caption for the written submission. Chapter 35 of title 44, United States Code, related to paperwork reduction, does not apply to information required for purposes of carrying out the Program.

Thomas J. Engels,

Administrator.

List of Petitions Filed

1. Katherine Cummings and Jared Cummings on behalf of O.C., Newark, Ohio, Court of Federal Claims No: 20–1358V
2. Wisteria Peoples on behalf of S.P., Cleveland, Ohio, Court of Federal Claims No: 20–1507V
3. Annette Thompson, Grand Rapids, Michigan, Court of Federal Claims No: 20–1508V
4. James Kunysz and Kathy Kunysz on behalf of C.K., Mason, Ohio, Court of Federal Claims No: 20–1509V
5. Gregory Thaxton, Greenville, South Carolina, Court of Federal Claims No: 20–1510V
6. Betty Haxton, Anaheim, California, Court of Federal Claims No: 20–1512V
7. Stanton Allaben, Cashiers, North Carolina, Court of Federal Claims No: 20–1513V
8. Kimberly Starnes, Monroe, North Carolina, Court of Federal Claims No: 20–1514V
9. Abigail Stratton, Dyer, Indiana, Court of Federal Claims No: 20–1515V
10. Bryan Stone on behalf of K.S., Reynoldsburg, Ohio, Court of Federal Claims No: 20–1516V
11. Gloria Supernaw, Coalinga, California, Court of Federal Claims No: 20–1517V
12. Linda Potts, Dallas, Texas, Court of Federal Claims No: 20–1518V
13. Todd Irish, Clarkston, Michigan, Court of Federal Claims No: 20–1519V
14. Judy Rousseau, Maple Grove, Minnesota, Court of Federal Claims No: 20–1523V
15. Sarah Voeller on behalf of N.V., St. Louis Park, Missouri, Court of Federal Claims No: 20–1526V
16. Dru Elliott, Walnut Creek, California, Court of Federal Claims No: 20–1527V
17. Kristin Bassett, Fort Wayne, Indiana, Court of Federal Claims No: 20–1528V
18. Stacee Blake, Jenks, Oklahoma, Court of Federal Claims No: 20–1532V
19. Andrew Bowling, Kingsport, Tennessee, Court of Federal Claims No: 20–1536V
20. Wilma Phillips, Lithonia, Georgia, Court of Federal Claims No: 20–1537V
21. Helena McHale, Saratoga Springs, Florida, Court of Federal Claims No: 20–1538V
22. Margarita Gonzalez-Figueroa, Canovanas, Puerto Rico, Court of Federal Claims No: 20–1540V
23. Mary K. Johnson, Hart, Michigan, Court of Federal Claims No: 20–1541V
24. Jacqueline Pankey, Fayetteville, Georgia, Court of Federal Claims No: 20–1542V
25. Lalita Nandkumar, Waterbury, Connecticut, Court of Federal Claims No: 20–1543V
26. Ralph Balcom, Oregon City, Oregon, Court of Federal Claims No: 20–1544V
27. George Japaridze, Tucker, Georgia, Court of Federal Claims No: 20–1545V
28. Sofia Jeorgina Galvan, San Diego, California, Court of Federal Claims No: 20–1546V
29. Sandy M. Foukarakis, Point Pleasant Beach, New Jersey, Court of Federal Claims No: 20–1547V
30. Alisen Hughes, Red Bank, New Jersey, Court of Federal Claims No: 20–1548V
31. Jane Derego on behalf of Estate of Lawrence Derego, Deceased, Boston, Massachusetts, Court of Federal Claims No: 20–1549V
32. Virginia Aldridge, Boston, Massachusetts, Court of Federal Claims No: 20–1550V
33. Deborah Wharton, Loganville, Georgia, Court of Federal Claims No: 20–1551V
34. Travis Lutz, Knoxville, Iowa, Court of Federal Claims No: 20–1553V
35. Ambra Rankins, Lake Charles, Louisiana, Court of Federal Claims No: 20–1554V
36. John Courson, Lake Oswego, Oregon, Court of Federal Claims No: 20–1555V
37. Linda Jarosz, Perrysburg, Ohio, Court of Federal Claims No: 20–1556V
38. Valerie E. Wuebben, Yankton, South Dakota, Court of Federal Claims No: 20–1558V
39. Carla Carter on behalf of C.C., Annapolis, Maryland, Court of Federal Claims No: 20–1559V
40. Virginia Lamine, Green Bay, Michigan, Court of Federal Claims No: 20–1560V
41. Carolyn Parker, Washington, Missouri, Court of Federal Claims No: 20–1561V
42. Dawn Patterson, Altoona, Pennsylvania, Court of Federal Claims No: 20–1562V
43. Hayley Chang, Fairfax, Virginia, Court of Federal Claims No: 20–1564V
44. Lyndsey Langley, Missoula, Montana, Court of Federal Claims No: 20–1568V
45. Daniel Egan, M.D., Alpine, Utah, Court of Federal Claims No: 20–1569V
46. Christine Cossette, Boston, Massachusetts, Court of Federal Claims No: 20–1570V
47. Julie Cornell, Canton, Ohio, Court of Federal Claims No: 20–1571V
48. Rose Marie Donahue, Huntington Station, New York, Court of Federal Claims No: 20–1572V
49. Jennifer Zimmerman and Chad Zimmerman on behalf of C.Z., Middletown, Pennsylvania, Court of Federal Claims No: 20–1573V

50. Larry Kroninger, Troy, Missouri, Court of Federal Claims No: 20–1575V
51. Elizabeth Eshelman on behalf of A.E., Norman, Oklahoma, Court of Federal Claims No: 20–1576V
52. Travis Childress, Winston-Salem, North Carolina, Court of Federal Claims No: 20–1577V
53. Dianne Leach, Sanford, Florida, Court of Federal Claims No: 20–1578V
54. Towanda Banks, Baton Rouge, Louisiana, Court of Federal Claims No: 20–1580V
55. Jenna Roberts, Fort Campbell, Kentucky, Court of Federal Claims No: 20–1581V
56. Natalie C. Espinoza, Santa Barbara, California, Court of Federal Claims No: 20–1582V
57. Susan Hodgin, Nashville, Tennessee, Court of Federal Claims No: 20–1583V
58. David Carl Letner, Lisbon, Ohio, Court of Federal Claims No: 20–1584V
59. Michael Cannon, Jr. on behalf of Estate of Katie Cannon, Deceased, Wyandotte, Michigan, Court of Federal Claims No: 20–1586V
60. Louis Ciminieri, Boston, Massachusetts, Court of Federal Claims No: 20–1587V
61. Willie L. Carter, Seattle, Washington, Court of Federal Claims No: 20–1588V
62. Cherish Moore, Plattsburgh, New York, Court of Federal Claims No: 20–1589V
63. Brent Stamm, Columbus, Ohio, Court of Federal Claims No: 20–1590V
64. Geraldine Mavin, Allentown, Pennsylvania, Court of Federal Claims No: 20–1591V
65. Amy Tappendorf, Des Moines, Iowa, Court of Federal Claims No: 20–1592V
66. Seth M. Niesen, Seattle, Washington, Court of Federal Claims No: 20–1593V
67. Joanne Davies, New York, New York, Court of Federal Claims No: 20–1595V
68. Meloni Sue DeVries, Bend, Oregon, Court of Federal Claims No: 20–1596V
69. Keith Pickett, Stuttgart, Arkansas, Court of Federal Claims No: 20–1598V
70. Eddie Darrell Alexander, II, Los Angeles, California, Court of Federal Claims No: 20–1599V
71. Cheri Brewster, Indianapolis, Indiana, Court of Federal Claims No: 20–1604V
72. Sherran Lynn Wasserman, Toccoa, Georgia, Court of Federal Claims No: 20–1605V
73. Amy Laws, Columbus, Ohio, Court of Federal Claims No: 20–1606V
74. Laura Liebenrood on behalf of A.H., Collierville, Tennessee, Court of Federal Claims No: 20–1607V
75. Julia Marino, Morristown, New Jersey, Court of Federal Claims No: 20–1608V
76. Jennifer Grow, Glenview, Illinois, Court of Federal Claims No: 20–1609V
77. Kaitlin McKenzie, Morgantown, West Virginia, Court of Federal Claims No: 20–1610V
78. Rita A. Parks, Rochester, New York, Court of Federal Claims No: 20–1611V
79. Reine Carre, Austin, Texas, Court of Federal Claims No: 20–1613V
80. Raena Todd, Utica, New York, Court of Federal Claims No: 20–1615V
81. Cynthia Cole, Williamsville, New York, Court of Federal Claims No: 20–1616V
82. Christine Davidson, Manchester, Ohio, Court of Federal Claims No: 20–1617V
83. Lois Bejma, Mt. Vernon, Illinois, Court of Federal Claims No: 20–1619V
84. Hau'oli Makaonaonakupana L. Sproat-Lancaster, Grand Junction, Colorado, Court of Federal Claims No: 20–1620V
85. Kimerley Hilbrich, Boston, Massachusetts, Court of Federal Claims No: 20–1621V
86. Yashica Tuttle and M.H. on behalf of Marcus Hairston, Lexington, North Carolina, Court of Federal Claims No: 20–1622V
87. D. Douglas Rice, Sioux City, Iowa, Court of Federal Claims No: 20–1623V
88. Robin England, Knoxville, Tennessee, Court of Federal Claims No: 20–1625V
89. Andrea C. Everhart, Winston-Salem, North Carolina, Court of Federal Claims No: 20–1626V
90. Linda Cox, Boston, Massachusetts, Court of Federal Claims No: 20–1628V
91. Jude Gaydos, Allentown, Pennsylvania, Court of Federal Claims No: 20–1629V
92. Barbara Mills, London, Kentucky, Court of Federal Claims No: 20–1630V
93. Courtney Kunysz, Mason, Ohio, Court of Federal Claims No: 20–1633V
94. Dorris Lund, Kokomo, Indiana, Court of Federal Claims No: 20–1635V
95. Tracee Gleichner, Boston, Massachusetts, Court of Federal Claims No: 20–1636V
96. Jennifer Walton, Butler, Pennsylvania, Court of Federal Claims No: 20–1637V
97. Jillian Merrill, Indianapolis, Indiana, Court of Federal Claims No: 20–1638V
98. Cynde Wall, Guthrie, Oklahoma, Court of Federal Claims No: 20–1639V
99. Anita Delaney, Jackson, Tennessee, Court of Federal Claims No: 20–1640V
100. William Plummer, Jr., San Dimas, California, Court of Federal Claims No: 20–1641V
101. Maria Quinones, Carmel, Indiana, Court of Federal Claims No: 20–1642V
102. Margo Davis, Galveston, Texas, Court of Federal Claims No: 20–1643V
103. Cindy Stuart, Lubbock, Texas, Court of Federal Claims No: 20–1644V
104. Tina Lekas, Allison Park, Pennsylvania, Court of Federal Claims No: 20–1645V
105. Jeffrey Braun, Colorado Springs, Colorado, Court of Federal Claims No: 20–1646V
106. Janis Geist, Wichita, Kansas, Court of Federal Claims No: 20–1647V
107. Rhonda Hernandez, Nashville, Tennessee, Court of Federal Claims No: 20–1648V
108. Andrew Peterson, Oakland Park, Florida, Court of Federal Claims No: 20–1649V
109. Jennifer Lindsay, Clackamas, Oregon, Court of Federal Claims No: 20–1650V
110. April Parsons, Santa Rosa, California, Court of Federal Claims No: 20–1651V
111. Lori Seawel, Boston, Massachusetts, Court of Federal Claims No: 20–1652V
112. Bruce Edmonds, Boston, Massachusetts, Court of Federal Claims No: 20–1653V
113. Mallory J. Spiker, Pittsburgh, Pennsylvania, Court of Federal Claims No: 20–1657V
114. David Kim, Lawrenceville, Georgia, Court of Federal Claims No: 20–1658V
115. Melody Gerry, Madison, Wisconsin, Court of Federal Claims No: 20–1659V
116. Janis Berson, Boston, Massachusetts, Court of Federal Claims No: 20–1660V
117. Tammy Sweeney, Greensboro, North Carolina, Court of Federal Claims No: 20–1661V
118. Eric Mates, Lyons, New Jersey, Court of Federal Claims No: 20–1662V

119. Lisa Eisman, Norwalk, Connecticut, Court of Federal Claims No: 20–1664V
120. William Ranks, Camp Verde, Arizona, Court of Federal Claims No: 20–1665V
121. Nancy Richmond, Greenville, North Carolina, Court of Federal Claims No: 20–1666V
122. Carol Kempkes, Des Moines, Iowa, Court of Federal Claims No: 20–1667V
123. Anna-Lis Seevers, Big Rapids, Michigan, Court of Federal Claims No: 20–1669V
124. Lisa Jackson, Englewood, Ohio, Court of Federal Claims No: 20–1670V
125. Marilyn Duncan, Burkesville, Kentucky, Court of Federal Claims No: 20–1671V
126. Mary Brown, Frankenmuth, Michigan, Court of Federal Claims No: 20–1672V
127. Nina Watkins, Upper Marlboro, Maryland, Court of Federal Claims No: 20–1673V
128. Thomas Ross, Olmsted Township, Ohio, Court of Federal Claims No: 20–1674V
129. Michele Hunter, Torrington, Connecticut, Court of Federal Claims No: 20–1675V
130. Jacqueline Bowling, Pikeville, Kentucky, Court of Federal Claims No: 20–1676V
131. Janet Sincebaugh, Williamsville, New York, Court of Federal Claims No: 20–1677V
132. Stacey Neves on behalf of I. N., New York, New York, Court of Federal Claims No: 20–1678V
133. Elisabeth Preitauer, Wichita Falls, Texas, Court of Federal Claims No: 20–1679V
134. Dominick Clemente, Brooklyn, New York, Court of Federal Claims No: 20–1680V
135. Theresa Jackson, Boston, Massachusetts, Court of Federal Claims No: 20–1681V
136. Charles Edwards, Lumberton, Texas, Court of Federal Claims No: 20–1682V
137. Charles Edwards, Lumberton, Texas, Court of Federal Claims No: 20–1683V
138. Barbara Lytes-Williams, Batesburg, South Carolina, Court of Federal Claims No: 20–1684V
139. Yaneth Garcia on behalf of A.M., Williamsville, New York, Court of Federal Claims No: 20–1685V
140. Frances Kraemer, Boston, Massachusetts, Court of Federal Claims No: 20–1687V
141. Jane Robinson, Boston, Massachusetts, Court of Federal Claims No: 20–1688V
142. Pavlo Chyshkevych and Nataliya Chyshkevych on behalf of R.C., Phoenix, Arizona, Court of Federal Claims No: 20–1689V
143. Janet Burgo, Atlanta, Georgia, Court of Federal Claims No: 20–1691V
144. Reginald Holmes, Clermont, Florida, Court of Federal Claims No: 20–1693V
145. Jean Cefalu, New Orleans, Louisiana, Court of Federal Claims No: 20–1694V
146. Joel Nichols, North Billerica, Massachusetts, Court of Federal Claims No: 20–1695V
147. Paul Wooters, Southlake, Texas, Court of Federal Claims No: 20–1696V
148. Deborah Liter, Madison, Indiana, Court of Federal Claims No: 20–1697V
149. Carrie Parent, Myrtle Beach, South Carolina, Court of Federal Claims No: 20–1698V
150. Charles Stella, New York, New York, Court of Federal Claims No: 20–1699V
151. Pamela Havice, Boston, Massachusetts, Court of Federal Claims No: 20–1701V
152. Anita Hall Darroca, Indianapolis, Indiana, Court of Federal Claims No: 20–1702V
153. Regis Grice, Waupun, Wisconsin, Court of Federal Claims No: 20–1703V
154. Stephen Vaccaro, Boston, Massachusetts, Court of Federal Claims No: 20–1704V
155. Bill Tackett, Jr., Lutz, Florida, Court of Federal Claims No: 20–1705V
156. Shakeyla Barber, Bronx, New York, Court of Federal Claims No: 20–1706V
157. Teresa Davis, Boston, Massachusetts, Court of Federal Claims No: 20–1707V
158. Clifford Gray, Antioch, Tennessee, Court of Federal Claims No: 20–1708V
159. Barbara Benson, Dresher, Pennsylvania, Court of Federal Claims No: 20–1709V
160. Nancy Dubrow, Beverly Hills, California, Court of Federal Claims No: 20–1710V

[FR Doc. 2020–28548 Filed 12–23–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Interdisciplinary, Community-Based Linkages

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL) will hold public meetings for the 2021 calendar year (CY). Information about ACICBL, agendas, and materials for these meetings can be found on the ACICBL website at *https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/meetings/index.html.*

DATES: ACICBL meetings will be held on:

- January 14, 2021, 10:00 a.m.–5:00 p.m. Eastern Time (ET) and January 15, 2021, 10:00 a.m.–5:00 p.m. ET;
- February 17, 2021, 10:00 a.m.–5:00 p.m. ET; and
- August 5, 2021, 10:00 a.m.–5:00 p.m. ET.

ADDRESSES: Meetings may be held by teleconference, Adobe Connect webinar, and/or in-person. For updates on how the meetings will be held, visit the ACICBL website 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will also be posted. If a meeting is held in-person, it will be held at 5600 Fishers Lane, Rockville, Maryland 20857. For meeting information updates, go to the ACICBL website meeting page at *https://www.hrsa.gov/advisory-committees/interdisciplinary-community-linkages/index.html.*

FOR FURTHER INFORMATION CONTACT: Shane Rogers, Designated Federal Official, Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, Room 15N142, Rockville, Maryland 20857; 301–443–5260; or *SRogers@hrsa.gov.*

SUPPLEMENTARY INFORMATION: The ACICBL provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning the activities under sections 750–760, Title VII, Part D of the Public Health Service (PHS) Act. The ACICBL

submits an annual report to the Secretary of HHS and to Congress describing its activities, including findings and recommendations made by the ACICBL concerning the activities under sections 750–760 of the PHS Act.

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2021 meetings, agenda items may include, but are not limited to, policy and program development and other significant matters related to activities authorized under Part D of the PHS Act as well as issues related to the pending Committee reports. Refer to the ACICBL website listed above for all current and updated information concerning the CY 2021 ACICBL meetings, including meeting times, draft agendas, and meeting materials that will be posted 30 calendar days before the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to the ACICBL should be sent to Shane Rogers using the contact information above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Shane Rogers using the contact information listed above at least 10 business days before the meeting(s) they wish to attend.

If a meeting is held in-person, it will occur in a federal government building and attendees must go through a security check to enter. Non-U.S. citizen attendees must notify HRSA of their planned attendance at an in-person meeting at least 20 business days prior to the meeting in order to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–28466 Filed 12–23–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made against Yihong Wan, Ph.D. (Respondent), Associate Professor, Department of Pharmacology, University of Texas Southwestern Medical Center (UTSMC). Respondent engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Institute of Diabetes and Digestive and Kidney (NIDDK), National Institutes of Health (NIH), grant R01 DK089113. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on December 8, 2020, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Yihong Wan, Ph.D., University of Texas Southwestern Medical Center: Based on the report of an investigation conducted by UTSMC and additional analysis conducted by ORI in its oversight review, ORI found that Respondent, Associate Professor, Department of Pharmacology, UTSMC, engaged in research misconduct in research supported by PHS funds, specifically NIDDK, NIH, grant R01 DK089113.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, and/or recklessly falsifying and/or fabricating bone histomorphometry data by altering or creating Excel data table values for additional bone samples that did not exist or were not analyzed and by falsely stating means and standard deviations calculated from experiments with N values

(*i.e.,* number of mouse samples) that were larger than the actual N values in the following published paper:

• miR–34a blocks osteoporosis and bone metastasis by inhibiting osteoclastogenesis and Tgif2. *Nature* 2014;512(7515):431–5 (hereafter referred to as ''*Nature* 2014''). Retraction in: *Nature* 2020 Jun;582(7810):134.

Specifically, ORI found that Respondent knowingly, intentionally, and/or recklessly falsified and/or fabricated bone histomorphometry data in eight (8) extended figures of one (1) published paper by manually falsifying and/or fabricating data values within multiple Excel spreadsheets and by creating increased N values without testing additional samples. Specifically:

• In Extended Figure 1i of *Nature* 2014, Respondent fabricated female vertebrae histomorphometry data by multiplying fourteen (14) different numerical values representing male mouse vertebrae data by a factor of 0.95 to create female vertebrae values in one (1) Excel spreadsheet

• in Extended Figures 1i, 2d, 3d, 3h, 4h, 6a, 6e, and 9g of *Nature* 2014, Respondent falsified histomorphometry data for ninety-nine (99) data table values from two (2) Excel spreadsheets representing bone parameters for male distal femur, male vertebrae, female distal femur, and female vertebrae samples

• in Extended Figure 4h of *Nature* 2014, respondent fabricated bone histomorphometry data by reporting that the means and standard deviations were calculated from experiments with a value of six (6) to eight (8) mice per experimental condition, when respondent calculated the means and standard deviations from only three (3) mice (N = 3)

Dr. Wan entered into a Voluntary Settlement Agreement (Agreement) and agreed to the following:

(1) Respondent agreed to have her research supervised for a period of three (3) years beginning on December 8, 2020. Respondent agreed that prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval. The supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution. Respondent agreed that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI. Respondent agreed to maintain responsibility for compliance with the agreed upon supervision plan.

(2) The requirements for Respondent's supervision plan are as follows:

i. A committee of 2–3 senior faculty members at the institution who are familiar with Respondent's field of research, but not including Respondent's supervisor or collaborators, will provide oversight and guidance for a period of three (3) years from the effective date of the Agreement. The committee will review primary data from Respondent's laboratory on a quarterly basis and submit a report to ORI at six (6) month

intervals, setting forth the committee meeting dates and Respondent's compliance with appropriate research standards and confirming the integrity of Respondent's research.

ii. The committee will conduct an advance review of any PHS grant applications (including supplements, resubmissions, etc.), manuscripts reporting PHS-funded research submitted for publication, and abstracts. The review will include a discussion with Respondent of the primary data represented in those documents and will include a certification to ORI that the data presented in the proposed application/publication are supported by the research record.

(3) Respondent agreed that for a period of three (3) years beginning on December 8, 2020, any institution employing her shall submit, in conjunction with each application of PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract.

(4) If no supervisory plan is provided to ORI, Respondent agreed to provide certification to ORI at the conclusion of the supervision period that she has not engaged in, applied for, or had her name included on any application, proposal, or other request for PHS funds without prior notification to ORI.

(5) Respondent agreed to exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on December 8, 2020.

Dated: December 21, 2020.

Elisabeth A. Handley,

Director, Office of Research Integrity, Office of the Assistant Secretary for Health.

[FR Doc. 2020–28566 Filed 12–23–20; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Biomedical Devices for Ventricular Repair.

Date: January 22, 2021.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Stephanie J Webb, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–V, Bethesda, MD 20892, (301) 827–7992, *stephanie.webb@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 18, 2020.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28527 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: September 1–2, 2021.

Open: September 01, 2021, 10:00 a.m. to 1:15 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 02, 2021, 1:25 p.m. to 1:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition Subcommittee.

Date: September 1–2, 2021.

Open: September 02, 2021, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 02, 2021, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: September 1–2, 2021.

Open: September 02, 2021, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy

Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 02, 2021, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: September 1–2, 2021.

Open: September 02, 2021, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: September 02, 2021, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm.,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 18, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28523 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: February 1, 2021.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.

Date: February 2, 2021.

Open: 11:00 a.m. to 4:00 p.m.

Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council.

Place: National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Thomas M. Vollberg, Sr., Ph.D., National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, Maryland 20892–5465, 301–402–1366, *Thomas.Vollberg@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: NIMHD: *https://www.nimhd.nih.gov/about/advisory-council/,* where an agenda and any additional information for the meeting will be posted when available.

Dated: December 18, 2020.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28528 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Chimeric Antigen Receptor (CAR) Therapies for the Treatment of FMS-Like Tyrosine Kinase 3 (FLT3) Expressing Malignancies Using Natural Killer Cells (NK Cells) Transduced With Retroviral or Lentiviral Vectors

AGENCY: National Institutes of Health, HHS

ACTION: Notice

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Senti Bio (''Senti''), located in South San Francisco, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before January 12, 2021 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: at Email: *jim.knabb@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–133–2016–0: FLT3-Specific Chimeric Antigen Receptors and Methods Using Same

1. US Provisional Patent Application 62/342,394, filed May 27, 2016 (E–133–2016–0–US–01)
2. International Patent Application PCT/US2017/034,691, filed May 26, 2017 (E–133–2016–0–PCT–02)
3. EP Patent Application No.:17729627.4, filed December 11, 2018 (E–133–2016/0–EP–03)

4. US Patent Application No.: 16/304,552, filed November 26, 2018 (E–133–2016/0–US–05
5. Australia Patent Application No.: 2017271606, filed November 13, 2018 (E–133–2016/0–AU–06)
6. Canadian Patent Application No.: 3025516, filed November 23, 2018 (E–133–2016/0–CA–07)
7. Japan Patent Application No.: 2018–561669, filed November 22, 2018 (E–133–2016/0–JP–08)

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the fields of use may be limited to the following:

An exclusive license to: ''the development and commercialization of a universal or split chimeric antigen receptor (CAR)-based immunotherapy using autologous or allogeneic T cells transduced with lentiviral vectors, or autologous or allogeneic NK cells transduced with retroviral vectors, including but not limited to lentiviral vectors, for the prophylaxis or treatment of cancers expressing FMS-like tyrosine kinase 3 (FLT3; also known as CD135), wherein the CAR construct binds to the FLT3-binding domain referenced as NC7 in the invention, but NC7 is not included in the CAR construct. Specifically excluded from the field of use for this exclusive license are FLT3-specific CAR-based immunotherapies wherein the CAR construct comprises the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain.'' For clarity, ''universal/split CAR-based immunotherapy'' in the context of this license means CAR therapies wherein the FLT3-binder is soluble and infused into the patient independent from the modified lymphocytes. The patient is then infused with lymphocytes expressing a CAR construct that recognizes the FLT3-binder (an exogenous protein tag like FITC or the heavy chain of an scFv for example).

A co-exclusive license to: ''the development and commercialization of a multi-specific FLT3 CAR-based immunotherapy using autologous or allogeneic T cells transduced with lentiviral vectors, or autologous or allogeneic NK cells transduced with retroviral vectors, including but not limited to lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets FLT3 (comprised of the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of FLT3-expressing cancers.'' For clarity, ''multi-specific FLT3 CAR-based immunotherapy'' in the context of this license means therapies wherein the CAR-expressing lymphocytes recognize FLT3 and additional antigens.

A co-exclusive license to: ''the development of a FLT3-specific Regulated or Switch or Logic-Gated CAR-based immunotherapy using autologous or allogeneic T cells transduced with lentiviral vectors, or autologous or allogeneic NK cells transduced with retroviral vectors, including but not limited to lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets FLT3 (comprised of the FLT3-binding domain referenced as NC7 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of FLT3-expressing cancers.'' For clarity, FLT3-specific Regulated or Switch or Logic-Gated CAR-based immunotherapy in the context of this license means therapies wherein the CAR-expressing lymphocytes recognize FLT3 and are engineered to respond to one or more signals, such as recognizing one or more additional antigens, responding to an exogenous small molecule, or responding to a biological signal (but not necessarily all of the signals).

These technologies disclose therapies to treat AML by utilizing CARs that recognize AML cells through a binder for FLT3, specifically through the FLT3 binder known as NC7. FLT3 is a validated immunotherapeutic target that is expressed on the surface of cancerous cells, its expression is amplified on the surface of acute myelogenous leukemia (AML) blasts and cells in chronic myeloid leukemia-blast crisis (CML–BC).

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 17, 2020.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2020–28569 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; NTU Bench/Clinical Testing for COVID–19.

Date: February 3, 2021.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jing Chen, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892–4874, *chenjing@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 18, 2020.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28526 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Improving Oxygen Delivery.

Date: January 22, 2021.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Giuseppe Pintucci, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205–H, Bethesda, MD 20892, (301) 827–7969, *Pintuccig@nhlbi.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: December 18, 2020.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28530 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Basic Neuroscience of Aging Review Committee, January 19, 2021, 11:00 a.m. to January 21, 2021, 04:00 p.m., National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 which was published in the **Federal Register** on November 25, 2020, 85 FR 75345.

The meeting notice is amended to change the date of the meeting from January 20–21 to January 19–21, 2021. The meeting is closed to the public.

Dated: December 18, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28525 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The cooperative agreement applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the cooperative agreement applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel CTSA Review.

Date: January 29, 2021.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Center for Advancing Translational Sciences; National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Victor Henriquez, Ph.D., Scientific Review Officer, Office of Scientific Director, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892–4878, 301–435–0813, *henriquv@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: December 18, 2020.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28529 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meeting will be open to the public as indicated below, with a short public comment period at the end. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: May 12–13, 2021.

Open: May 12, 2021, 10:00 a.m. to 1:15 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: May 13, 2021, 1:25 p.m. to 1:45 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757 *malikk@niddk.nih.gov.*

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory

Council; Diabetes, Endocrinology and Metabolic Diseases Subcommittee.

Date: May 12–13, 2021.

Open: May 13, 2021, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: May 13, 2021, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452, Bethesda, MD 20892 (301) 594–4757, *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition Subcommittee.

Date: May 12–13, 2021.

Open: May 13, 2021, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: May 13, 2021, 11:45 a.m. to 1:15 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Boulevard, Room 7329, MSC 5452 Bethesda, MD 20892, (301) 594–4757 *malikk@niddk.nih.gov*.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Kidney, Urologic and Hematologic Diseases Subcommittee.

Date: May 12–13, 2021.

Open: May 13, 2021, 10:00 a.m. to 11:30 a.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Closed: May 13, 2021, 11:45 a.m. to 1:15 p.m.

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Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm.,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: December 18, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–28524 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Use of A CD47 Phosphorodiamidate Morpholino Oligomer for the Treatment, Prevention, and Diagnosis Of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Morphiex Biotherapeutics (''Morphiex'') located in Boston, MA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before January 12, 2021 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Jaime M. Greene, Senior Licensing and Patenting Manager at *greenejaime@mail.nih.gov*.

SUPPLEMENTARY INFORMATION:

Intellectual Property

- U.S. Provisional Patent Application No. 60/850,132, filed October 6, 2006, now abandoned (HHS Ref. No. E–227–2006–0–US–01);
- U.S. Provisional Patent Application No. 60/864,153, filed November 02, 2006, now abandoned (HHS Ref. No. E–227–2006–1–US–01);
- U.S. Provisional Patent Application No. 60/888,754, filed February 07, 2007, now
- abandoned (HHS Ref. No. E–227–2006–2–US–01);
- U.S. Provisional Patent Application No. 60/910,549, filed April 06, 2007, now abandoned (HHS Ref. No. E–227–2006–3–US–01);
- U.S. Provisional Patent Application No. 60/956,375, filed August 16, 2007, now abandoned (HHS Ref. No. E–227–2006–4–US–01);
- PCT Patent Application No. PCT/2007/080647, filed October 5, 2007, now abandoned (HHS Ref. No. E–227–2006–5–PCT–01);
- U.S. Patent No. 8,236,313, filed April 3, 2009, issued August 7, 2012 (HHS Ref. No. E–227–2006–5–US–02);
- Canadian Patent Application No. 2,665,287, October 5, 2007 (HHS Ref. No. E–227–2006–5–CA–03);
- Australian Patent No. 2007319576, filed October 5, 2007, issued May 1, 2014 (HHS Ref. No. E–227–2006–5–AU–04);
- European Patent No. 2076537, filed March 27, 2009, issued August 22, 2018 (HHS Ref. No. E–227–2006–5–EP–05);
- U.S. Patent Application No. 13/546,931, filed July 11, 2012 (HHS Ref. No. E–227–2006–5–US–06);
- U.S. Patent Number 8,557,788, filed July 11, 2012, issued October 15, 2013 (HHS Ref. No. E–227–2006–5–US–07);
- European Patent No. 2695896, filed October 5, 2007, issued August 22, 2018(HHS Ref. No. E–227–2006–5–EP–08);
- Australian Patent No. 2014201936, filed April 4, 2014, issued October 20, 2016 (HHS Ref. No. E–227–2006–5–AU–09);
- U.S. Patent No. 10370439, filed September 29, 2014, issued August 6, 2019 (HHS Ref. No. E–227–2006–5–US–10);
- Australian Patent No. 2016238894, filed October 6, 2016, issued February 22, 2018 (HHS Ref. No. E–227–2006–5–AU–11);
- Australian Patent No. 2018200921, filed February 8, 2018, issued September 24, 2020 (HHS Ref. No. E–227–2006–5–AU–12)

• European Patent Application No. 18183780.8, filed July 16, 2018 (HHS Ref. No. E–227–2006–5–EP–13);
• German Patent No. 2076537, issued August 22, 2018, filed March 27, 2009 (HHS Ref. No. E–227–2006–5–DE–14);
• French Patent No. 2076537, issued August 22, 2018, filed March 27, 2009 (HHS Ref. No. E–227–2006–5–FR–15);
• United Kingdom Patent No. 2076537, issued August 22, 2018, filed March 27, 2009 (HHS Ref. No. E–227–2006–5–GB–16);
• German Patent No. 2695896, issued August 22, 2018, filed October 5, 2007 (HHS Ref. No. E–227–2006–5–DE–17);
• French Patent No. 2695896, issued August 22, 2018, filed October 5, 2007 (HHS Ref. No. E–227–2006–5–FR–18);
• United Kingdom Patent No. 2695896, issued August 22, 2018, filed October 5, 2007 (HHS Ref. No. E–227–2006–5–GB–19);
• U.S. Patent Application No. 16/443,415, filed June 17, 2019 (HHS Ref. No. E–227–2006–5–US–20);
• Australia Patent Application No. 2020230283, filed September 10, 2020 Pending (HHS Ref. No. E–227–2006–5–AU–21);
• Provisional Patent Application No. 61/621,994, filed April 9, 2012, now abandoned (HHS Ref. No. E–086–2012–0–US–01);
• Provisional Patent Application No. 61/735,701, filed December 11, 2012, now abandoned (HHS Ref. No. E–086–2012–1–US–01);
• PCT Patent Application No. PCT/US2013/035838, filed April 9, 2013, now abandoned (HHS Ref. No. E–086–2012–2–PCT–01);
• Australian Patent No. 2013246040, issued March 14, 2019, filed April 9, 2013 (HHS Ref. No. E–086–2012–2–AU–02);
• Canadian Patent No. 2869913, issued September 10, 2019, filed April 9, 2013 (HHS Ref. No. E–086–2012–2–CA–03);Start Printed Page 327
• European Patent No. 2836591, filed April 9, 2013, issued June 6, 2018 (HHS Ref. No. E–086–2012–2–EP–04);
• US Patent No. 10407665, issued September 10, 2019, filed October 2, 2014 (HHS Ref. No. E–086–2012–2–US–05);
• German Patent No. 2836591, issued June 6, 2018, filed April 9, 2013 (HHS Ref. No. E–086–2012–2–DE–07);
• French Patent No. 2836591, issued June 6, 2018, filed April 9, 2013 (HHS Ref. No. E–086–2012–2–FR–08);
• United Kingdom Patent No. 2836591, issued June 6, 2018, filed April 9, 2013 (HHS Ref. No. E–086–2012–2–GB–09);
• US Patent Application No. 16/521,251, filed July 24, 2019 (HHS Ref. No. E–086–2012–2–US–10);
• Provisional Patent Application No. 61/086,991, filed August 7, 2008, now abandoned (HHS Ref. No. E–153–2008–0–US–01);
• PCT Patent Application No. PCT/US2009/052902, filed August 5, 2009, now abandoned (HHS Ref. No. E–153–2008–0–PCT–02);
• Australian Patent No. 2009279676, issued July 30, 2015, filed August 5, 2009 (HHS Ref. No. E–153–2008–0–AU–03);
• Canadian Patent No. 2732102, issued January 2, 2018, filed August 5, 2009 (HHS Ref. No. E–153–2008–0–CA–04);
• European Patent No. 2340034, filed August 5, 2009, issued January 27, 2016 (HHS Ref. No. E–153–2008–0–EP–05);
• US Patent No. 8951527, issued February 10, 2015, filed February 3, 2011 (HHS Ref. No. E–153–2008–0–US–06);
• German Patent No. 602009036069.8, issued January 27, 2016, filed August 5, 2009 (HHS Ref. No. E–153–2008–0–DE–07);
• French Patent No. 2340034, issued January 27, 2016, filed August 5, 2009 (HHS Ref. No. E–153–2008–0–FR–08);
• United Kingdom Patent No. 2340034, issued January 27, 2016, filed August 5, 2009 (HHS Ref. No. E–153–2008–0–GB–09);
• Provisional Patent Application No. 61/779,587, filed March 13, 2013, now abandoned (HHS Ref. No. E–296–2011–0–US–01);
• PCT Patent Application No. PCT/US2014/025989, filed March 13, 2014, now abandoned (HHS Ref. No. E–296–2011–0–PCT–02);
• Australian Patent No. 2014244083, issued January 10, 2019, filed March 13, 2014, now abandoned (HHS Ref. No. E–296–2011–0–AU–03);
• Canadian Patent Application No. 2905418, filed March 13, 2014 (HHS Ref. No. E–296–2011–0–CA–04);
• European Patent Application No. 14718255.4, filed March 13, 2014 (HHS Ref. No. E–296–2011–0–EP–05);
• US Patent Application No. 14/775,428, filed September 11, 2015 (HHS Ref. No. E–296–2011–0–US–06).
• U.S. Provisional Patent Application No. 62/062,675, filed October 10, 2014, now abandoned (HHS Ref. No E–263–2014–0–US–01);
• PCT Patent Application No. PCT/US2015/055029, filed October 9, 2015, now abandoned (HHS Ref. No E–263–2014–0–PCT–02);
• Australia Patent Application No. 2015329696, filed October 9, 2015(HHS Ref. No E–263–2014–0–AU–03);
• Canadian Patent Application No. 2964173, filed October 9, 2015 (HHS Ref. No. E–263–2014–0–CA–04);
• European Patent No. 3204420, filed October 9, 2015, issued September 2, 2020 (HHS Ref. No E–263–2014–0–EP–05);
• U.S. Patent Application No. 15/517,345, filed April 6, 2017 (HHS Ref. No E–263–2014–0–US–06);
• German Patent No. 3204420, issued September 2, 2020, filed October 9, 2015 (HHS Ref. No E–263–2014–0–DE–07);
• French Patent No. 3204420, issued September 2, 2020, filed October 9, 2015 (HHS Ref. No E–263–2014–0–FR–08);
• United Kingdom Patent No. 3204420, issued September 2, 2020, filed October 9, 2015 (HHS Ref. No E–263–2014–0–GB–09).

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of all of the above Licensed Patent Rights for the following: ''The use of the CD47 phosphorodiamidate morpholino oligomers (PMO, morpholino, Sequence: 5'-CGTCACAGGCAGGACCCACTGCCCA-3'), in combination with radiotherapy, for the treatment, prevention, and diagnosis of cancer.'' For the Licensed Patent Rights encompassed by technologies with the HHS. Ref. No. starting with E–263–2014, the prospective exclusive license territory may be worldwide and the field of use may be limited to: ''The use of the CD47 phosphorodiamidate morpholino oligomers (PMO, morpholino, Sequence: 5'-CGTCACAGGCAGGACCCACTGCCCA-3') for the treatment, prevention, and diagnosis of cancer.''

This technology concerns CD47, originally named integrin-associated protein, which is a receptor for thrombospondin-1 (TSP1), a major component of platelet α-granules from which it is secreted on platelet activation. A number of important roles for CD47 have been defined in regulating the migration, proliferation, and survival of vascular cells, and in regulation of innate and adaptive immunity. Nitric Oxide (NO) plays an important role as a major intrinsic vasodilator, and it increases blood flow to tissues and organs. Disruption of this process leads to peripheral vascular disease, ischemic heart disease, stroke, diabetes and many more significant diseases. The inventors have discovered that TSP1 blocks the beneficial effects of NO and prevents it from dilating blood vessels and increasing blood flow to organs and tissues. Additionally, they discovered that this regulation requires

TSP1 interaction with its cell receptor, CD47. These inventors have also found that blocking TSP1–CD47 interaction through the use of antisense morpholino oligonucleotides, peptides or antibodies have several therapeutic benefits including the treatment of cancer.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: December 17, 2020.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2020–28570 Filed 12–23–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The date of April 21, 2021 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Los Angeles County, California and Incorporated Areas Docket No.: FEMA–B–1716	
City of El Segundo	City Hall, 350 Main Street, El Segundo, CA 90245.
City of Hermosa Beach	City Hall, 1315 Valley Drive, Hermosa Beach, CA 90254.
City of Long Beach	City Hall, 333 West Ocean Boulevard, 9th Floor, Long Beach, CA 90802.
City of Los Angeles	Department of Public Works, 1149 South Broadway, Suite 810, Los Angeles, CA 90015.
City of Malibu	City Hall, 23825 Stuart Ranch Road, Malibu, CA 90265.
City of Manhattan Beach	Engineering Department, 3621 Bell Avenue, Manhattan Beach, CA 90266.
City of Palos Verdes Estates	City Hall, 340 Palos Verdes Drive West, Palos Verdes Estates, CA 90274.

Community	Community map repository address
City of Rancho Palos Verdes	City Hall, 30940 Hawthorne Boulevard, Rancho Palos Verdes, CA 90275.
City of Redondo Beach	Planning Department, 531 North Gertruda Avenue, Redondo Beach, CA 90277.
City of Santa Monica	Department of Public Works, 1685 Main Street, Santa Monica, CA 90401.
City of Torrance	Community Development, 3031 Torrance Boulevard, Torrance, CA 90503.
Unincorporated Areas of Los Angeles County	Los Angeles County Watershed Management, 900 South Fremont Avenue, Alhambra, CA 91803.
Gallatin County, Montana and Incorporated Areas Docket No.: FEMA–B–1836	
City of Bozeman	Stiff Professional Building, Engineering Department, 20 East Olive Street, 1st Floor, Bozeman, MT 59715.
Unincorporated Areas of Gallatin County	Gallatin County Courthouse, Planning Department, 311 West Main Street, Room 108, Bozeman, MT 59715.

[FR Doc. 2020–28474 Filed 12–23–20; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0013]

Agency Information Collection Activities; Revision, of a Currently Approved Collection: Application for Travel Document. Removal of Instructions Regarding the Haitian Family Reunification Program and Filipino World War II Veteran Parole Program

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration

Services (USCIS) invites the general public and other Federal agencies to comment on this proposed revision of a currently approved collection of information. The revision is necessary to announce and implement a change in USCIS policy to terminate the Haitian Family Reunification Parole (HFRP) program and the Filipino World War II Veterans Parole (FWVP) program, to rescind the applicable policy statements, and to revise the Instructions for USCIS Form I–131, Application for Travel Document, to remove references to and provisions regarding those programs. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding these policy changes, the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments will be accepted for 60 days until February 26, 2021.

Effective date of changes: These changes will be effective as of the date the form is approved by OMB. Cases that have already been filed as of the effective date of the new form and policies will be processed to a decision.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0013 in the body of the letter, the agency name and Docket ID USCIS–2007–0045. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2007–0045. USCIS is limiting communications for this Notice as a result of USCIS' COVID–19 response actions.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

I. Background:

Section 11 of Executive Order 13767 of January 25, 2017, ''Border Security and Immigration Enforcement Improvements, (Section 11) provides that ''[i]t is the policy of the executive branch to end the abuse of parole and asylum provisions currently used to prevent the lawful removal of removable aliens.'' Section 11(d) instructs DHS to ''take appropriate action to ensure that parole authority under section 212(d)(5) of the [Immigration and Nationality Act (''INA'')] (8 U.S.C. 1182(d)(5)) is exercised only on a case-by-case basis in accordance with the plain language of the statute, and in all circumstances only when an alien demonstrates an urgent humanitarian need or a significant public benefit derived from such parole.''

On February 20, 2017, then-Secretary of Homeland Security Kelly issued a memorandum entitled ''Implementing the President's Border Security and Immigration Enforcement Improvements Policies.'' In that memorandum, Secretary Kelly stated that ''[t]he statutory language authorizes parole in individual cases only where, after careful consideration of the circumstances, it is necessary because of demonstrated urgent humanitarian reasons or significant public benefit. . . .[i]n my judgment, such authority should be exercised sparingly.'' Additionally, it stated that ''[t]he practice of granting parole to certain aliens in pre-designated categories in order to create immigration programs not established by Congress, has contributed to a border security crisis, undermined the integrity of the immigration laws and the parole

process, and created an incentive for illegal immigration.'' [1]

Accordingly, USCIS undertook a review of existing categorical parole programs. USCIS is announcing the termination of HFRP and FWVP programs and is revising the Instructions for Form I–131 to remove references to and provisions regarding those programs. USCIS is also revising the form to remove references to the Cuban Family Reunification Parole (CFRP) Program.

A. HFRP

DHS established the HFRP program in 2014 as an exercise of its discretionary parole authority to permit certain eligible Haitians in Haiti who are the beneficiaries of approved family-based immigrant petitions to join their family members in the United States for an initial period of three years while they wait for immigrant visas to become available. 79 FR 75581 (Dec. 18, 2014). Consistent with INA section 212(d)(5), 8 U.S.C. 1182(d)(5), the decision to parole a particular alien into the country was a case-by-case, discretionary determination.

B. FWVP

In 2016, USCIS determined that paroling qualified applicants under FWVP would generally yield a ''significant public benefit'' (recognizing sacrifices of Filipino World War II veterans). 81 FR 28907 (May 9, 2016). USCIS also determined that grants of parole under the FWVP program would often address urgent humanitarian concerns (recognizing the advanced age of these veterans and the need for care by their alien family members). *Id.* Consistent with section 212(d)(5), 8 U.S.C. 1182(d)(5), the decision to parole a particular alien was a case-by-case, discretionary determination.

C. Explanation for Change

For both the HFRP and FWVP programs, DHS broadly exercised its statutory parole authority for multiple members of a narrowly defined group. Notwithstanding the perceived benefits of these categorical parole programs when they were established, this Administration undertook a renewed analysis. Consistent with Secretary Kelly's February 20, 2017 implementing memorandum, USCIS has determined that, as a matter of policy, the HRFP and FWVP programs do not meet DHS's obligation to narrowly exercise its parole authority.

[1] *https://www.dhs.gov/sites/default/files/publications/17_0220_S1_Implementing-the-Presidents-Border-Security-Immigration-Enforcement-Improvement-Policies.pdf.*

Therefore, DHS is now rescinding the determination that there is a presumption that there are significant public benefit or urgent humanitarian reasons for parole requests from new applicants who meet the specific criteria established under HFRP and FWVP programs. Accordingly, new applicants who meet the FWVP and HFRP criteria will no longer be presumed to have demonstrated that there are significant public benefit or urgent humanitarian reasons present in their case by virtue of meeting HFRP and FWVP criteria.

USCIS will continue to adjudicate requests from current beneficiaries of the HFRP and FWVP programs who are already in the United States under the existing standards of those programs and who request a new period of parole.

II. Administrative Procedure Act (APA)

A. Discretionary Policy Statement

USCIS established the HFRP and FWVP programs through policy statements announced by **Federal Register** notice (FRN). 81 FR 28907; 79 FR 75581. USCIS also revised the Instructions for Form I–131 to provide instructions and evidence requirements to implement the policies. USCIS did not change its regulations.

The HFRP and FWVP programs were established using DHS' discretionary parole authority found in INA section 212(d)(5)(A), 8 U.S.C. 1182(d)(5)(A), and 8 CFR 212.5(c)–(d). An alien does not have a right to parole and there is no obligation for DHS to grant parole. Parole is an exercise of the Secretary's discretionary authority to permit an alien to temporarily enter the United States for certain reasons on a case-by-case basis for urgent humanitarian reasons or for a significant public benefit. The APA exempts from its requirements for public notice and comment general statements of policy, ''issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power.'' *Lincoln* v. *Vigil,* 508 U.S. 182, 197 (1993) (quoting *Chrysler Corp.* v. *Brown,* 441 U.S. at 302, n. 31 (1979) (quoting Attorney General's Manual on the Administrative Procedure Act 30, n. 3 (1947))). The termination of the HFRP and FWVP programs does not change the statutory standard for parole, and parole will remain an avenue for DHS to authorize, in its discretion, for certain aliens to travel to the United States. Therefore, terminating the HFRP and FWVP programs is exempt from the notice and comment requirements of the APA as a general statement of policy advising the public prospectively of the manner in which USCIS will exercise a discretionary power. *Lincoln,* 508 U.S. at 197.

DHS has reviewed this policy change and determined that it would be highly unlikely to adversely affect the substantive rights of some of the affected parties. DHS understands that it must show that there are good reasons for the new policy and acknowledge its conscious change of course, and that reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy. *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502 (2009) (citing *Smiley* v. *Citibank (South Dakota), N. A.,* 517 U.S. 735, 742 (1996). Executive Order 13767 instructs DHS to take appropriate action to ensure that parole authority under section 212(d)(5) of the INA, 8 U.S.C. 1182(d)(5), is exercised only on a case by case basis in accordance with the plain language of the statute, and in all circumstances only when an alien demonstrates urgent humanitarian reasons or a significant public benefit derived from such parole. DHS believes the existing broad presumption that there are significant public benefit or urgent humanitarian reasons to consider parole for new applicants who meet the specific pre-established criteria under the HFRP and FWVP programs is inconsistent with the Executive Order and Secretary Kelly's implementing guidance directing that the policy of DHS is to exercise its parole authority narrowly.

1. HFRP

The **Federal Register** notice establishing HFRP states, ''By expanding existing legal means for Haitians to immigrate, the HFRP Program serves a significant public benefit by promoting safe, legal, and orderly migration to the United States. Furthermore, it supports U.S. goals for Haiti's long-term reconstruction and development. Once paroled into the United States, HFRP Program beneficiaries will be eligible to apply for employment authorization, and those who are able to work may contribute to Haiti's post-earthquake reconstruction and development through remittances.'' 79 FR 75581.

DHS has determined Haiti has made significant progress recovering from the 2010 earthquake and subsequent effects. With U.S. and international support for recovery, reconstruction, and development programs, Haiti has achieved significant improvements in basic health indicators, agricultural production, and jobs creation, according to the U.S. Department of State. 98 percent of 1.5 million people displaced

following the earthquake have been resettled as of 2020, according to the International Organization for Migration. In light of these determinations, DHS has determined that the HFRP program no longer serves a significant public benefit for new applicants.

2. FWVP

The **Federal Register** notice establishing FWVP states, ''Recognizing the contributions and sacrifices of Filipino veterans who fought for the United States during World War II and their families, USCIS has decided to implement the FWVP policy. In many cases, ''paroling these family members may also allow them to provide support and care for elderly veterans or their surviving spouse. . . . For certain Filipino American family members, this wait can exceed 20 years'' 81 FR 28097. Further, ''In light of the circumstances described above, among other considerations, USCIS believes that the parole of qualified applicants who establish on a case-by-case basis that they are eligible for consideration under this policy and merit a favorable exercise of discretion would generally yield a 'significant public benefit.' Additionally, considering the advanced age of World War II Filipino veterans and their spouses, and their increased need for care and companionship, grants of parole under the FWVP policy would often address urgent humanitarian concerns. In all cases, whether to parole a particular alien under this policy is a discretionary determination that will be made on a case-by-case basis.'' *Id.*

DHS has determined that the FWVP program is inconsistent with the policy decision to narrowly exercise DHS' parole authority in making determinations of significant public benefit. With regard to urgent humanitarian concerns, DHS has no data substantiating that the admission of participants in the FWVP program routinely addresses an urgent humanitarian concern. An eligible alien may request parole even if the veteran and spouse the alien is petitioning to support are both deceased. The parole of an alien may not actually be yielding any significant public or humanitarian benefit in such instances. For these reasons, DHS believes that new FWVP program applications are more appropriately adjudicated through an individual application instead of a categorical program with a presumption of a significant public benefit or urgent humanitarian concern.

B. Reliance Interest

DHS has taken into account serious reliance interests that may be engendered by the 2014 and 2016 HFRP and FWVP policies. With respect to initial and pending applicants, DHS has determined that potential applicants cannot reasonably be determined to have taken an action in detrimental reliance on DHS or USCIS continuing these programs. It is not reasonable that potential applications would make major changes in their lives or incur significant expenses in anticipation that DHS would continue these programs in perpetuity and that they would be able to apply and be approved. With respect to current HFRP and FWVP parolees, DHS acknowledges the reliance interest of those aliens who are not yet lawful permanent residents and will make a new period of parole under the criteria of these programs available to them, on a case-by-case basis, to ensure continued eligibility. Further discussion of these reliance interests follows.

1. Reliance Interest of HFRP Parolees

For HFRP, DHS has determined that any alien who has not yet applied for the HFRP program is unlikely to have incurred costs or been harmed based on relying on DHS continuing that policy because the petitioner must receive an invitation to apply, and USCIS has not issued any such invitations since 2016. Thus, although DHS is changing its past pattern and practice, the program has not been open for new applicants for four years, and a potential applicant will not be surprised by the change and will not have suffered harm as a result of acting in reliance on the continuation of the HFRP program. Haitian petitioners with an approved Form I–130 or their Haitian beneficiary relatives should not complete a Form I–131, incur expenses, and take actions in reliance on USCIS being able to process their application when they cannot do so on their own accord and without an invitation from USCIS. Nevertheless, DHS is formally announcing in this notice that the HFRP program will be terminated to provide advance notice to parties who may be affected. To the extent that an alien has a pending Form I–131 for HFRP as of the date of this notice, USCIS will process and adjudicate that request to completion. USCIS welcomes public comments on all of the effects of this change in policy.

With respect to granting a new parole period (''re-parole'') for HFRP beneficiaries already paroled into the United States, DHS acknowledges that a current beneficiary has significant reliance interest in the continuation of the program as they were when they were granted parole. A current parolee decided to accept the USCIS invitation to apply for parole and expend the time, effort, and expense to uproot his or her life and move to the United States as a parolee, instead of staying in Haiti and waiting for an immigrant visa to become available. When the program was established, USCIS informed HFRP beneficiaries that it was their responsibility to seek re-parole in the United States until eligible to adjust status and they should apply for re-parole at least 90 days before parole expires. USCIS informed approved HFRP beneficiaries that, if their immigrant visa is still unavailable at the time their parole expires, they must apply to USCIS for a new parole authorization and pay the required fee. Therefore, HFRP program beneficiaries are expected to apply for lawful permanent resident status as soon as their immigrant visa becomes available. The majority of HFRP beneficiaries will have an immigrant visa available at the time their parole expires. Given these reliance interests, DHS will accept requests for re-parole under the existing standards of the HFRP program.

2. Reliance Interest of FWVP Parolees

For FWVP, DHS has determined that an applicant who has not yet applied for the FWVP program is unlikely to have incurred costs or been harmed based on relying on DHS continuing that policy. To the extent that an alien is in the process of completing and filing a request, USCIS will provide two public notices of the impending form, policy and procedure change. Aliens who are currently in the process of completing their paperwork may also apply for the FWVP program until the date that it is terminated, which is when the Form I–131 changes go into effect. To the extent that applicants who are not yet working on, researching, and gathering necessary evidence for an application may no longer receive parole after this change, DHS believes the FWVP program is inconsistent with its narrower interpretation of the parole authority and the public policy goals supported by a narrow use of its parole authority (as described in Secretary Kelly's memorandum) justify and outweigh any minor reliance interests of those aliens who may have contemplated filing an application for FWVP but have not yet done so at the time the program is formally terminated. If an alien has an I –131 application for FWVP pending as of December 28, 2020, USCIS will process and adjudicate that request to completion. USCIS welcomes public

comments on all of the effects of this change in policy.

As for granting re-parole to FWVP beneficiaries already paroled initially into the United States, DHS acknowledges that a current beneficiary as well as U.S. citizen petitioners may have a significant reliance interest in the continuation of the program as it was when the alien was granted parole. A current parolee decided to avail himself or herself to the USCIS opportunity to apply for parole and expend the time, effort, and expense to uproot his or her life and move to the United States as a parolee, instead of staying in the Philippines and waiting for an immigrant visa to become available. The beneficiary (the Filipino war veteran or his or her spouse) may also have a reliance interest. The veteran or spouse may have paid the fees and expended other resources in contemplation of relatives coming to the United States to care for them, or may have forgone other living situations that were available to them if they did not have the care of the relative who had been able to join them in the US. When the program was established, USCIS informed FWVP parolees that it was their responsibility to seek re-parole in the United States until eligible to adjust status and they should apply for re-parole at least 90 days before parole expires. USCIS informed approved FWVP parolees that if their immigrant visa is still unavailable at the time their parole expires, they must apply to USCIS for a re-parole and pay the required fee. Therefore, FWVP program beneficiaries are expected to apply for lawful permanent resident status as soon as their immigrant visa becomes available.

Given these reliance interests, DHS will accept requests for re-parole under the existing standards of the FWVP program.

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0045 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application for Travel Document.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–131; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Certain aliens, principally permanent or conditional residents, refugees or asylees, applicants for adjustment of status, aliens in Temporary Protected Status (TPS), and aliens abroad seeking humanitarian parole who need to apply for a travel document to lawfully enter or reenter the United States. Eligible recipients of deferred action under childhood arrivals (DACA) may now request an advance parole documents based on humanitarian, educational and employment reasons. Lawful permanent residents may now file requests for travel permits (transportation letter or boarding foil).

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–131 is 379,483 and the estimated hour burden per response is 1.9 hours; the estimated total number of respondents for biometrics processing is 75,100 and the estimated hour burden per response is 1.17 hours; the estimated total number of respondents for passport-style photos is 325,000 and the estimated hour burden per response is 0.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 971,385 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $111,568,002.

Dated: December 18, 2020.

Joseph Edlow,

Deputy Director for Policy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2020–28475 Filed 12–23–20; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–CONC–30740; PPWOBSADC0, PPMVSCS1Y.Y00000]

Notice of Intent to Extend Concession Contracts and Award Temporary Concession Contracts

AGENCY: National Park Service, Interior.

ACTION: Public Notice.

SUMMARY: The National Park Service gives public notice that it proposes to extend each concession contract listed in the Table 1 below until the date shown in the ''Extension Expiration Date'' column or until the effective date of a new contract, whichever comes first. The National Park Service also gives public notice that it proposes to award the temporary concession contracts listed in Table 2 below.

DATES: The National Park Service intends that the concession contract extensions and temporary concession contracts will be effective on the dates shown in the ''Extension Effective Date'' and ''Effective Date'' columns, respectively.

FOR FURTHER INFORMATION CONTACT: Kurt Rausch, Program Chief, Commercial Services Program, National Park Service, 1849 C Street, NW, Mail Stop 2410, Washington, DC 20240; Telephone: 202–513–7156.

SUPPLEMENTARY INFORMATION: The concession contracts listed in Table 1

below will expire by their terms on or before October 31, 2021. Under 36 CFR 51.23 the National Park Service proposes to extend each contract until the date shown in the ''Extension Expiration Date'' column or until the effective date of a new contract, whichever comes first. The National Park Service has determined that the proposed extensions are necessary to avoid an interruption of visitor services and has taken all reasonable and appropriate steps to consider alternatives to avoid such an interruption. The extension of the existing contracts does not confer or affect any rights with respect to the award of new concession contracts.

Under 36 CFR 51.24(a) the National Park Service proposes to award a temporary concession contract, for a term not to exceed three years, to a qualified person to provide the visitor services currently provided under each contract listed in Table 2 below. The National Park Service has determined that the proposed award of a temporary contract is necessary to avoid an interruption of visitor services and has taken all reasonable and appropriate steps to consider alternatives to avoid such an interruption. The National Park Service intends that the temporary contract will be effective on the dates shown in the ''Effective Date'' column below. This notice is not a request for proposals.

The publication of this notice reflects the intent of the National Park Service but does not bind the National Park Service to extend or award any of the contracts listed in the tables below.

TABLE 1—CONCESSION CONTRACTS EXTENDED UNTIL THE DATE SHOWN OR UNTIL THE EFFECTIVE DATE OF A NEW CONTRACT, WHICHEVER COMES FIRST

Park unit	CONCID	Concessioner	Extension effective date	Extension expiration date
Acadia NP	ACAD014–09	Carriages of Acadia, Inc	1/1/2021	12/31/2021
Badlands NP	BADL001–09	Badlands Lodge, LLC	1/1/2021	12/31/2021
Bryce Canyon NP	BRCA003–10	The Lodge at Bryce Canyon, LLC	1/1/2021	12/31/2021
Channel Islands NP	CHIS001–11	The Island Packers Corporation	1/1/2022	12/31/2022
Death Valley NP	DEVA002–11	NEG282, LLC	1/13/2021	1/12/2022
Dry Tortugas NP	DRTO001–08	Yankee Freedom III, LLC	11/1/2021	10/31/2022
Everglades NP	EVER005–10	Florida National Parks and Monuments Assoc	9/1/2021	8/31/2022
Fire Island NS	FIIS003–09	Sayville Ferry Service, Inc	11/1/2020	10/31/2021
Fire Island NS	FIIS004–11	Davis Park Ferry Co., Inc	11/1/2020	10/31/2021
Fort McHenry NM&HS	FOMC001–10	Evelyn Hill Corporation	12/1/2020	11/30/2021
Glacier Bay NP&P	GLBA038–16	Lindblad's Special Expeditions, Inc	1/1/2021	12/31/2022
Glacier Bay NP&P	GLBA041–16	Alaskan Catamaran LLC	1/1/2021	12/31/2022
Glacier Bay NP&P	GLBA042–16	Inner Sea Discoveries, LLC	1/1/2021	12/31/2022
Glacier Bay NP&P	GLBA043–16	American Cruise Lines	1/1/2021	12/31/2022
Golden Gate NRA	GOGA002–09	American Youth Hostels, Inc	5/1/2021	4/30/2022
Grand Canyon NP	GRCA004–10	Mangum Enterprises, Inc	1/1/2021	12/31/2021
Great Smoky Mtns NP	GRSM002–09	LeConte Lodge Limited Partnership	1/1/2021	12/31/2021
Great Smoky Mtns NP	GRSM003–10	Tammy Monhollen	1/1/2021	12/31/2021
Great Smoky Mtns NP	GRSM010–10	Great Smoky Mountains Association	1/1/2021	12/31/2021
Muir Woods NM	MUWO001–09	Cloudless Skies Parks Company, LLC	10/1/2020	9/30/2021
Olympic NP	OLYM003–10	Aramark Sports & Entertainment Services LLC	2/1/2021	1/31/2022
Ozark NSR	OZAR001–10	Alley Spring Canoe Rental, LLC	1/1/2021	12/31/2021
Ozark NSR	OZAR018–10	Two Rivers Canoes, LLC	1/1/2021	12/31/2021
Point Reyes NS	PORE003–11	American Youth Hostels, Inc	10/17/2021	10/16/2022
Prince William Forest P	PRWI001–08	Recreational Adventures Campground, LLC	1/1/2021	12/31/2021
Southeast Region	SERO001–09	America's National Parks, Inc	1/1/2021	12/31/2021
Statue of Liberty NM	STLI004–09	Evelyn Hill Corporation	11/1/2021	10/31/2022
Voyageurs NP	VOYA002–11	Oveson Kab-Con, Inc	1/1/2021	12/31/2021
Yellowstone NP	YELL004–08	Yellowstone Park Service Stations, Inc	11/1/2020	10/31/2021
Yosemite NP	YOSE001–10	Best's Studio, Inc	3/1/2021	2/28/2022
Zion NP	ZION003–09	Xanterra Parks & Resorts, Inc	1/1/2021	12/31/2021

TABLE 2—TEMPORARY CONCESSION CONTRACTS

Park Unit	CONCID	Services	Effective date
Big Bend NP	BIBE002–08	Lodging, Food and Beverage, Retail, RV Park, Service Stations, and Other Services.	7/1/2021
Buck Island Reef NM	BUIS015–07	Interpretive Boat Tours, Guided Snorkeling and Guided Scuba Diving.	12/3/2020
Grand Canyon NP	GRCA002–08	Lodging, Food and Beverage, Retail, Service Station, and Other Services.	1/1/2021
Great Smoky Mtns NP	GRSM006–07	Guided Horseback Rides and Vending	12/1/2020
Statue of Liberty NM	STLI001–07	Ferry Service	3/29/2021

Justin Unger,

Associate Director, Business Services.

[FR Doc. 2020–28568 Filed 12–23–20; 8:45 am]

BILLING CODE 4312–53–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–644 and 731–TA–1494 (Final)]

Non-Refillable Steel Cylinders From China; Scheduling of the Final Phase of Countervailing Duty and Antidumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–644 and 731–TA–1494 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of non-refillable steel cylinders from China, provided for in 7310.29.00 and 7311.00.00 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be subsidized and sold at less-than-fair-value.

DATES: October 30, 2020.

FOR FURTHER INFORMATION CONTACT: Kristina Lara ((202) 205–3386), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov*.

SUPPLEMENTARY INFORMATION: *Scope.*—For purposes of these investigations, Commerce has defined the subject merchandise as ''certain seamed (welded or brazed), non-refillable steel cylinders meeting the requirements of, or produced to meet the requirements of, U.S. Department of Transportation (USDOT) Specification 39, TransportCanada Specification 39M, or United Nations pressure receptacle standard ISO 11118 and otherwise meeting the description provided below (non-refillable steel cylinders). The subject non-refillable steel cylinders are portable and range from 300-cubic inch (4.9 liter) water capacity to 1,526-cubic inch (25 liter) water capacity. Subject non-refillable steel cylinders may be imported with or without a valve and/or pressure release device and unfilled at the time of importation. Non-refillable steel cylinders filled with pressurized air otherwise meeting the physical description above are covered by this investigation. Specifically excluded are seamless nonrefillable steel cylinders.''

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by Commerce that certain benefits which constitute subsidies within the meaning of § 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in China of non-refillable steel cylinders, and that such products are being sold in the United States at less than fair value within the meaning of § 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on March 27, 2020, by Worthington Industries, Columbus, Ohio.

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*.) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on March 2, 2021, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on March 16, 2021. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html*. Interested parties should check the Commission's website periodically for updates. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before March 9, 2021. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on March 12, 2021. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to

present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is March 9, 2021. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for filing posthearing briefs is March 23, 2021. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before March 23, 2021. On April 9, 2021, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before April 13, 2021, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.
Issued: December 18, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020–28476 Filed 12–23–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Electrical Connectors and Cages, Components Thereof, and Products Containing the Same, DN 3516;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov* . The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Amphenol Corp. on December 18, 2020. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation certain electrical connectors and cages, components thereof, and products containing the same. The complaint names as respondents: Luxshare Precision Industry Co., Ltd. of China; Dongguan Luxshare Precision Industry Co. Ltd. of China; Luxshare Precision Limited (HK) of Hong Kong; and Luxshare-ICT Inc. of Milipitas, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the

issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3516'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel [2], solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS [3].

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.
Issued: December 18, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020–28520 Filed 12–23–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Plant-Derived Recombinant Human Serum Albumins (''rHSA'') and Products Containing Same, DN 3513;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov* . The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Ventria Bioscience Inc. on December 16, 2020. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain plant-derived recombinant human serum albumins (''rHSA') and products containing same. The complaint names as respondents: Wuhan Healthgen Biotechnology Corp. of China; ScienCell Research Laboratories, Inc. of Carlsbad, CA; Aspira Scientific, Inc. of Milpitas, CA; United States Biological Corporation of Salem, MA; eEnzyme LLC of Gaithersburg, MD; and antibodies-online, Inc. of Germany. The complainant requests that the Commission issue a general exclusion order, a limited exclusion order, cease and desist orders and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3513'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: December 16, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020–28465 Filed 12–23–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain IP Camera Systems including Video Doorbells and Components Thereof, DN 3517;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.*

General information concerning the Commission may also be obtained by accessing its internet server at United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of SkyBell Technologies, Inc., SB IP Holdings, LLC, and Eyetalk365, LLC on December 18, 2020. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain IP camera systems including video doorbells and components thereof. The complaint names as respondents: Vivint Smart Home, Inc. of Provo, UT; SimpliSafe, Inc. of Boston, MA; and Arlo Technologies Inc. of San Jose, CA. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3517'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: December 18, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020–28516 Filed 12–23–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–456 and 731–TA–1152 (Second Review)]

Citric Acid and Certain Citrate Salts From China

Determination

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the countervailing and antidumping duty orders on citric acid and certain citrate salts from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on May 1, 2020 (85 FR 25475) and determined on August 4, 2020 that it would conduct expedited reviews (85 FR 74759, November 23, 2020).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on December 18, 2020. The views of the Commission are contained in USITC Publication 5147 (December 2020), entitled *Citric Acid and Certain Citrate Salts from China: Investigation Nos. 701–TA–456 and 731–TA–1152 (Second Review).*

By order of the Commission.

Issued: December 18, 2020.

William Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2020–28502 Filed 12–23–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1125–NEW]

Agency Information Collection Activities; Proposed collection; comments requested; Office of the Chief Administrative Hearing Officer E-Filing Portal

AGENCY: Executive Office for Immigration Review, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Executive Office for Immigration Review (EOIR), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional days until January 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

If you need a copy of the proposed information collection instrument with instructions or additional information,

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

please contact Lauren Alder Reid, Assistant Director, Office of Policy, Executive Office for Immigration Review, 5107 Leesburg Pike, Suite 2500, Falls Church, VA 22041, telephone: (703) 305–0289.

SUPPLEMENTARY INFORMATION:

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Enhance the quality, utility, and clarity of the information to be collected; and/or

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1. *Type of Information Collection:* New Voluntary Collection.

2. *The Title of the Form/Collection:* Office of the Chief Administrative Hearing Officer E-Filing Portal.

3. *The agency form number:* There is no agency form number for this collection. The applicable component within the Department of Justice is the Office of the Chief Administrative Hearing Officer (OCAHO).

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals, Business or other for-profit, and not-for-profit institutions.

Abstract: The portal will allow parties in OCAHO cases to file complaints electronically, request electronic access to a case to which they are a party, file motions and requests electronically, and receive service of orders and decisions from OCAHO by email.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 69 respondents will respond and it will take approximately 10 minutes per response.

6. *An estimate of the total public burden (in hours) associated with the collection:* 18 annual burden hours.

If additional information is required contact: Melody D. Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405B, Washington, DC 20530.

Dated: December 21, 2020.

Melody D. Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–28578 Filed 12–23–20; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OMB Number NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection; Fourth National Juvenile Online Victimization Study (N–JOV4)

AGENCY: Office of Justice Programs, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until February 26, 2021.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Benjamin Adams, Social Science Analyst, National Institute of Justice, 810 Seventh Street NW, Washington, DC 20531 (email: *benjamin.adams@usdoj.gov;* telephone: 202–616–3687).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

—Evaluate whether the accuracy of the agency's estimate of the burden on the proposed collection of information, including the validity of the methodology and assumptions that were used;

—Evaluate whether and if so how the quality, utility, and clarity of the information collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

1. *Type of Information Collection:* New collection.

2. *The Title of the Form/Collection:* Fourth National Juvenile Online Victimization Study (N–JOV4).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Not applicable (new collection).

4. *Affected public who will be asked or required to respond, as well as a brief abstract:*

State, county, and local law enforcement agencies (LEAs). *Abstract:* The Fourth National Juvenile Online Victimization Study (N–JOV4) will include a pilot study to test data collection instruments and methods and a full survey administration designed to provide national estimates of technology facilitated sex crimes against children as well as details about victim, offenders, and investigations. The National Institute of Justice (NIJ) will use the information gathered in the national study in published reports and statistics. The reports will be made available to the U.S. Congress, practitioners, researchers, students, the media, and the general public via the NIJ website.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

Burden Hours for N–JOV4 Pilot Study

NIJ expects the 25 law enforcement agencies to spend an average of 15 minutes completing the mail screener survey, including the time to read the accompanying letter, identify eligible cases, consider additional search strategies as requested in the cover letter, and answer the questions (25×15 minutes = 6.25 hours). NIJ expects the

25 chiefs/department heads/Commanders to spend 20 minutes completing the telephone debriefing about the mail screener (25 × 20 minutes = 8.33 hours). NIJ expects the five internet Crimes Against Children (ICAC) investigators who are asked to complete telephone interviews on specific cases identified in the mail screener to spend an average of 60 minutes of their time which includes the debriefing about the interview (5 × 60 minutes = 5 hours). The total amount of time for the N–JOV4 pilot is 19.58 hours.

Burden Hours for N–JOV4 National Study

A total of 2,689 local, county, state and federal law enforcement agencies are included in the national stratified sample. All of these agencies except the three federal agencies will receive a mail screener, resulting a total of 2,686 non-federal agencies. NIJ estimates that the time to complete the screener will be five minutes for agencies with no eligible cases and 10 minutes for agencies with eligible cases, including the time to read the accompanying letter, identify eligible cases, and answer the questions. NIJ estimates that 1,343 (50%) of the law enforcement agencies will complete the screener by mail. Of these, 35% are expected to have at least one case; these agencies will take approximately 10 minutes each to complete the mail screener (470 × 10 = 78.33 hours). The remaining agencies who complete the screener survey by mail are expected to take approximately 5 minutes each to complete the mail screener (873 × 5 = 72.75 hours). This equals a total of 151.08 hours for completing the screener by mail. NIJ estimates that 36 percent of the law enforcement agencies will complete the screener by telephone. NIJ estimates that, of these 967 agencies who complete the screener by telephone, 338 will have a case (338 × 10 = 56.33 hours) and 629 will have no cases (629 × 5 = 52.42 hours) for a total of 108.75 hours for completing the mail screener by phone. Based on power analysis calculations, case-level telephone interviews will be completed for a sample of 2,000 eligible cases identified in the mail screener. NIJ estimates that the telephone surveys will take an average of 45 minutes, including 5 minutes for introductions and study details, 3 minutes for data retrieval, and 37 minutes for study questions (2,000 × 45 = 1,500 hours). The total amount of time for the N–JOV4 national study is 1,759.83 hours.

6. *An estimate of the total public burden (in hours) associated with the collection:*

There are an estimated 1,779.41 total burden hours associated with the N–JOV4 pilot study and the national study.

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: December 21, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–28579 Filed 12–23–20; 8:45 am]

BILLING CODE 4410–30–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Employment Navigator Data Collection and Matching

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Veterans' Employment and Training Service (VETS)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before January 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Anthony May by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Employment Navigator Data Collection and Matching information collection contains three forms:

- *Employment Navigator Intake Form:* A data collection mechanism for transitioning service members to provide general characteristics and background information as services are received from Employment Navigators.
- *Employment Navigator Partner Form:* Captures additional data that is captured from government and non-government partners who will provide the service member, veteran, or spouse addition job seeker assistance after Employment Navigator data entry is complete. This form also includes any employment-related outcomes (*e.g.* job placement, job retention, hourly wages earned) for each participant.
- *Transition Assistance Program (TAP) Partner Registration Form:* A registration and validation form that all necessary partner entities must complete in order to be considered for partner status.

For additional substantive information about this ICR, see the related notice published in the **Federal Register** on July 29, 2020 (85 FR 45701).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–VETS.

Title of Collection: Employment Navigator Data Collection and Matching.

OMB Control Number: 1293–0NEW.

Affected Public: Private Sector—Businesses or other for-profits; Individuals and Households.

Total Estimated Number of Respondents: 22,550.

Total Estimated Number of Responses: 22,550.

Total Estimated Annual Time Burden: 6,885 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: December 18, 2020.

Anthony May,

Management and Program Analyst.

[FR Doc. 2020–28571 Filed 12–23–20; 8:45 am]

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MILLENNIUM CHALLENGE CORPORATION

[MCC FR 20–10]

Report on the Selection of Eligible Countries for Fiscal Year 2021

AGENCY: Millennium Challenge Corporation.

ACTION: Notice.

SUMMARY: This report is provided in accordance with the Millennium Challenge Act of 2003, as amended. The report is set forth in full below.

Authority: Section 608(d)(2) of the Millennium Challenge Act of 2003, as amended, 22 U.S.C. 7707(d)(2) (the Act).

Dated: December 18, 2020.

Brian Finkelstein,

Acting VP/General Counsel and Corporate Secretary.

Report on the Selection of Eligible Countries for Fiscal Year 2021

Summary

This report is provided in accordance with section 608(d)(1) of the Millennium Challenge Act of 2003, as amended (the Act) (22 U.S.C. 7707(d)(1)).

The Act authorizes the provision of assistance under section 605 of the Act (22 U.S.C. 7704) to countries that enter into compacts with the United States to support policies and programs that advance the progress of such countries in achieving lasting poverty reduction through economic growth, and are in furtherance of the Act. The Act requires the Millennium Challenge Corporation (MCC) to determine the countries that will be eligible to receive assistance for the fiscal year, based on their demonstrated commitment to just and democratic governance, economic freedom, and investing in their people, as well as on the opportunity to reduce poverty through economic growth in the country. The Act also requires the submission of reports to appropriate congressional committees and the publication of notices in the **Federal Register** that identify, among other things:

1. The countries that are ''candidate countries'' for assistance for fiscal year (FY) 2021 based on their per-capita income levels and their eligibility to receive assistance under U.S. law, and countries that would be candidate countries, but for specified legal prohibitions on assistance (section 608(a) of the Act (22 U.S.C. 7707(a)));

2. The criteria and methodology that the Board of Directors of MCC (the Board) used to measure and evaluate the policy performance of the ''candidate countries'' consistent with the requirements of section 607 of the Act in order to determine ''eligible countries'' from among the ''candidate countries'' (section 608(b) of the Act (22 U.S.C. 7707(b))); and

3. The list of countries determined by the Board to be ''eligible countries'' for FY 2021, with justification for eligibility determination and selection for compact negotiation, including with which of the eligible countries the Board will seek to enter into compacts (section 608(d) of the Act (22 U.S.C. 7707(d))).

This is the third of the above-described reports by MCC for FY 2021. It identifies countries determined by the Board to be eligible under section 607 of the Act (22 U.S.C. 7706) for FY 2021 with which the MCC will seek to enter into compacts under section 609 of the Act (22 U.S.C. 7708), as well as the justification for such decisions. The report also identifies countries selected by the Board to receive assistance under MCC's threshold program pursuant to section 616 of the Act (22 U.S.C. 7715).

Eligible Countries

The Board met on December 15, 2020 to select those eligible countries with which the United States, through MCC, will seek to enter into a Millennium Challenge Compact pursuant to section 607 of the Act (22 U.S.C. 7706). The Board selected the following eligible country for such assistance for FY 2021: Sierra Leone. The Board also selected the following previously selected countries for compact assistance for FY 2021: Benin, Burkina Faso, Côte d'Ivoire, Malawi, Mozambique, Niger, Timor-Leste, and Tunisia.

Criteria

In accordance with the Act and with the ''Report on the Criteria and Methodology for Determining the Eligibility of Candidate Countries for Millennium Challenge Account Assistance in Fiscal Year 2021'' formally submitted to Congress on September 15, 2020, selection was based primarily on a country's overall performance in three broad policy categories: *Ruling Justly, Encouraging Economic Freedom,* and *Investing in People.* The Board relied, to the fullest extent possible, upon transparent and independent indicators to assess countries' policy performance and demonstrated commitment in these three broad policy areas. The Board compared countries' performance on the indicators relative to their income-level peers, evaluating them in comparison to either the group of countries with a GNI per capita equal to or less than $1,945, or the group with a GNI per capita between $1,946 and $4,045.

The criteria and methodology used to assess countries on the annual scorecards are outlined in the ''Report on the Criteria and Methodology for Determining the Eligibility of Candidate Countries for Millennium Challenge Account Assistance for Fiscal Year 2021.'' [1] Scorecards reflecting each country's performance on the indicators are available on MCC's website at *https://www.mcc.gov/who-we-select/scorecards.*

The Board also considered whether any adjustments should be made for data gaps, data lags, or recent events since the indicators were published, as well as strengths or weaknesses in particular indicators. Where appropriate, the Board took into account additional quantitative and qualitative information, such as evidence of a country's commitment to fighting corruption, investments in human development outcomes, or poverty rates. In keeping with legislative directives, the Board also considered the opportunity to reduce poverty and promote economic growth in a country, in light of the overall information available, as well as the availability of appropriated funds.

The Board sees the selection decision as an annual opportunity to determine where MCC funds can be most effectively used to support poverty reduction through economic growth in relatively well-governed, poor countries. The Board carefully considers the appropriate nature of each country partnership—on a case-by-case basis—based on factors related to poverty reduction through economic growth, the sustainability of MCC's investments, and the country's ability to attract and

[1] Available at *https://www.mcc.gov/resources/doc/report-selection-criteria-methodology-fy21.*

leverage public and private resources in support of development.

This was the third year the Board considered the eligibility of countries for concurrent compacts. In addition to the considerations for compact eligibility detailed above, the Board considered whether a country being considered for a concurrent compact is making considerable and demonstrable progress in implementing the terms of its existing compact.

This was the twelfth year the Board considered the eligibility of countries for subsequent compacts, as permitted under section 609(l) of the Act. MCC's engagement with partner countries is not open-ended, and the Board is deliberate when selecting countries for follow-on partnerships, particularly regarding the higher bar applicable to subsequent compact countries. In making these selection decisions, the Board considered—in addition to the criteria outlined above—the country's performance implementing its first compact, including the nature of the country's partnership with MCC, the degree to which the country has demonstrated a commitment and capacity to achieve program results, and the degree to which the country has implemented the compact in accordance with MCC's core policies and standards. To the greatest extent possible, these factors were assessed using pre-existing monitoring and evaluation targets and regular quarterly reporting. This information was supplemented with direct surveys and consultation with MCC staff responsible for compact implementation, monitoring, and evaluation. MCC published a Guide to Supplemental Information [2] and a related web page [3] regarding how MCC assesses performance on the Access to Credit, Business Start-Up, and Land Rights and Access indicators on the scorecard, in order to increase transparency about the type of supplemental information the Board uses to assess a country's policy performance. The Board also considered a country's commitment to further sector reform, as well as evidence of improved scorecard policy performance.

In addition, this is the fifth year where the Board considered an explicit higher bar for those countries close to the upper end of the candidate pool, looking closely in such cases at a country's access to development financing, the nature of poverty in the country, and its policy performance.

[2] Available at *https://www.mcc.gov/resources/doc/guide-to-supplemental-information.*

[3] Available at *https://www.mcc.gov/who-we-select/indicators/doing-business-indicators-fy21.*

Countries Newly Selected for Compact Assistance

Using the criteria described above, one candidate country under section 606(a) of the Act (22 U.S.C. 7705(a) was newly selected for assistance under section 607 of the Act (22 U.S.C. 7706): Sierra Leone. In accordance with section 609(k) of the Act, no candidate countries were newly selected to explore development of a concurrent compact program under section 607 of the Act (22 U.S.C. 7706).

Sierra Leone: Sierra Leone has been an engaged and committed partner in the threshold program, consistently demonstrating a willingness to adopt challenging reforms. It is also a remarkable example of the ''MCC Effect'', having strengthened its scorecard performance substantially through sustained reform efforts spanning two administrations. Sierra Leone passes the scorecard for the second year in a row in FY 2021, passing 13 indicators overall with strong performance on both the Democratic Rights and Control of Corruption ''hard hurdles.'' The country also took steps to strengthen its investment climate this year, including acceding to the New York Convention on the Recognition and Enforcement of Foreign Arbitral Awards. By selecting Sierra Leone for a compact, MCC will support the government's efforts to strengthen economic growth to reduce poverty.

Countries Selected to Continue Compact Development

Eight of the countries selected for compact assistance for FY 2021 were previously selected for FY 2020. Malawi, Mozambique, Timor-Leste, and Tunisia were selected to continue developing bilateral compacts. Benin, Burkina Faso, Côte d'Ivoire, and Niger were selected to continue developing concurrent compacts for the purpose of regional integration. Selection of these countries for FY 2021 was based on their continued or improved policy performance since their prior selection.

Countries Selected To Receive Threshold Program Assistance

The Board selected Kiribati to receive threshold program assistance.

Kiribati: Kiribati offers MCC the opportunity to engage with a country that faces significant challenges to economic growth. Kiribati is a strong scorecard performer, having consistently met the scorecard criteria, and passes 13 of 20 indicators in FY 2021. It passes the Control of Corruption hard hurdle and demonstrates some of the highest democratic rights scores of any MCC candidate country. Kiribati has been an important United States partner in the central Pacific since a treaty of friendship was signed in 1979, and this threshold program will build upon that relationship.

Countries Selected To Continue Developing Threshold Programs

The Board selected Ethiopia, The Gambia, and Kenya to continue developing threshold programs. Selection of these countries for FY 2021 was based on their continued performance since their prior selection.

Ongoing Review of Partner Countries' Policy Performance

The Board emphasized the need for all partner countries to maintain or improve their policy performance. If it is determined during compact implementation that a country has demonstrated a significant policy reversal, MCC can hold it accountable by applying MCC's Suspension and Termination Policy.[4]

[FR Doc. 2020–28491 Filed 12–21–20; 4:15 pm]

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[4] Available at *https://www.mcc.gov/who-we-select/suspension-or-termination.*

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (20–101)]

NASA Advisory Council; Technology, Innovation and Engineering Committee Meeting AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the National Aeronautics and Space Administration (NASA) announces a meeting of the Technology, Innovation and Engineering Committee of the NASA Advisory Council (NAC). This Committee reports to the NAC.

DATES: Wednesday, January 27, 2021, 11:00 a.m.–3:00 p.m., Eastern Time.

ADDRESSES: Meeting will be virtual only. See dial-in and Webex information below under ''Supplementary Information.''

FOR FURTHER INFORMATION CONTACT: Mr. Mike Green, Designated Federal Officer, Space Technology Mission Directorate, NASA Headquarters, Washington, DC 20546, via email at *g.m.green@nasa.gov* or 202–358–4710

SUPPLEMENTARY INFORMATION: As noted above, this meeting will be available telephonically or Webex only. If dialing

in via toll number, you must use a touch-tone phone to participate in this meeting. Any interested person may join via Webex at *https://nasaenterprise.webex.com,* the meeting number is 199 288 6288, and the password is n@cTIE012721. The toll number to listen by phone is 1–415–527–5035. To avoid using the toll number, after joining the Webex meeting, select the audio connection option that says, ''Call Me'' and enter your phone number. If using the desktop or web app, check the ''Connect to audio without pressing 1 on my phone'' box to connect directly to the meeting.

Note: If dialing in, please ''mute'' your telephone. The agenda for the meeting includes the following topics:

—Space Technology Mission Directorate (STMD) Update
—Lunar Surface Innovation Initiative Update
—Office of the Chief Technologist Update
—Office of the Chief Engineer Update

It is imperative that this meeting be held on this day to accommodate the scheduling priorities of the key participants.

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2020–28489 Filed 12–23–20; 8:45 am]

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NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (20–100)]

NASA Advisory Council; Human Exploration and Operations Committee Meeting, Including Joint Meeting With Science Committee

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the National Aeronautics and Space Administration (NASA) announces a meeting of the NASA Advisory Council (NAC) Human Exploration and Operations Committee. This meeting will include a joint meeting with the NAC Science Committee. These committees report to the NAC.

DATES: Wednesday, January 13, 2021, 11:30 a.m. to 2:30 p.m., Eastern Time; and Thursday, January 14, 2021, 1:00 p.m. to 5:15 p.m., Eastern Time.

ADDRESSES: Meeting will be virtual only. See dial-in and Webex information below under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Dr. Bette Siegel, Designated Federal Officer, Human Exploration and Operations Mission Directorate, NASA Headquarters, Washington, DC 20546, via email at *bette.siegel@nasa.gov* or 202–358–2245.

SUPPLEMENTARY INFORMATION: As noted above, this meeting will be open to the public telephonically and by Webex. Webex connectivity information is provided below. For audio, when joining the Webex event, you may use your computer or provide your phone number to receive a call back, otherwise, call the U.S. toll conference number listed. The Webex event address for January 13, 2021, is *https://nasaenterprise.webex.com/nasaenterprise/onstage/g.php?MTID=ef268da6a9daa9bd59ba35b80dd54bd65.* The event number is 199 568 2184, and the event password is 7mP6pAJvW@7. If needed, the U.S. toll conference number is 1–415–527–5035, the global call-in number is *https://nasaenterprise.webex.com/nasaenterprise/globalcallin.php?MTID=e2674fb32caeca0bff43bda0b1cae7208, and the* access code is 199 568 2184.

The Webex event address for January 14, 2021, is *https://nasaenterprise.webex.com/nasaenterprise/onstage/g.php?MTID=e6a0f7dd70d769cb581af3a729d8e4e85.* The event number is 199 200 6220 and the event password is YmpNdfH*926.

If needed, the U.S. toll conference number is 1–415–527–5035, the global call-in number is *https://nasaenterprise.webex.com/nasaenterprise/globalcallin.php?MTID=ef59221cc82e122a9c22f81cede9fc9b9,* and the access code is 199 200 6220.

The agenda for the meeting includes the following topics:

—Artemis Overview
—International Space Station
—Commercial Space
—Space Communications and Navigation
—Artemis Lunar Exploration and Science Planning by NASA's Human Exploration and Operations Mission Directorate (HEOMD) and Science Mission Directorate (SMD)

It is imperative that this meeting be held on this day to accommodate the scheduling priorities of the key participants

Patricia Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2020–28488 Filed 12–23–20; 8:45 am]

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NATIONAL CREDIT UNION ADMINISTRATION

Overhead Transfer Rate Methodology and Operating Fee Schedule Methodology

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice.

SUMMARY: In July 2020, the NCUA Board (Board) invited comment on the methodology used to determine the Overhead Transfer Rate (OTR). The Board also requested comment on proposed changes to the methodology it uses to determine how it apportions operating fees charged to federal credit unions (FCUs). The Board also proposed: clarifying the treatment of capital project budgets when calculating the operating fees; clarifying the treatment of miscellaneous revenues when calculating the operating fees; and modifying the approach for calculating the annual inflationary adjustments to the thresholds for the operating fee rate tiers. This final notice adopts those proposals and responds to comments on these topics as well as other subjects on which the Board sought comment in the notice.

FOR FURTHER INFORMATION CONTACT: James Holm, Supervisory Budget Analyst, Office of the Chief Financial Officer, at (703) 518–6570, Amy Ward or Julie Decker, Risk Officers, Office of Examination and Insurance at (703) 819–1770 or (703) 518–6384.

SUPPLEMENTARY INFORMATION: In July 2020, the Board issued a notice and request for comment on the OTR and operating fee methodologies.[1] In the notice, the Board detailed the legal background and historical and current practice for both methodologies. The notice also described how each process works within the Board's annual budget process.

The Board applies the OTR to the NCUA's operating budget to determine the portion of the budget that will be funded from the National Credit Union Share Insurance Fund (Share Insurance Fund). The Board described and sought comment on the current OTR methodology.

The Board also described and requested comment on three proposed changes to the methodology it uses to determine how it apportions operating fees charged to federal credit unions (FCUs). The Board uses operating fees to fund part of the NCUA's annual budget.

[1] Request for Comment Regarding National Credit Union Administration Overhead Transfer Rate Methodology and Operating Fee Schedule 85 FR 53854 (Aug. 31, 2020).

In particular, the Board proposed: (1) Clarifying the treatment of capital project budgets when calculating the operating fees; (2) clarifying the treatment of miscellaneous revenues when calculating the operating fees; and (3) modifying the approach for calculating the annual inflationary adjustments to the thresholds for the operating fee rate tiers. The Board also solicited comment on adjusting the asset-size rate tiers in the operating fee scale, increasing the current $1 million asset-size threshold below which an FCU pays no fee, and on incentivizing FCUs and federally insured, state-chartered credit unions (FISCUs) to complete an annual, voluntary diversity survey.

In a separate proposed rule, the Board proposed amending its regulation governing the determination of total assets used as the basis for calculating the operating fee due from any FCU and encouraged public comments on that proposed rule.[2]

The Board received eight comments on the July 2020 notice, three from credit union trade associations, four from credit union leagues, and one from a credit union service organization. The following sections reiterate the background from the July 2020 notice, respond to the comments, and adopt as proposed three changes to the operating fee methodology for application to the 2020–2021 NCUA budget. The Board will study the remainder of the issues and comments in connection with potential future changes to these practices.

I. Legal Background

The NCUA charters, regulates, and insures deposits in FCUs and insures deposits in state-chartered credit unions that have their shares insured through the Share Insurance Fund. To cover expenses related to its tasks, the Board adopts an annual budget in the fall of each year. The Federal Credit Union Act (FCU Act) provides two primary sources to fund the budget: (1) Requisitions from the Share Insurance Fund, referred to as the OTR; [3] and (2) Operating Fees charged to FCUs.[4]

The first budget funding source, the OTR, represents the methodology the NCUA uses to allocate insurance-related expenses to the Share Insurance Fund under Title II of the FCU Act. Two statutory provisions directly limit the Board's discretion with respect to the OTR. First, expenses funded from the Share Insurance Fund must carry out the purposes of Title II of the Act, which relate to share insurance.[5] Second, the NCUA may not fund its entire annual budget through charges to the Share Insurance Fund.[6] The NCUA has not imposed additional policy or regulatory limitations on its discretion for determining the OTR.

With regard to the Operating Fee, the FCU Act requires each FCU to, ''in accordance with rules prescribed by the Board, . . . pay to the [NCUA] an annual operating fee which may be composed of one or more charges identified as to the function or functions for which assessed.'' [7] The fee must ''be determined according to a schedule, or schedules, or other method determined by the Board to be appropriate, which gives due consideration to the expenses of the [NCUA] in carrying out its responsibilities under the [FCU Act] and to the ability of [FCUs] to pay the fee.'' [8] The statute requires the Board to, among other things, ''determine the periods for which the fee shall be assessed and the date or dates for the payment of the fee or increments thereof.'' [9]

Accordingly, the FCU Act imposes three requirements on the Board in connection with assessing an operating fee on all FCUs: (1) The fee must be assessed according to a schedule or schedules, or other method that the Board determines to be appropriate, which gives due consideration to NCUA's responsibilities in carrying out the FCU Act and the ability of FCUs to pay the fee; (2) the Board must determine the period for which the fee will be assessed and the due date for payment; and (3) the Board must deposit collected fees into the Treasury to defray the Board's expenses in carrying out the FCU Act. Once collected, Operating Fees, ''may be expended by the Board to defray the expenses incurred in carrying out the provisions of [the FCU Act,] including the examination and supervision of [FCUs].'' [10]

II. Historical Practice in Determining the Overhead Transfer Rate and Assessing the Operating Fee

Overhead Transfer Rate

The Share Insurance Fund was established by Title II of the FCU Act on October 19, 1970. Section 1783(a) of Title II authorizes the Board to use Share Insurance Funds to pay for ''such administrative and other expenses incurred in carrying out the purposes of this title as it may determine to be proper.''

In 1973, a Government Accountability Office audit [11] recommended the NCUA adopt a method of allocating costs between the operating fund and the newly formed Share Insurance Fund. Between 1973 and 1980, various cost allocation methods were employed, including direct charges to the Share Insurance Fund for insurance expenses including costs to liquidate or merge credit unions and examiner time spent conducting safety and soundness examinations. Starting in 1981, the OTR ranged between 30 and 34 percent, and stayed in that range through 1984.

From 1985 through 1994, the NCUA conducted annual examiner time surveys (ETS) to determine an appropriate factor for apportioning the agency's total operating expenses. The survey results supported a transfer rate between 50.1 percent and 60.4 percent for insurance related activities; however, the Board maintained the OTR at 50 percent.

Following the 1994 survey, the Board approved surveys that were conducted every three years. Three-year surveys covered fiscal years 1995 through 1997 and fiscal years 1998 through 2000. During that period, the OTR was kept at 50 percent. The Board voted to resume annual ETS in 2000 and expanded the survey to include more examiners. The 2000 survey results supported an OTR of 66.72 percent and, after 15 years of holding the OTR at 50 percent, the Board increased the OTR to 66.72 percent for fiscal year 2001.

In 2001, the Board hired an independent party, Deloitte & Touche, to assess the OTR process. Deloitte & Touche's review [12] of the OTR process was issued on September 5, 2001 and included several recommendations to improve the OTR process. These recommendations were implemented in 2002.

[2] Fees Paid by Federal Credit Unions, 85 FR 53708 (Aug. 31, 2020).

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

[4] 12 U.S.C. 1755(a) (''In accordance with rules prescribed by the Board, each [FCU] shall pay to the [NCUA] an annual operating fee which may be composed of one or more charges identified as to the function or functions for which assessed.'') and 12 U.S.C. 1766(j)(3). Other sources of income for the Operating Budget include interest income, funds from publication sales, parking fee income, and rental income.

[5] 12 U.S.C. 1783(a).

[6] 12 U.S.C. 1755.

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

[8] 12 U.S.C. 1755(b).

[9] *Id.*

[10] 12 U.S.C. 1755(d).

[11] Gen. Accounting Off., Examination of Financial Statements of the Nat'l Credit Union Admin. (Sept. 18, 1973), *available at http://www.gao.gov/assets/210/203181.pdf.*

[12] *https://www.ncua.gov/files/publications/budget/2001DeloitteReportonOTRProcess.pdf*

At the November 20, 2003 Board meeting,[13] the Board adopted a revised, comprehensive methodology for calculating the OTR that was in place until 2017. The methodology used the results of an automated annual ETS process. The following were also factored into the methodology:

- The value to the Share Insurance Fund of the insurance-related work performed by state supervisory authorities (SSAs).
- The cost of the NCUA resources and programs with different allocation factors from the examination and supervision program.
- The distribution of insured shares between FCUs and FISCUs.
- Operational costs charged directly to the Share Insurance Fund.

In 2016, the NCUA published in the **Federal Register** the OTR methodology used to calculate the OTR and requested comments from the public.[14] In conjunction with the 2016 **Federal Register** notice, the Board committed to periodically review the methodologies for calculating both the OTR and the Operating Fee, and to propose changes to the methodologies that would result in more equitable alignment of fees to the resource levels required to supervise and regulate both FCUs and FISCUs.

In 2017, the NCUA published in the **Federal Register** a request for comment regarding a revised OTR methodology based on the Board's internal assessment and comments received from the 2016 notice.[15] The primary goal of the proposed changes to the OTR methodology at that time was to simplify and streamline the methodology and reduce the resources needed to administer the OTR. The simplified OTR methodology incorporated four key principles in allocating agency operating costs:

Principle 1: 50 percent insurance related—Time spent examining and supervising FCUs.

Principle 2: 100 percent insurance related—All time and costs the NCUA spends supervising or evaluating the risks posed by FISCUs or other entities the NCUA does not charter or regulate (*e.g.* third-party vendors and credit union service organizations).

Principle 3: Zero percent insurance related—Time and costs related to the NCUA's role as charterer and enforcer of consumer protection and other noninsurance based laws governing the operation of credit unions, for example, field of membership requirements.

Principle 4: 100 percent insurance related—Time and costs related to the NCUA's role in administering federal share insurance and the Share Insurance Fund.

The Board adopted this principles-based OTR methodology in 2017.[16] At that time, the Board committed to subject the four principles, but not the particulars of their application, to public comment every three years and in the event it proposes a change to one or more of the principles.

III. Overhead Transfer Rate Methodology

To calculate the OTR, the four principles are applied to the activities and costs of the agency to arrive at the portion of the agency's budget to be charged to the Share Insurance Fund.

Step 1—Workload Program

Annually, the NCUA develops a workload budget based on the NCUA's examination and supervision program to carry out the agency's core mission. The workload budget reflects the time necessary to examine and supervise federally insured credit unions (FICUs), along with other related activities, and therefore the level of NCUA field staff needed to implement the exam program. Applying principles 1, 2, and 3 (those relevant to the workload budget) to the applicable elements of the workload budget results in a composite rate that reflects the portion of the agency's overall insurance related mission program activities.

Step 2—Annual Budget

The annual budget represents the costs of the activities associated with achieving the strategic goals and objectives set forth in the NCUA's Strategic Plan. The annual budget is based on agency priorities and initiatives that drive resulting resource needs and allocations. Information related to the NCUA's budget process, including details on the Board-approved budgets, is available on the agency's website.[17]

The agency achieves its primary mission through the examination and supervision program. The percentage of insurance-related workload hours derived from Step 1 represents the main allocation factor used in Step 2 and is applied to the budgets for the examination and supervision programs to calculate the insurance-related costs of the offices conducting field work (currently the Regions and ONES). A few agency offices have roles distinct enough to warrant their own allocation factors, which are developed by applying the four factors described above to their respective activities. Each of these offices tracks their activities annually to determine their factors. These factors are then applied to the respective offices' budgets to determine their insurance-related costs.

A weighted average allocation factor, calculated by dividing the aggregate insurance-related costs for the field offices conducting the examination and supervision program and the agency offices with their own unique allocation factors by their aggregate total budgets, is applied to the central offices that design or oversee the examination and supervision program or support the agency's overall operations. This factor is then applied to the aggregate budgets for the remaining offices. As such, the proportion of insurance-related activities for these offices corresponds to that of the mission offices. The NCUA's total insurance-related costs are calculated by summing the insurance cost calculated for the field offices, the offices with unique allocations factors, and the insurance cost for all other NCUA offices.

Step 3—Calculate the OTR

The OTR represents the percentage of the NCUA budget funded by a transfer from the Share Insurance Fund.[18] The OTR is calculated by dividing the total insurance-related costs determined in Step 2 by the NCUA's total annual budget.

IV. Responses to Comments on OTR Methodology

In the July 2020 notice, the Board sought comment on the current OTR methodology. The Board noted that the principles-based OTR methodology has streamlined the process for calculating the OTR and reduced the resources needed to gather the cost center time allocation used in the calculation. In addition, the methodology established some consistency in the calculated OTR each year, seen previously only briefly during the three-year period ended 2013.

The Board also noted that the consistency in the calculation allows for the minor variations in the OTR to be driven by the variables that affect the OTR, not the calculation itself. These variables include, but are not limited to, the normal fluctuations in the workload budget from one calendar year to the

[13] The methodology was refined in 2013.

[14] 81 FR 4804 (Jan. 27, 2016).

[15] 82 FR 29935 (June 30, 2017).

[16] 82 FR 55644 (Nov. 22, 2017).

[17] *https://www.ncua.gov/About/Pages/budget-strategic-planning/supplementary-materials.aspx.*

[18] The percentage of actual expenses funded by the Share Insurance Fund as they are incurred each month.

next, changes in FICU CAMEL ratings, variation in the number and size of FICUs that meet the annual exam and extended exam eligibility criteria, emerging risk indicators inherent in FICU operational changes, variations in individual state regulator programs, and small fluctuations in the timing of the examinations related to a particular calendar year. This streamlined and simplified approach to calculating the OTR has provided a level trend in the OTR, with only minor fluctuations due to the variables that affect the OTR.

Finally, the Board stated that the current OTR methodology is fair and equitable, more transparent and less complex than prior methodologies, reduces OTR administrative costs as compared to the prior OTR methodology, and recognizes that safety and soundness is not the sole domain of the NCUA as insurer.

Accordingly, while the Board did not propose changes to the OTR methodology, it invited comments on its OTR methodology. The Board specifically invited comments on the four principles used in the methodology to calculate the OTR discussed in the preceding section.[19]

The Board received eight comments from credit union leagues, trade associations, and CUSOs. Many of the commenters stressed the importance of having an OTR methodology that allocates the agency's operating costs equitably among FCUs and FISCUs, but emphasized that prudent management of NCUA's budget is necessary to reduce costs to credit unions. Overall, the commenters believe apportioning a proportionate share of the capital budget to the NCUSIF is consistent with the 2017 OTR methodology and presents a more equitable treatment of capital expenditures with respect to the OTR and the FCU's operating fees. Commenters who supported the inclusion of the capital budget in the OTR also supported including miscellaneous revenues in the OTR.

General Comments on the OTR Methodology

Transparency; Fair and Equitable Allocation of Expenses

Commenters appreciated NCUA's transparency in seeking comments on the OTR process and while they acknowledge the conflicting viewpoints among stakeholders throughout the industry, overall, commenters are seeking a fair and equitable means for determining and substantiating insurance-related costs and apportioning these costs among insured credit unions. Commenters hope the furtherance of technology will be beneficial in NCUA's future identification, tracking, and allocation of insurance-related costs among insured credit unions.

OTR Methodology Comments and Responses

There were several comments specific to the allocations used in the OTR methodology and the distinction and differentiation between NCUA's role as a charterer/regulator and that of insurer.

50 Percent Allocation—Examining and Supervising FCUs—Distinction Between NCUA's Role as Regulator Versus Insurer

One commenter questioned NCUA's assessment of a 50 percent allocation to the insurance-related costs of supervising FCUs when NCUA has not demonstrated publicly that its role as insurer reflects 50 percent of its operating costs. The commenter requested more documentation to substantiate that NCUA's role as insurer truly encompasses 50 percent of its operating costs. One commenter suggested a sensible compromise would be for NCUA to examine FCUs pursuant to Title I of the FCU Act; and the NCUSIF-related time would be based on NCUA's review of those Title I examinations in the same manner as it does for state FISCU examinations, thus providing a clearer distinction between NCUA's role as regulator versus insurer. One commenter questioned NCUA's statement that the 50 percent allocation for FCUs ''is consistent with the alternating examinations FDIC and state regulators conduct for insured state-chartered banks as mandated by Congress'' because there is no public evidence available to demonstrate that NCUA's supervision process emulates the FDIC's practice of alternating examinations with prudential state banking regulators. Not specific to the OTR calculation, the commenter stated that if NCUA's practice does emulate a supervision program that differentiates between its insurance function and its prudential regulator function, then it follows that there must be uniqueness or differentiation between the protocols of a regulatory exam and an insurance review.

NCUA Response: The Board still believes the 50 percent allocation is a realistic approximation of the split between NCUA's roles as regulator and insurer of FCUs. NCUA's focus with each examination of an FCU is to assess the ongoing safety and soundness of the credit union and to determine if the FCU's operations pose a risk to the Share Insurance Fund. In instances where an FCU's financial condition or operations do pose a risk to the Share Insurance Fund, the workload naturally contributes a heavier weight toward NCUA's role of insurer. On the contrary, in instances where the FCU's safety and soundness is not a concern to the Share Insurance Fund, NCUA's insurance-related time spent on these credit unions is lower. The FDIC asserts its primary focus is to protect its insurance fund by ensuring the safety and soundness of the institutions it insures. Like the FDIC, NCUA's primary focus in its role as insurer is to protect the Share Insurance Fund; but unlike the FDIC, NCUA also has chartering and regulatory authority. Since the NCUA has the dual responsibility of serving as both the primary regulator with chartering authority and insurer of FCUs, attributing equal weights to each of NCUA's dual roles creates a cost sharing similar in time structure to NCUA employing FDIC's alternating exam cycle within one regulatory agency.

100 Percent Allocation—Examining and Supervising FISCUs

A commenter stated that if the alternating exam practice that NCUA uses to describe its 50 percent allocation between its role as regulator versus insurer of FCUs is an actual practice and there is no discernable difference between an NCUA regulatory exam and an NCUSIF insurance review, then a state regulatory examination could serve to fulfill the requirements of Title II of the FCU Act, thus reducing budgeted NCUA workload hours for FISCUs and more properly reflecting the distinction between the proper authority of the state regulator and the insurer. One commenter questioned NCUA's 100 percent allocation for third-party vendors and CUSOs. The commenter noted that NCUA does not have supervisory authority of third-party vendors and CUSOs like other federal regulators and state regulators, but NCUA, as chartering authority for FCUs, has an obligation to ensure that FCU CUSOs and other third parties are operating safely and complying with applicable rules and regulations. Thus, NCUA's review of these entities is related to the FCU's examination process and does not necessarily have a direct impact to the NCUSIF unless noncompliance has led to a safety and soundness issue that impacts the Share Insurance Fund.

NCUA Response: The Board has clearly defined NCUA's role with FISCUs and other entities that NCUA

[19] *https://www.ncua.gov/files/publications/budget/overhead-transfer-rate-summary-2020.pdf*

does not charter or regulate as 100 percent insurance-related. The alternating exam example is used as a description of NCUA's dual functions of regulator and insurer of FCUs and is not actual practice. NCUA has taken steps in recent history to reduce the workload budget and costs to FISCUs, providing greater responsibility on the State regulator. The Board's adoption of the Exam Flexibility Initiative in 2016 served to lengthen the examination cycle and reduce the frequency with which NCUA participates on FISCU examinations. Likewise, NCUA does not charter or regulate CUSOs or third-party vendors and therefore the NCUA's role is also solely as the insurer. A CUSO and third-party vendor are at times subject to a limited review during a FICU examination. This review generally covers compliance with the CUSO's lending and investing regulatory requirements and a review of the service or function the third party provides the FICU. Examiners may also assess the risk a CUSO or third-party vendor's activities pose to the FICU as part of the FICU examination. This CUSO/third-party vendor-related time is captured in the examination and supervision of an FCU under Principle 1 and a FISCU under Principle 2. The Board has no direct regulatory authority with respect to CUSOs and third-party vendors, and currently there is no support to allocate time specifically designated for CUSO and third-party vendor reviews as anything other than the NCUA's role as insurer.

Zero Percent Allocation—NCUA's Role as Charterer and Enforcer of Consumer Protection and Other Noninsurance-Based Laws

One commenter questioned the zero percent allocation for consumer protection enforcement, stating that noncompliance with consumer regulations could result in a safety and soundness issue and therefore this function is not entirely unrelated to insurance.

NCUA Response: The Board recognizes the importance of ensuring compliance with consumer protection laws and regulations. As such each full scope examination of a FICU includes a review of the FICUs' compliance with consumer laws and regulations. This review time is allocated to examining and supervising FCUs and FISCUs in Principle 1 and Principle 2, respectively. The zero percent allocation is associated with the non-examination aspect of consumer protection focused on supporting low-income and minority FICUs and all FICUs seeking growth and development in areas of charter conversions and expansions, bylaw amendments, field of membership expansions, and low-income designations. The safety and soundness and risk to the Share Insurance Fund considered in the growth and development areas is a very small portion of NCUA's workload budget and does not warrant an allocation factor.

Other Office Allocation

One commenter requested NCUA to provide more clarity on the unique allocation factors used by certain offices within NCUA's central office. The commenter suggested that rather than relying on weighed allocation factors to determine the OTR, simply calculating how much time each regional and central office spends on insurance-related activities each year might be a more straightforward method of determining how much of the operating budget should be borne by the NCUSIF.

NCUA Response: The weighted average allocation applied to the central offices is based on the aggregate insurance-related costs for the field offices and agency offices with their own unique allocation factors. NCUA uses a weighted average allocation factor applied to the central offices' aggregate total budget because these offices provide direct support to the field offices in their examination and supervision of FICUs and to the other central offices. Therefore, the central offices' time is allocated proportionate to the weighted average of these offices. Central offices that have ''unique allocation factors'' have chartering functions that are not entirely related to insurance, so their insurance-related time is allocated separately. The Asset Management Assistance Center, on the other hand, manages liquidation payouts and assets acquired from liquidations on behalf of the Share Insurance Fund. Since AMAC's role is 100 percent insurance related, AMAC's ''unique allocation factor'' is based on its sole function being insurance related.

Other Comments

Inequity in the OTR Methodology

Other comments focused on the OTR's inequity between FISCUs and FCUs. One commenter noted the importance of the OTR methodology because FISCUs pay the full cost of their state examinations and then through the OTR pay 100 percent of NCUA's insurance reviews of FISCUs, as well as a portion of FCU examinations and CUSO and third-party reviews. One commenter noted that FISCUs make up only 37 percent of the total number of credit unions, but because FISCUs encompass approximately 50 percent of insured shares, the cost of the OTR is borne equally from the funds of both FISCUs and FCUs even though there are more FCUs whose examination costs are being charged to the NCUSIF. While this commenter recognized the alternative argument that FCUs would assert that they pay an aggregate greater amount of NCUA's overall budget when aggregating the total expense to FCUs from the operating fee and the OTR, the commenter noted the assertion ignores the fact that the NCUSIF is not expending resources to conduct examinations on a majority of FICUs because it relies on exam work conducted by the state regulators; exam work that is paid for entirely by FISCUs. The commenter noted that historically, the majority of NCUA's annual budget has been paid by the OTR, reaching a high of nearly 75 percent of NCUA's 2016 budget. The commenter highlighted the significance of the OTR funding the majority of the budget because of the perceived inequities within the methodology that result in FISCUs shouldering an ''inordinate cost of supervising the safety and soundness of the credit union system.'' The commenter also noted its concern with the overall increase in the OTR from the current proposal.

NCUA Response: The Board fully supports an equitable distribution of costs among FICUs. The Board continues to believe the current OTR methodology is a fair and equitable means of allocating costs to the Share Insurance Fund. The operating fee is charged to FCUs based on a tiered assessment structure that recognizes the FCU's ability to pay the operating fee based on its total assets. The operating fee funds a portion of NCUA's operations similar to the assessments some State regulatory agencies charge FISCUs to fund the respective State agencies' operations. Since NCUA also serves in the role as insurer, the FCU Act permits for a portion of NCUA's operations to be funded by the Share Insurance Fund. This funding is not a direct cost to the FISCUs or the FCUs.

Principles-Based Methodology vs Metric-Based Methodology—Precision vs Assumption

A commenter noted that the adoption of the current principles-based methodology marked a departure from the well-established ETS, which was a metrics-based approach designed to capture examiner time spent on insurance related matters versus non-insurance related through the assessment of individual regulations and other measures. The commenter felt

the ETS approach was, by necessity, more complex than the current principles-based allocation methodology, but it also made fewer assumptions about the allocation of the NCUA's insurer and examiner resources. The commenter noted that eliminating the data-oriented assessment of insurance-related activities under the ETS would make it harder to track how much time examiners actually spend on insurance-related activities. In the absence of the ETS data, the commenter opined it is now harder to evaluate the effectiveness of the current methodology. The commenter highlighted the potential inequities resulting from using the current assumption-based methodology versus the precision from the older model.

NCUA Response: While the current OTR methodology is less complex than the ETS, the OTR methodology is objective and remains formula driven. The NCUA's goal in using a formula-driven OTR methodology is to provide a comprehensive, fair, and equitable allocation of costs within a framework that can be administered at a relatively low cost such as the current methodology. As noted in the Final Notice for the current methodology, this methodology is simpler than its predecessor and is still both objective and formula driven. Additionally, the ETS and the assignment of time as insurance, insurance regulatory, and consumer regulatory has been an area of debate. The Board noted that continued refinement of the categories would not alleviate this debate or eliminate the confusion that existed around the process.[20] Further, while the OTR is formula driven, the Board can adjust the methodology at any time to ensure it continues to reflect the most equitable and suitable approach to allocating costs.

Quantification of Benefits Derived From the Current OTR Methodology

One commenter acknowledged the administrative benefit in adopting a simpler methodology, but stated NCUA has not sought to quantify its statement that the adoption of a principles-based OTR has ''reduced the resources needed to gather the cost center time allocation used in the OTR calculation.'' The commenter continued by saying there has also been no attempt to compare the noted savings with those predicted by the agency when it first proposed the principles-based methodology. The commenter's expectation is that when NCUA says there are cost savings associated with a particular rule or policy change, it should endeavor to maintain a level of transparency and supply estimates and retrospective data for the industry to consider.

NCUA Response: When the Board adopted the revised OTR methodology in 2017,[21] the NCUA saw an immediate cost savings in 2018 due to the elimination of the ETS. As noted in the 2017 OTR Final Notice, under the prior OTR methodology, ETS were conducted annually. The process included regulatory mapping prior to the beginning of the ETS cycle to make any necessary adjustments to classifications.[22] Additionally, the examiners and their supervisors participating in the ETS received training on how to complete the survey. Examination or supervision time was also increased at each contact where an ETS was completed by roughly one hour. The process also included aggregation and analysis of the data by the Office of Examination and Insurance (E&I). Eliminating the ETS from the OTR methodology resulted in a resource savings in examiner time, training time, and office analysis and support.

Working Group or Advisory Committee To Oversee the OTR

Some commenters suggested NCUA establish a working group or advisory committee made up of equal representation of NCUA and state regulators to establish a new OTR methodology that accurately and fairly represents the shared work and contributions of the insurer and the state regulator. The commenters suggested this committee would be charged with continuing oversight and review of all factors contributing to the OTR methodology and recommendation of future OTR charges. Another commenter offered that the establishment of a credit union advisory committee would provide a means for the debate and exchange of ideas about the OTR that is difficult to facilitate in the notice and comment process.

NCUA Response: The Board believes the current OTR is transparent and provides for stakeholder input, therefore, a committee to oversee the OTR is not needed. Further, while not required by the Administrative Procedure Act, the Board remains committed to solicit through the **Federal Register** public comment on the OTR methodology at least every three years, and whenever the NCUA seeks to change the OTR methodology.

V. Operating Fee for FCUs

The NCUA's regulations govern certain of the operating fee processes.[23] The regulation establishes: (i) The basis for charging operating fees (total assets); (ii) a notice process; (iii) rules for new charters, conversions, mergers, and liquidations; and (iv) administrative fees and interest for late payment, among other principles and processes.[24] Certain aspects of and adjustments to the operating fee process, such as changes to which FCUs are exempt from operating fees or the multipliers used to determine fees applicable to FCUs that fall within designated asset tiers, are usually not published in the **Federal Register**. Instead, in November 2015, the Board delegated authority to the NCUA's Chief Financial Officer to administer the Board-approved methodology, and to set the operating fees as calculated per the approved methodology during each annual budget cycle beginning with 2016. Although it is not required to do so under the Administrative Procedure Act,[25] in January 2016, the Board published its methodology in the **Federal Register** and requested comment.[26] The Board provided notice of a clarification to the operating fee methodology in July 2020, and sought comment on several potential updates to the methodology. This notice provides the NCUA's response to comments about the July 2020 methodology, and documents the Board's final revisions to the operating fee methodology.

The Board proposed the current operating fee methodology in 1979, after Congress passed the Financial Institutions Regulatory and Interest Rate Control Act of 1978.[27] This legislation permitted the Board to consolidate previously separate chartering, supervision, and examination fees into a single operating fee, charged ''in accordance with schedules, and for time periods, as determined by the Board, in an amount necessary to offset the expenses of the Administration at a rate consistent with a credit union's ability to pay.'' [28] In combination with a proposed change to § 701.6 of the NCUA's regulations in 1979, the Board proposed an initial fee schedule in the **Federal Register**, including rates for 12

[20] 82 FR 55655 (November 2017).

[21] Ibid.

[22] Information on the last regulatory mapping performed by the NCUA in 2017 can be found on the NCUA's website *https://www.ncua.gov/files/publications/about/mapping-ncua-regulations-2017.pdf.*

[23] 12 CFR 701.6.

[24] *Id.*

[25] 5 U.S.C. 551 *et seq.*

[26] 81 FR 4674 (Jan. 27, 2016).

[27] 44 FR 11785 (Mar. 2, 1979).

[28] *Id.* at 11786.

asset tiers.[29] It later published a final rule in the **Federal Register**, which included a finalized fee schedule for 1979.[30]

On four additional occasions prior to the July 2020 notice, the Board had requested comments on potential changes to the operating fee schedule through a **Federal Register** notice, independent of any changes to 12 CFR 701.6. First, in 1990, the Board provided notice to the public that it was considering consolidating the operating fee schedule from 14 asset tiers to two asset tiers, retaining an exemption for FCUs under $50,000 in assets and implementing a $100 minimum fee.[31] Second, in 1992, the Board requested comments on a plan to limit operating fees to the first $1 billion of each FCU's assets.[32] Third, in 1995, the Board requested comments on a plan to restructure the operating fee schedule for natural person FCUs, to exempt FCUs with assets of $500,000 or less based on concern about small FCUs' ability to pay the fees.[33] The Board also requested comments on imposing a minimum fee of $100 on all natural person FCUs with assets over $500,000 but less than or equal to $750,000.[34]

In 2016, the Board published its current methodology in detail in the **Federal Register** and solicited comment. The Board made no changes in response to comments on the methodology published in 2016 and delegated authority to the NCUA Chief Financial Officer to apply the published methodology. Since then, the Chief Financial Officer has applied the published Operating Fee methodology and explained its application in the NCUA's annual budget documents.

In general, the Board has not used **Federal Register** notices in connection with annual adjustments to the asset tiers and rates of the operating fee schedule. Instead, the Board has opted to adopt such changes at open meetings. As recently as 2012, for example, the Board increased the asset threshold used to exempt FCUs from operating fees from $500,000 to $1 million at an open meeting, without requesting advance comment in the **Federal Register**.[35] While the Board has varied its practice with respect to fee schedule changes, it has done so within the FCU Act's broad directive that the fee schedule should be as ''determined by the Board to be appropriate,'' subject to its consideration of its expenses and the ability of FCUs to pay.[36] In addition, the NCUA's regulation on operating fee processes includes a standing invitation for written comments from FCUs on existing fee schedules [37] and each year the Board invites comments on the draft NCUA budget, which includes a detailed explanation of how the operating fee is calculated and how changes to the operating fee rate are determined based on application of the published methodology.

VI. Methodology for Determining the Aggregate Operating Fee Amount

The Board adopts an annual budget in the fall of each year, which includes as an operating budget the costs of day-to-day operations such as employee compensation, travel and training expenses, support purchased through contracts with service providers that have expertise outside of the agency's core capabilities, and other miscellaneous administrative expenses. The annual budget also includes as a capital budget the estimated spending on capital projects, such as for computer hardware and software, and for investments in agency owned real property and equipment, and provides the resources required to execute the goals and objectives as outlined in the NCUA's strategic plan.[38] As discussed above, two primary sources fund the annual budget: (1) requisitions from the Share Insurance Fund, determined through the OTR and (2) operating fees paid by FCUs.

Adjustments to the Budget. When calculating the aggregate annual operating fee requirements, the Board first subtracts amounts transferred from the Share Insurance Fund through the OTR and other expected income amounts, as discussed below, from the operating budget, which funds the day-to-day needs for the upcoming year.

Overhead Transfer Rate: As discussed above, the FCU Act authorizes the NCUA to expend funds from the Share Insurance Fund for administrative and other expenses related to federal share insurance.[39] An overhead transfer from the Share Insurance Fund covers the expenses associated with insurance-related functions of the NCUA's operations. The OTR is one of the funding sources for the budget, but the OTR does not affect the amount of the annual budget. The Board approves the annual budget separately and without regard to the OTR. The OTR is applied to actual expenses incurred each month.

Other Income: Other income reduces the required operating fees by providing an additional source of funds to cover regulatory (*i.e.,* non-insurance) related aspects of operating the NCUA. Other income is projected based on the latest financial statements and includes interest income and miscellaneous revenues. Interest income includes interest on operating fund balances invested in short-term Treasury securities because the funds are not immediately required to pay expenses. Other income includes miscellaneous revenues, such as revenues from the production or sale of NCUA reports and publications, rent collected from other federal agencies that share NCUA facilities, and parking fee revenues. The NCUA owns a share of the parking garage underneath the complex of buildings that includes the agency's Central Office, and the NCUA receives its share of the revenue collected from fees charged to those who park in the garage.

Adjustments for capital project budgets and notes payable. The budgets for capital projects and notes payable are added to the balance remaining after deducting the estimated overhead transfer share of the operating budget. These budgets include capital acquisitions planned for the year and the annual payment of the note payable for the NCUA Central Office building on King Street.

Capital Projects. Each year the NCUA conducts a rigorous assessment of its needs for information technology (IT), facility improvements and repairs, and other multi-year capital investments. Routine repairs and lifecycle-driven property renovations are necessary to properly maintain investments in the NCUA's Central Office building in Alexandria, Virginia, and the agency's office building in Austin, Texas. IT systems and hardware are another significant capital expenditure for modern organizations, and the budget includes investments both for maintaining and upgrading currently operational systems and networks as well for developing replacements for systems and hardware that has reached the end of its useful life.

Repayment of NCUA Central Office on King Street, Note Payable. In 1992, the Operating Fund entered into a commitment to borrow up to $42.0 million in a 30-year secured term note with the Share Insurance Fund to fund the costs of constructing the NCUA's Central Office in 1993. Since the

[29] *Id.* at 11787.

[30] 44 FR 27379 (May 10, 1979).

[31] 55 FR 29857 (July 23, 1990).

[32] 57 FR 34152 (Aug. 3, 1992).

[33] 60 FR 32925 (June 26, 1995).

[34] *Id.*

[35] Board Action Memorandum on 2013 Operating Fee (Nov. 15, 2012).

[36] 12 U.S.C. 1755(b).

[37] 12 CFR 701.6(c).

[38] Additional information on the NCUA budget may be found at the following Web address: *http://www.ncua.gov/About/Pages/budget-strategic-planning/supplementary-materials.aspx.*

[39] 12 U.S.C. 1783(a).

Operating Fund borrowed monies from the Share Insurance Fund, the annual scheduled principal payments are excluded from the OTR and overhead transfer amount. The annual scheduled principal payments are treated as a cash need and applied as an increase to operating fee requirements.

Operating Fee Requirements. The result after adjustments for capital project and notes payable needs is the total budget subject to the operating fee and payable by both natural person and corporate FCUs. The natural person FCU operating fees are determined by deducting the corporate FCU operating fees from the total budget operating fee requirements.

VII. Methodology for Determining the Operating Fee Schedule

The corporate credit union fee schedule was established in 1979 and has changed little over the years. Corporate FCUs hold assets of natural person credit unions, which are already assessed under the natural person operating fees for those members that are FCUs. Assessing corporate FCUs at the same rate would, effectively, assess the same assets twice for natural person FCU members of corporate FCUs. Corporate FCUs return a large portion of their earnings to natural person credit unions in the form of lower fees and higher dividends. Raising operating fee assessments for corporate FCUs would result in higher expenses for corporate FCUs. Corporate FCUs would need to pass the higher expenses to natural person credit unions in the form of higher fees and lower investment yields. The corporate FCU fee schedule is a method of charging corporate FCUs a supervisory fee to defray costs and is now published annually in the budget.

The Board delegated authority to the Chief Financial Officer to administer the methodology approved by the Board for calculating the operating fees, and to set the fee schedule as calculated per the approved methodology, beginning in 2016. After determining the operating fee requirements for natural person FCUs, the Chief Financial Officer creates the natural person FCU operating fee schedule for the upcoming year. The FCU operating fee schedule is published annually in the budget.

The current fee schedule for natural person FCUs uses three asset tiers. A different assessment rate is applied to each tier, and the threshold for each tier is adjusted annually to reflect inflationary growth of the credit union system. FCUs with $1 million or less in assets pay no operating fee.

There are two steps used to determine adjustments to the operating fee schedule for the upcoming year: (1) Updating the prior-year asset tier thresholds using the projected asset growth rate; and (2) updating the prior-year assessment rates for each asset tier by determining the average assessment rate adjustment.

Updating prior year asset levels. The first step in determining the new operating fee schedule is to increase the threshold for each asset tier from the prior-year by the projected asset growth rate. Tier thresholds are adjusted annually to preserve the same relative relationship of the scale to the applicable asset base.

The projected asset growth rate is a forecast of FCU asset growth rates for a year. The NCUA's Office of Chief Economist (OCE) uses three different methods to forecast asset growth and combines them to generate an overall asset growth rate forecast.

Forecasting method one uses Call Report data for the first half of the year to predict full-year asset growth. This is done by first calculating the ratio of first-half asset growth to full-year asset growth. The percentage of full-year growth accounted for by first-half asset growth varies from year to year but, on average, nearly 80 percent of the asset growth for FCUs occurs in the first half of the year. Using the growth rate in the first half of the year, OCE projects the full-year growth rate.

Forecasting Method two uses Call Report data to determine the most recent four-quarter growth rate and sets this rate to the full-year asset growth rate. This approach is based on the idea that an FCU is likely to establish and maintain a relatively constant growth rate over a short period, after accounting for variations in the growth rate that is attributable to seasonal fluctuations. This implies that a good forecast of full-year asset growth is the most recently available four-quarter asset growth.

Forecasting method three uses a time series statistical model. Using quarterly Call Report data, NCUA predicts future four-quarter asset growth using the four-quarter growth in assets for the period ending two quarters earlier (that is, four-quarter asset growth lagged two quarters).

In general, forecasting literature shows that combining forecasts from different approaches can improve forecast accuracy and decrease the likelihood of forecast errors. Using the root mean squared error statistic to calculate the accuracy of the individual approaches and combined forecast approaches, NCUA has found that the combined forecast approach is better at predicting the final asset growth rate than any of the individual approaches. NCUA therefore averages the forecasts from the three approaches to maximize accuracy.

Updating the prior year's assessment rates. After updating the prior-year asset tier thresholds, the next step is to project operating fees using the updated asset tier thresholds and the prior year assessment rates charged for each tier. The percentage difference between the projected operating fee collections and the operating fee collections required to support the budget is the average rate adjustment.

The average rate adjustment is used to amend the prior-year's assessment rates for each asset tier either upwards or downwards. If the projected amount of operating fees is less than the required budgeted amount, then the assessment rates for each asset tier are adjusted upwards. If the projected amount is more than the required budgeted amount, then the assessment rates for each asset tier are adjusted downwards.

The resulting new operating fee schedule and due date are communicated via a Letter to Federal Credit Unions and posted to *NCUA.gov* within 30 days of Board approval of the annual budget. The Board also makes available an online operating fee calculator on the NCUA website for FCUs to estimate their individual fees for the upcoming year. No later than March of each year, natural person FCUs with assets greater than $1 million will receive an invoice for their operating fee. Operating fees are based on actual assets reported as of December 31 of the previous year. The NCUA combines operating fee and capitalization deposit adjustment into a single invoice normally due in April. As required by the FCU Act, the NCUA will deposit the collected fees in the United States Treasury.[40]

VIII. Changes to Operating Fee Methodology

As summarized above, the Board sought comment on three proposed changes to the Operating Fee methodology and is adopting each change as proposed.

1. Treatment of Capital Budget

Under current practice, the Board initially funds the NCUA's planned capital projects budget entirely through operating fees assessed on FCUs. The Board proposed to change this practice by reimbursing the appropriate portion of these expenditures through the OTR.

In recent years, the NCUA Office of the Chief Financial Officer (OCFO) has

[40] *https://www.ncua.gov/files/agenda-items/AG20191212Item1b.pdf,* pages 57 to 64.

worked to improve the agency's financial management processes and modified some of its practices to align with contemporary Federal financial management standards. This allows the agency to manage its cash flow more effectively and to record appropriately on its books the contractual commitments its makes, particularly for complex and multi-year capital projects.

As a result of these improvements and modifications, in the 2018 budget NCUA clarified how non-cash transactions such as the estimated value of employees' earned but unused annual leave and projected depreciation expenses for capital assets would be treated from a budgetary perspective. Namely, such amounts would no longer be included in annual budgets presented to the Board as they result in no expenditure tied to the recognition of an expense under GAAP. Since that time, the calculation for the operating fee has also excluded such items when determining the allocation of the annual budget between the share paid through the OTR and the share paid through the operating fee.

Accordingly, in the July 2020 notice, the Board proposed to clarify that for the purposes of calculating the operating fee, the budget for capital projects will be included within the total annual budget subject to the OTR. This approach ensures that the cost of new capital acquisitions is borne equitably between FCUs and FISCUs *at the time such acquisitions are made* and is consistent with the 2018 change that excluded other non-cash expenses from the budget. Under the existing methodology, the Share Insurance Fund reimburses the operating fund for capital projects at the OTR and over several years according to depreciation schedules, which are non-cash transactions. Including capital project budgets in the total annual amount subject to the OTR at the point of acquisition effectively accelerates OTR reimbursements for capital project spending to the point at which such expenditures occur. This change also increases consistency with the current OTR methodology, which generally requires that a proportionate share of expenses not exclusively related to the regulation of FCUs be borne in part by the Share Insurance Fund.

As provided in the July 2020 notice, the following table compares how the operating fee calculation for the 2020 budget would have differed had funds for capital projects been subject to the OTR like for the other parts of the annual budget for that year.

OPERATING FEE CALCULATION FOR BOARD-APPROVED 2020 BUDGET COMPARED TO 2020 OPERATING FEE CALCULATION SHOWING PROPOSED CAPITAL BUDGET TREATMENT

($ millions)

	Board-Approved 2020 Budget	2020 w/ Capital Budget Change
1 Proposed Operating Budget	**$ 315.883**	**$ 315.883**
Capital Acquisitions	$ -	$ 25.076
2 Remove King Street Station Note from Calculation	$ (1.340)	$ (1.340)
3 Operating Budget to apply OTR	**$ 314.543**	**$ 339.619**
4 Overhead Transfer Rate **61.3%**	$ (192.815)	$ (208.186)
5 Interest Income	$ (2.250)	$ (2.250)
6 Miscellaneous (rent and publication fees)	$ (1.000)	$ (1.000)
7 Net (sum lines 3 - 6)	**$ 118.478**	**$ 128.183**
8 Operating Fund adjustment	$ -	$ -
9 Capital Acquisitions	$ 25.076	$ -
10 Payment of King Street Note Payable (scheduled principal payments)*	$ 1.340	$ 1.340
11 Budgeted Operating Fee/Capital Requirements (sum lines 5 -10)	**$ 144.894**	**$ 129.523**
12 Corporate Federal CU Operating Fees	$ (0.200)	$ (0.200)
13 Natural Person FCU Operating Fees Required (sum lines 11 -12)	**$ 144.694**	**$ 129.323**
14 Fees projected with Asset Growth of **5.6%**	$ (143.072)	$ (143.072)
15 Difference (lines 13 & 14)	**$ 1.622**	**$ (13.749)**
16 Average Rate Adjustment Indicated (line 15 divided by line 14)	**1.13%**	**-9.61%**

Comments Received: None of the commenters objected to the proposed change to the treatment of capital project budgets for purposes of computing the operating fee. One commenter recommended that the costs of capital projects whose sole benefit accrues to the NCUA should not be subject to the OTR and provided as an example the fact that the agency will discontinue its NCUSIF computer lease program for State Supervisory Authorities in 2021, meaning that capital project funds will be used to provide computers only to NCUA employees.

NCUA Response: While it is a factual statement that the NCUA will discontinue its NCUSIF computer lease program for State Supervisory Authorities in 2022, the agency believes it misstates the purpose of applying the OTR to the capital budget. The computed OTR is an estimate of the share of the NCUA's work that relates to its role as insurer. Although the NCUA will not provide computers for State Supervisory Authorities in the future, that does not eliminate the share of insurance-related work that NCUA employees perform. As a result, even though some capital projects such as the agency's computer lease provides direct benefit only to NCUA employees, it is still appropriate to apply the OTR to such project costs since the purpose of the OTR is to pay for the insurance-related share of the NCUA's budget via reimbursement from the SIF. Accordingly, the Board adopts this change to the operating fee methodology without modification.

2. Treatment of Miscellaneous Revenues

Under current practice, miscellaneous revenues collected by the NCUA reduce operating fees charged to FCUs. The Board proposed to change the treatment of miscellaneous revenues, reducing the percentage of the NCUA budget funded by the OTR transfer from the Share Insurance Fund.

As discussed in the preceding sections, miscellaneous revenues includes revenues from the production and sale of NCUA reports and publications, rent collected from other federal agencies that share NCUA facilities, and parking fee revenues. The NCUA's miscellaneous revenues vary from year to year, but typically total approximately $1,000,000.

The Board proposed to clarify that for the purposes of calculating the operating fee, projected miscellaneous revenues will be included within the total annual budget subject to the OTR. The Board stated that it believes this approach is consistent with its proposed change to the treatment of capital project budgets, and that it better reflects the equitable distribution of the agency's net expenses between FCUs and FISCUs.

As provided in the July 2020 notice, the following table compares how the operating fee calculation for the 2020 budget would have differed had miscellaneous revenues reduced the amount of the budget funded through the OTR for that year.

OPERATING FEE CALCULATION FOR BOARD-APPROVED 2020 BUDGET COMPARED TO 2020 OPERATING FEE CALCULATION SHOWING PROPOSED MISC. REVENUE TREATMENT

($ millions)

	Board-Approved 2020 Budget	2020 w/ Misc. Revenue Change
1 Proposed Operating Budget	**$ 315.883**	**$ 315.883**
Miscellaneous Revenue (rent and publication fees)	$ -	$ (1.000)
2 Remove King Street Station Note from Calculation	$ (1.340)	$ (1.340)
3 Operating Budget to apply OTR	**$ 314.543**	**$ 313.543**
4 Overhead Transfer Rate **61.3%**	$ (192.815)	$ (192.202)
5 Interest Income	$ (2.250)	$ (2.250)
6 Miscellaneous (rent and publication fees)	$ (1.000)	$ -
7 Net (sum lines 3 - 6)	**$ 118.478**	**$ 119.091**
8 Operating Fund adjustment	$ -	$ -
9 Capital Acquisitions	$ 25.076	$ 25.076
10 Payment of King Street Note Payable (scheduled principal payments)*	$ 1.340	$ 1.340
11 Budgeted Operating Fee/Capital Requirements (sum lines 5 -10)	**$ 144.894**	**$ 145.507**
12 Corporate Federal CU Operating Fees	$ (0.200)	$ (0.200)
13 Natural Person FCU Operating Fees Required (sum lines 11 -12)	**$ 144.694**	**$ 145.307**
14 Fees projected with Asset Growth of **5.6%**	$ (143.072)	$ (143.072)
15 Difference (lines 13 & 14)	**$ 1.622**	**$ 2.235**
16 Average Rate Adjustment Indicated (line 15 divided by line 14)	**1.13%**	**1.56%**

Comments Received: The majority of the commenters that supported the inclusion of the capital budget in the OTR also commented on and stressed the importance of including the projected miscellaneous revenues in the OTR calculation to reduce the overall amount of funding needed from the Share Insurance Fund. Accordingly, the Board adopts this change to the operating fee methodology.

3. Annual Inflationary Updates to Operating Fee Schedule Asset Tier Thresholds

Separately from the July 2020 notice, the Board proposed to amend its rule at 12 CFR 701.6 for determining total assets used as the basis for calculating the operating fee due from any FCU.[41] Under the proposed rule, total assets would be calculated as the average of total assets reported on an FCU's previous four Call Reports available at the time the NCUA Board approves the agency's budget for the upcoming year. The Board has adopted that proposed rule without change, and it will go into effect 30 days after publication in the **Federal Register**.

In the July 2020 notice, to maintain consistency between the total assets used for billing the operating fee to an individual FCU and the asset thresholds used for determining the rate tier into which each FCU falls, the Board proposed changing its approach for adjusting the rate tier thresholds. Specifically, for purposes of determining the annual adjustment to the rate tier thresholds, the Board proposes comparing the average of total system assets reported in Call Reports for the four quarters available at the time it approves the budget to the average of total system assets in Call Reports for the four quarters of the respective previous years. In this way, the tier thresholds shown on the operating fee schedule would be increased each year based on the same reporting data that will be used for computing individual FCU invoice amounts.

Comments Received: None of the commenters objected to the proposed change to adjusting the operating fee rate tier thresholds. Accordingly, the Board adopts this change to the operating fee methodology.

4. Other Requests for Comment on Operating Fee Methodology

The Board also solicited comment on three additional topics to inform potential future enhancements to the methodology. The Board will study these comments and consider future changes in these areas.

First, the Board noted that it has not substantially modified the current three-tier operating fee schedule since 1993. The current fee schedule is regressive; that is, credit unions with a larger amount of total assets pay a lower marginal rate on those assets above the threshold levels for the lower tiers. Given growth and consolidation in the credit union system, the Board is interested in whether such an approach is an equitable method for allocating the agency's operating costs. There is a potentially wide range of approaches for distributing the cost of the NCUA's budget that is funded by the operating fee. For example, the Board could adopt a single, flat-rate operating fee for all credit unions with total assets that exceed a standard exemption threshold. Overall, a flat-rate operating fee would shift costs away from relatively smaller credit unions to relatively larger ones, making the fee schedule less regressive. The Board could also make the operating fee schedule less regressive by increasing the rates for the second and third tiers on the schedule. Alternatively, adjusting the rates upward for the first and second tiers of the current operating fee would create a more regressive schedule. The Board sought comment on approaches to this issue.

Comments Received: None of the commenters provided specific recommendations for how or whether to revise the current three-tier operating fee schedule. Two commenters recommended that the NCUA review its operating fee schedule in a fully transparent process. The first commenter recommended that the NCUA convene a representative working group of credit union executives who could provide their perspectives on adjustment to the operating fee schedule. The second commenter recommended that the NCUA consider how share growth that resulted from the COVID–19 pandemic could affect the intent of proposed changes to the operating fee schedule.

NCUA Response: The Board agrees with the respondents to this question that recommend following a fully transparent process for developing a new operating fee schedule. The Board will study the issue further and consider potential future changes. The Board is not making any changes to the current operating fee schedule at this time.

Second, the Board sought comment on changing the threshold below which FCUs are not required to pay an operating fee. Currently, the Board does not assess an operating fee to FCUs with assets less than $1 million. This level was most recently adjusted in 2012 for the 2013 assessment. In the past, the Board has accounted for the ability of small FCUs to pay the fees by exempting those under this threshold from paying any fee. In light of growth in total FCU assets, and of consolidation among FCUs, the Board sought comment on what factors it might consider when adjusting this threshold. The Board provided the following table to inform the public of the potential impact of raising the exemption threshold to various levels above the current $1 million threshold:

[41] 85 FR 53708 (Aug. 31, 2020).

Revenue Impact of Increasing Exclusion Level to New Minium Level

(counts based on 2019 Q4 Call Report, amounts based on 2020 Operating Fee invoices)

	Current Structure		Exclude FCUs with <$1.5M assets			Exclude FCUs with <$5M assets			Exclude FCUs with <$10M assets		
Rate Tier	Count	Revenue	Count	Revenue	Change in Revenue	Count	Revenue	Change in Revenue	Count	Revenue	Change in Revenue
Total Assets less than $1 million	180	---	180	---	---	180	---	---	180	---	---
Additional CUs with Assets between $1 million and new minium	N/A	N/A	60	-$ 20,315	-$ 20,315	401	-$ 317,170	-$ 317,170	765	-$ 1,054,870	-$ 1,054,870
Total Assets more than exclusion threshold and less than $1,599,193,665	3,005	$ 90,483,240	2,945	$90,495,885.69	$ 12,646	2,604	$ 90,680,673	$ 197,433	2,240	$ 91,139,878	$ 656,638
Total Assets more than $1,599,193,665 and less than $4,839,136,005	70	$ 35,838,526	70	$35,843,535.10	$ 5,009	70	$ 35,916,725	$ 78,199	70	$ 36,098,607	$ 260,081
Total Assets greater than $4,839,136,005	20	$ 19,036,855	20	$19,039,515.37	$ 2,661	20	$ 19,078,393	$ 41,538	20	$ 19,175,006	$ 138,151
Total	3,275	$ 145,358,621	3,275	$ 145,358,621	---	3,275	$ 145,358,621	---	3,275	$ 145,358,621	---

Comments Received: Five commenters provided their views about the exemption threshold. One commenter did not believe the exemption threshold should be changed, three commenters recommended raising the exemption threshold from $1 million to $10 million, and one commenter noted they were not opposed to raising the exemption threshold but argued that any foregone revenue should result in a dollar-for-dollar reduction to the NCUA budget.

NCUA Response: Given the lack of consensus between the respondents to this question, the Board will study the operating fee exemption threshold further and consider potential future changes. The Board is not making any changes to the current exemption threshold at this time.

Third, the Board sought comment on ways to encourage FCUs and FISCUs to complete an annual diversity survey. The NCUA provides credit unions an annual voluntary diversity self-assessment, as authorized by law.[42] The Board sought comment on whether and in what amount FCUs that complete an annual voluntary diversity self-assessment should receive a modest discount on the FCU operating fee due in the subsequent year. The Board also sought comment on appropriate incentives in this area for FISCUs, which do not pay an annual operating fee to the NCUA. Alternatively, the Board sought comment on other non-financial incentives that might encourage both FCUs and FISCUs to participate in the survey.

Comments Received: The NCUA received six comments in response to questions about incentives for completing the voluntary diversity self-assessment. None of the commenters provided specific or actionable recommendations for incentives that would encourage participation in the self-assessment. Four commenters encouraged the NCUA to ensure that equal incentives are provided to both FCUs and FISCUs, while one commenter raised concerns that any incentive provided to FCUs not result in changes to the OTR without appropriate notice to the public. One commenter opposed any incentives for participating in the assessment.

NCUA Response: Given the lack of clear consensus among respondents to this question, the Board believes it must study further how to create incentives for completing the voluntary diversity self-assessment. The Board will be mindful of those commenters that suggested that there should be equity between FCUs and FICUs for any incentive program. The Board is not establishing any incentives for completing the diversity self-assessment at this time.

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

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2020–28487 Filed 12–23–20; 8:45 am]

BILLING CODE 7535–01–P

[42] Section 342(b)(2)(C) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203.

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board (NSB), pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended, (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the scheduling of meetings for the transaction of NSB business as follows:

TIME AND DATE: Wednesday, December 9, 2020 from 11:00 a.m. to 6:30 p.m., and Thursday, December 10, 2020 from 11:00 a.m. to 6:45 p.m. EST.

PLACE: These meetings will be held by videoconference. There will be no in-person meetings to attend. The public may observe the public meetings, which will be streamed to the NSF You Tube channel. For meetings on Wednesday, December 9, go to: *https://www.youtube.com/watch?v=Rl3HttPA_b4.* For meetings on Thursday, December 10, go to: *https://www.youtube.com/watch?v=uGjqM0yX4rI.*

STATUS: Some of these meetings will be open to the public. Others will be closed to the public. See full description below.

MATTERS TO BE CONSIDERED:

Wednesday, December 9, 2020

Plenary Board meeting

Open Session: 11:00 a.m.–12:55 p.m.; 1:25 p.m.–2:10 p.m.

- NSB Chair's Remarks
- NSF Director's Remarks
- NSB Chair Activity Summary
- COVID–19 Impact on Women
- NSF Planning and Response to COVID–19
- Vision 2030 Implementation Working Group Update

Committee on Oversight (CO)

Open Session: 2:10 p.m.–3:25 p.m.

- Committee Chair's Opening Remarks
- Approval of Committee Meeting Minutes
- Approval of Merit Review Digest Overview
- Presentations and Discussion of Broader Impacts
- Inspector General's Update

- Chief Financial Officer's Update
- Chair's Closing Remarks

Committee on National Science and Engineering Policy (SEP)

Open Session: 3:45 p.m.–4:35 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Update on planning for *Indicators 2022*
- Impacts of COVID–19 on NCSES Data and Data Products
- Update and Discussion of SEP Policy Products

Committee on Awards and Facilities (A&F)

Open Session: 4:35 p.m.–4:45 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Rolling Calendar Year 2020–2021 Schedule of Planned Action and Context Items

Plenary Board Meeting

Open Session: 5:00–6:30 p.m.

- Celebrating Science and Public Service with the 2020 Waterman and Honorary Awards Winners

Thursday, December 10, 2020

Plenary Board meeting

Open Session: 11:00 a.m.–11:30 a.m.

- Committee on Equal Opportunities in Science and Engineering (CEOSE) Briefing

Committee on Strategy (CS)

Open Session: 11:30 a.m.–1:40 p.m.

- Committee Chair's Remarks
- Approval of Prior Minutes
- Update on FY 2021 Budget Appropriations
- NSF Strategic Plan 2022–2026
- EHR Advisory Committee STEM Education for the Future Report
- NSF Workforce/Missing Millions Briefing
- NSF Translation, Innovation, and Partnerships (TIP) Briefing

Committee on Strategy (CS)

Closed Session: 2:00 p.m.–2:45 p.m.

- Committee Chair's Remarks
- Approval of Prior Minutes
- Update on FY 2022 Budget Request Development
- Translation, Innovation and Partnerships/Workforce/Missing Millions Discussion

Committee on Awards and Facilities (A&F)

Closed Session: 2:45 p.m.–4:35 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Written Item: Regional Class Research Vessels
- Annual Report from the Chief Officer for Research Facilities
- Arecibo Observatory

Plenary Board

Closed Session: 4:45 p.m.–4:55 p.m.

- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- Closed Committee Reports

Plenary Board

Executive Closed Session: 4:55 p.m.–5:40 p.m.

- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- NSF Director's Discussion
  - Personnel updates
- 2021 Honorary Awards Discussion and Vote

Committee on External Engagement (EE)

Open Session: 5:45 p.m.–6:25 p.m.

- Committee Chair's Opening Remarks
- Approval of Prior Minutes
- Near Term Policy Engagement
- UT-Knoxville *Vision* Listening Session
- NSB Messaging

Plenary Board

Open Session: 6:25 p.m.–6:45 p.m.

- NSB Chair's Opening Remarks
- Approval of Prior Minutes
- NSF Director's Remarks
  - Senior Staff Updates
  - Office of Legislative and Public Affairs Update
- Open Committee Reports
- Votes on NSB CY 2021 Schedule and Overview to the 2019 Merit Review Digest

Meeting Adjourns: 6:45 p.m.

MEETINGS THAT ARE OPEN TO THE PUBLIC:

Wednesday, December 9, 2020

11:00 a.m.–12:55 p.m. Plenary NSB
1:25 p.m.–2:10 p.m. Plenary NSB
2:10 p.m.–3:25 p.m. CO
3:45 p.m.–4:35 p.m. SEP
4:35 p.m.–4:45 p.m. A&F
5:00 p.m.–6:30 p.m. Plenary NSB

Thursday, December 10, 2020

11:00 a.m.–11:30 a.m. Plenary NSB
11:30 a.m.–1:40 p.m. CS
5:45 p.m.–6:25 p.m. EE
6:25 p.m.–6:45 p.m. Plenary

MEETINGS THAT ARE CLOSED TO THE PUBLIC:

Thursday, December 10, 2020

2:00 p.m.–2:45 p.m. CS
2:45 p.m.–4:35 p.m. A&F
4:45–4:55 p.m. Plenary
4:55 p.m.–5:40 p.m. Plenary Executive

CONTACT PERSON FOR MORE INFORMATION: The NSB Office contact is Brad Gutierrez, *bgutierr@nsf.gov,* 703–292–7000. The NSB Public Affairs contact is Nadine Lymn, *nlymn@nsf.gov,* 703–292–2490. The following persons will be available to provide technical support in accessing the YouTube video: Angel Ntumy (*antumy@associates.nsf.gov*); Phillip Moulden (*pmoulden@associates.nsf.gov*).

Supplemental Information: Public portions of meetings will be streamed on YouTube so the public can view them. For meetings on Wednesday, December 9, go to: *https://www.youtube.com/watch?v=Rl3HttPA_b4.* For meetings on Thursday, December 10, go to: *https://www.youtube.com/watch?v=uGjqM0yX4rI.*

Please refer to the NSB website for additional information. You will find any updated meeting information and schedule updates (time, place, subject matter, or status of meeting) at *https://www.nsf.gov/nsb/meetings/notices.jsp#sunshine.*

Members of the public are advised that the NSB provides some flexibility around meeting times. A meeting may be allowed to run over by as much as 15 minutes if the Chair decides the extra time is warranted. The next meeting will start no later than 15 minutes after the noticed start time. If a meeting ends early, the next meeting may start up to 15 minutes earlier than the noticed start time. At no point will NSB or committee meetings vary from noticed times by more than 15 minutes. Open meetings can also be watched in their entirety later through the YouTube link.

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2020–26893 Filed 12–22–20; 4:15 pm]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–334, 50–412, 50–483, 50–413, 50–414, 50–346, 50–331, 50–341, 50–348, 50–364, 50–416, 50–354, 50–272, 50–311, 50–245, 50–336, 50–423, 50–528, 50–529, 50–530, 50–440, 50–171, 50–277, 50–278, 72–29, 50–282, 50–306, 50–254, 50–265, 50–458, 50–327, 50–328, 50–387, 50–388; NRC–2020–0110]

Issuance of Multiple Exemptions in Response to COVID–19 Public Health Emergency

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemptions; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) issued 20 exemptions in response to requests from 14 licensees. The exemptions afford these licensees temporary or permanent relief from certain requirements under NRC regulations. The exemptions are in response to the licensees' requests for relief due to the coronavirus disease 2019 (COVID–19) public health emergency (PHE). The NRC is issuing a single notice to announce the issuance of the exemptions.

DATES: During the period from November 2, 2020, to November 25, 2020, the NRC granted 20 exemptions in response to requests submitted by licensees from September 17, 2020, to November 20, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0110 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0110. Address questions about NRC Docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.*
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 between 8:00 a.m. and 4:00 p.m. (EST), Monday through Friday, except Federal holidays.

For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

FOR FURTHER INFORMATION CONTACT: James Danna, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7422, email: *James.Danna@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

During the period from November 2, 2020, to November 25, 2020, the NRC granted 20 exemptions in response to requests submitted by licensees from September 17, 2020, to November 20, 2020. These exemptions temporarily allow the licensees to deviate from certain requirements (as cited below) of various parts of chapter I of title 10 of the *Code of Federal Regulations* (10 CFR).

The exemptions from certain requirements of 10 CFR part 26, ''Fitness for Duty Programs,'' for Energy Harbor Nuclear Corp. (for Beaver Valley Power Station, Units 1 and 2; Davis-Besse Nuclear Power Station, Unit No. 1; and Perry Nuclear Power Plant, Unit No. 1); Union Electric Company (for Callaway Plant, Unit No. 1); DTE Electric Company (for Fermi-2); and Arizona Public Service Company (for Palo Verde Nuclear Generating Station, Units 1, 2, and 3), afford these licensees temporary relief from the work-hour controls under 10 CFR 26.205(d)(1) through (d)(7). The exemptions from 10 CFR 26.205(d)(1) through (d)(7) ensure that the control of work hours and management of worker fatigue do not unduly limit licensee flexibility in using personnel resources to most effectively manage the impacts of the COVID–19 PHE on maintaining the safe operation of these facilities. Specifically, these licensees have stated that their staffing levels are affected or are expected to be affected by the COVID–19 PHE, and they can no longer meet or likely will not meet the work-hour controls of 10 CFR 26.205(d)(1) through (d)(7). These licensees have committed to effecting site-specific administrative controls for COVID–19 PHE fatigue management for personnel specified in 10 CFR 26.4(a).

The exemptions from certain requirements of 10 CFR part 50, appendix E, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' section IV.F., ''Training,'' for Energy Harbor Nuclear Corp. (for Beaver Valley Power Station, Units 1 and 2); NextEra Energy Duane Arnold, LLC (for Duane Arnold Energy Center); Southern Nuclear Operating Company (for Joseph M. Farley Nuclear Plant, Units 1 and 2); Dominion Energy Nuclear Connecticut, Inc. (for Millstone Power Station, Unit Nos. 1, 2, and 3); Northern States Power Company (for Prairie Island Nuclear Generating Plant, Units 1 and 2); Exelon Generation Company, LLC (for Peach Bottom Atomic Power Station, Units 1, 2, and 3; and Quad Cities Nuclear Power Station, Units 1 and 2); Entergy Operations, Inc. (for River Bend Station, Unit 1); Tennessee Valley Authority (for Sequoyah Nuclear Plant, Units 1 and 2); and Susquehanna Nuclear, LLC (for Susquehanna Steam Electric Station, Units 1 and 2), grant temporary exemptions from the biennial emergency preparedness exercise requirement. The exemptions allow a temporary exemption from the requirements of 10 CFR part 50, appendix E, regarding the conduct of the biennial emergency preparedness exercise. These exemptions will not adversely affect the emergency response capability of the facilities because affected licensee personnel are currently qualified, and the licensees' proposed compensatory measures will enable their staff to maintain their knowledge, skills, and abilities without the conduct of the biennial emergency preparedness exercise during the exemption term.

The exemptions from certain requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' section VI, ''Nuclear Power Reactor Training and Qualification Plan for Personnel Performing Security Program Duties,'' for Duke Energy Carolinas, LLC (for Catawba Nuclear Station, Units 1 and 2); Entergy Operations, Inc. (for Grand Gulf Nuclear Station, Unit 1); and PSEG Nuclear LLC (for Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2), will help to ensure that these regulatory requirements do not unduly limit licensee flexibility in using personnel resources in a manner that most effectively manages the impacts of the COVID–19 PHE on maintaining the safe and secure operation of these facilities and the implementation of the licensees' NRC approved security plans, protective strategy, and implementing procedures. These licensees have committed to certain security measures to ensure

response readiness and for their security personnel to maintain performance capability.

The NRC is providing compiled tables of exemptions using a single **Federal Register** notice for COVID–19 related exemptions instead of issuing individual **Federal Register** notices for each exemption. The compiled tables below provide transparency regarding the number and type of exemptions the NRC has issued. Additionally, the NRC publishes tables of approved regulatory actions related to the COVID–19 PHE on its public website at *https://www.nrc.gov/about-nrc/covid-19/reactors/licensing-actions.html.*

II. Availability of Documents

The tables below provide the facility name, docket number, document description, and ADAMS accession number for each exemption issued. Additional details on each exemption issued, including the exemption request submitted by the respective licensee and the NRC's decision, are provided in each exemption approval listed in the tables below. For additional directions on accessing information in ADAMS, see the **ADDRESSES** section of this document.

Document description	ADAMS accession No.
Beaver Valley Power Station, Units 1 and 2 Docket Nos. 50–334 and 50–412	
Beaver Valley Power Station, Units 1 and 2—COVID–19 Related Request for Exemption from part 26 Work Hours Requirements, dated November 20, 2020.	ML20328A006.
Beaver Valley Power Station, Units 1 and 2—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0211 [COVID–19]), dated November 23, 2020.	ML20326A000.
Beaver Valley Power Station, Units 1 and 2 Docket Nos. 50–334 and 50–412	
Beaver Valley Power Station, Units 1 and 2—Request for One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Pandemic, dated September 22, 2020.	ML20266G336.
Submittal of Pennsylvania Letter Requesting Exemption from Biennial Exercise Requirements for Pennsylvania Nuclear Power Plants in Calendar Year 2020, dated October 9, 2020.	ML20283A772.
Beaver Valley Power Station, Units 1 and 2—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV (EPID L–2020–LLE–0149), dated November 6, 2020.	ML20288A640.
Callaway Plant, Unit No. 1 Docket No. 50–483	
Callaway Plant, Unit No. 1—Request for Exemption from Specific Requirements of 10 CFR part 26, ''Fitness for Duty Programs,'' dated November 5, 2020.	ML20310A333.
Callaway Plant, Unit No. 1—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0181 [COVID–19]), dated November 17, 2020.	ML20317A153.
Catawba Nuclear Station, Units 1 and 2 Docket Nos. 50–413 and 50–414	
Catawba Nuclear Station, Units 1 and 2—Response to ''U.S. Nuclear Regulatory Commission Planned Actions Related to the Requirements for 10 CFR part 73, appendix B, section VI During the Coronavirus Disease 2019 Public Health Emergency,'' dated October 5, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Catawba Nuclear Station, Units 1 and 2—Supplement to Request for Temporary Exemption from 10 CFR part 73, appendix B, VI.C.3.(I)(1), Force-on-Force Annual Exercises, dated October 22, 2020.	non-public, withheld pursuant to 10 CFR 2.390.
Catawba Nuclear Station, Units 1 and 2—Temporary Exemption from Certain Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' section VI, dated November 2, 2020.	ML20300A312.
Davis-Besse Nuclear Power Station, Unit No. 1 Docket No. 50–346	
Davis-Besse Nuclear Power Station, Unit No. 1—COVID–19 Related Request for Exemption from part 26 Work Hours Requirement, dated November 18, 2020.	ML20323A169.
Davis-Besse Nuclear Power Station, Unit No. 1—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0208 [COVID–19]), dated November 19, 2020.	ML20323A412.
Duane Arnold Energy Center Docket No. 50–331	
Duane Arnold—Request for One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Evaluated Exercise Requirements,'' due to COVID–19 Pandemic, dated September 22, 2020.	ML20266G292.
Duane Arnold Energy Center—Temporary Exemption from Requirements of 10 CFR part 50, appendix E, sections IV.F.2.B and IV.F.2.C (EPID L–2020–LLE–0150 [COVID–19]), dated November 25, 2020.	ML20301A846.
Fermi-2 Docket No. 50–341	
Fermi-2—Work Hour Limits Exemption Request due to COVID–19, dated November 10, 2020	ML20315A373.
Fermi-2—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0187 [COVID–19]), dated November 18, 2020.	ML20317A272.

Document description	ADAMS accession No.
Joseph M. Farley Nuclear Plant, Units 1 and 2 Docket Nos. 50–348 and 50–364	
Joseph M. Farley Nuclear Plant, Units 1 and 2—Request for One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Pandemic, dated September 21, 2020.	ML20265A353.
Joseph M. Farley Nuclear Plant, Units 1 and 2—Temporary Exemption from Requirements of 10 CFR part 50, appendix E, sections IV.F.2.B and IV.F.2.C (EPID L–2020–LLE–0148 [COVID–19]), dated November 10, 2020.	ML20295A502.
Grand Gulf Nuclear Station, Unit 1 Docket No. 50–416	
Grand Gulf Nuclear Station, Unit 1—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1) Regarding Annual Force-on-Force (FOF) Exercises, due to COVID 19 Pandemic, dated November 13, 2020.	ML20318A386.
Grand Gulf Nuclear Station, Unit 1—Exemption from Annual Force-On-Force Exercise Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' subsection VI.C.3(I)(1) (EPID L–2020–LLE–0196 [COVID–19]), dated November 24, 2020.	ML20323A047.
Hope Creek Generating Station Docket No. 50–354 Salem Nuclear Generating Station, Unit Nos. 1 and 2 Docket Nos. 50–272 and 50–311	
Salem Generating Station, Unit Nos. 1 and 2, and Hope Creek Generating Station—Request for a One-Time Exemption from 10 CFR part 73, appendix B, section VI, subsection C.3.(I)(1), Regarding Annual Force-on-Force (FOF) Exercises, due to COVID–19 Pandemic, dated October 26, 2020.	ML20300A588.
Hope Creek Generating Station and Salem Nuclear Generating Station, Unit Nos. 1 and 2—One-Time Exemption from Certain Requirements of 10 CFR part 73, appendix B, ''General Criteria for Security Personnel,'' section VI (EPID L–2020–LLE–0168 [COVID–19]), dated November 20, 2020.	ML20309A887.
Millstone Power Station, Unit Nos. 1, 2, and 3 Docket Nos. 50–245, 50–336, and 50–423	
Millstone Power Station Unit Nos. 1, 2, and 3—Request for Exemption from Biennial Emergency Preparedness Exercise Requirements in 10 CFR part 50, appendix E, sections IV.F.2.b and IV.F.2.c, dated September 17, 2020.	ML20261H597.
Millstone Power Station, Unit Nos. 1, 2, and 3—Temporary Exemption from Exercise Frequency Requirements of 10 CFR part 50, appendix E, sections IV.F.2.B and IV.F.2.C (EPID L–2020–LLE–0145 [COVID–19]), dated November 24, 2020.	ML20287A273.
Palo Verde Nuclear Generating Station, Units 1, 2, and 3 Docket Nos. 50–528, 50–529, and 50–530	
Palo Verde Nuclear Generating Station, Units 1, 2, and 3, and Independent Spent Fuel Storage Installation—Request for Exemption from Specific Requirements of 10 CFR part 26, ''Fitness for Duty Programs,'' dated October 28, 2020.	ML20302A417.
Palo Verde Nuclear Generating Station, Units 1, 2, and 3—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0170 [COVID–19]), dated November 2, 2020.	ML20303A015.
Perry Nuclear Power Plant, Unit No. 1 Docket No. 50–440	
Perry Nuclear Power Plant, Unit No. 1—COVID–19 Related Request for Exemption from 10 CFR part 26 Work Hours Requirements, dated November 20, 2020.	ML20325A070.
Perry Nuclear Power Plant, Unit No. 1—Exemption from Select Requirements of 10 CFR part 26 (EPID L–2020–LLE–0209 [COVID–19]), dated November 23, 2020.	ML20325A158.
Peach Bottom Atomic Power Station, Units 1, 2, and 3 Docket Nos. 50–171, 50–277, 50–278, and 72–29	
Peach Bottom Atomic Power Station, Units 1, 2, and 3—Request for One-Time Exemption from the Biennial Emergency Preparedness Exercise Requirements in 10 CFR part 50, appendix E, section IV.F.2.c, due to COVID–19 Public Health Emergency, dated September 25, 2020.	ML20269A267.
Submittal of Pennsylvania Letter Requesting Exemption from Biennial Exercise Requirements for Pennsylvania Nuclear Power Plants in Calendar Year 2020, dated October 9, 2020.	ML20283A772.
Peach Bottom Atomic Power Station, Independent Spent Fuel Storage Installation and Units 1, 2, and 3—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV.F (EPID L–2020–LLE–0151 [COVID–19]), dated November 6, 2020.	ML20288A718.

Document description	ADAMS accession No.
Prairie Island Nuclear Generating Plant, Units 1 and 2 Docket No. 50–282 and 50–306	
Prairie Island Nuclear Generating Plant, Units 1 and 2—Request for a One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Pandemic, dated October 7, 2020.	ML20281A665.
Prairie Island Nuclear Generating Plant, Units 1 and 2—Temporary Exemption Requirements of 10 CFR part 50, appendix E, sections IV.F.2.B and IV.F.2.C (EPID L–2020–LLE–0162 [COVID–19]), dated November 9, 2020.	ML20297A239.
Quad Cities Nuclear Power Station, Units 1 and 2 Docket Nos. 50–254 and 50–265	
Quad Cities Nuclear Power Station, Units 1 and 2—Renewed Facility Operating License Nos. DPR–29 and DPR–30, dated September 24, 2020.	ML20269A392.
Quad Cities Nuclear Power Station, Units 1 and 2—Temporary Exemption from Requirements of 10 CFR part 50, appendix E, section IV.F.2.C (EPID L–2020–LLE–0152), dated November 12, 2020.	ML20288A142.
River Bend Station, Unit 1 Docket No. 50–458	
River Bend Station, Unit 1—Request for One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Evaluated Offsite Exercise Requirements,'' due to COVID 19 Pandemic, dated October 6, 2020.	ML20280A734.
River Bend Station, Unit 1—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV.F.2.c (EPID L–2020–LLE–0163 [COVID–19]), dated November 25, 2020.	ML20315A345.
Sequoyah Nuclear Plant, Units 1 and 2 Docket Nos. 50–327 and 50–328	
Sequoyah Nuclear Plant, Units 1 and 2—Request for One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Evaluated Exercise Requirements due to COVID–19 Pandemic,'' dated September 30, 2020.	ML20274A362.
Sequoyah Nuclear Plant, Units 1 and 2—Temporary Exemption from Exercise Frequency Requirements of 10 CFR part 50, appendix E, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' section IV.F (EPID L–2020–LLE–0157 [COVID–19]), dated November 10, 2020.	ML20288A546.
Susquehanna Steam Electric Station, Units 1 and 2 Docket Nos. 50–387 and 50–388	
Susquehanna Steam Electric Station, Units 1 and 2—Request for One-Time Exemption from 10 CFR part 50, appendix E, ''Biennial Emergency Preparedness Exercise Requirements,'' due to COVID–19 Pandemic (PLA–7893), dated September 28, 2020.	ML20272A020.
Submittal of Pennsylvania Letter Requesting Exemption from Biennial Exercise Requirements for Pennsylvania Nuclear Power Plants in Calendar Year 2020, dated October 9, 2020.	ML20283A772.
Susquehanna Steam Electric Station, Units 1 and 2—Temporary Exemption from Biennial Emergency Preparedness Exercise Frequency Requirements of 10 CFR part 50, appendix E, section IV.F (EPID L–2020–LLE–0153 [COVID–19]), dated November 6, 2020.	ML20294A291.

Dated: December 21, 2020.

For the Nuclear Regulatory Commission.

James G. Danna,

Chief, Plant Licensing Branch I, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–28588 Filed 12–23–20; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF PERSONNEL MANAGEMENT

Excepted Service

AGENCY: Office of Personnel Management (OPM).

ACTION: Notice.

SUMMARY: This notice identifies Schedule A, B, and C appointing authorities applicable to a single agency that were established or revoked from September 1, 2020 to September 30, 2020.

FOR FURTHER INFORMATION CONTACT: Julia Alford, Senior Executive Resources Services, Senior Executive Services and Performance Management, Employee Services, 202–606–2246.

SUPPLEMENTARY INFORMATION: In accordance with 5 CFR 213.103, Schedule A, B, and C appointing authorities available for use by all agencies are codified in the Code of Federal Regulations (CFR). Schedule A, B, and C appointing authorities applicable to a single agency are not codified in the CFR, but the Office of Personnel Management (OPM) publishes a notice of agency-specific authorities established or revoked each month in the **Federal Register** at *www.gpo.gov/fdsys/*. OPM also publishes an annual notice of the consolidated listing of all Schedule A, B, and C appointing authorities, current as of June 30, in the **Federal Register**.

Schedule A

75. Woodrow Wilson International Center for Scholars (Sch. A 213.3175)

(a) One Asian Studies Program Administrator, one International Security Studies Program Administrator, one Latin American Program Administrator, one Russian Studies Program Administrator, four Social Science Program Administrators, one Middle East Studies Program Administrator, one African Studies Program Administrator, one Global Sustainability and Resilience Program

Administrator, one Canadian Studies Program Administrator; one China Studies Program Administrator, one Science, Technology and Innovation Program Administrator, and one Mexico Studies Program Administrator.

Schedule B

No Schedule B Authorities to report during September 2020.

Schedule C

The following Schedule C appointing authorities were approved during September 2020.

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF AGRICULTURE	Office of the Chief Financial Officer	Confidential Assistant	DA200125	09/11/2020
UNITED STATES AGENCY FOR GLOBAL MEDIA.	United States Agency for Global Media.	Special Assistant and Director of Executive Office Operations.	IB200007	09/02/2020
		Principal Director of Public Affairs	IB200004	09/11/2020
		Principal Director Office of Contracts.	IB200009	09/29/2020
DEPARTMENT OF COMMERCE	Office of International Trade Administration.	Press Secretary	DC200181	09/21/2020
	National Oceanic and Atmospheric Administration.	Deputy Assistant Secretary for Oceans and Atmosphere.	DC200175	09/03/2020
	Office of the Chief Financial Officer and Assistant Secretary for Administration.	Confidential Assistant	DC200147	09/11/2020
		Special Assistant	DC200187	09/21/2020
COMMISSION ON CIVIL RIGHTS	Office of the Commissioners	Special Assistant	CC200003	09/11/2020
COUNCIL ON ENVIRONMENTAL QUALITY.	Council on Environmental Quality	Special Assistant	EQ200001	09/09/2020
DEPARTMENT OF DEFENSE	Office of the Assistant Secretary of Defense (Legislative Affairs).	Special Assistant	DD200240	09/03/2020
	Office of the Under Secretary of Defense (Acquisition and Sustainment).	Special Assistant	DD200271	09/26/2020
	Office of the Under Secretary of Defense (Comptroller).	Special Assistant	DD200266	09/29/2020
	Office of the Under Secretary of Defense (Personnel and Readiness).	Special Assistant	DD200247	09/11/2020
	Office of the Under Secretary of Defense (Policy).	Special Assistant	DD200255	09/10/2020
	Washington Headquarters Services	Defense Fellow	DD200269	09/21/2020
DEPARTMENT OF THE AIR FORCE.	Office of the General Counsel	Special Assistant	DF200016	09/18/2020
	Office of the Assistant Secretary Air Force, Installations, Environment, and Energy.	Special Assistant (2)	DF200014	09/19/2020
			DF200017	09/30/2020
DEPARTMENT OF THE NAVY	Office of the Secretary of the Navy	Deputy Chief of Staff	DN200057	09/16/2020
DEPARTMENT OF EDUCATION	Office of Legislation and Congressional Affairs.	Senior Advisor	DB200071	09/24/2020
DEPARTMENT OF ENERGY	Office of the Advanced Research Projects Agency—Energy.	Deputy Chief of Staff	DE200191	09/26/2020
	Office of the Assistant Secretary for Environmental Management.	Special Advisor for Communications (2).	DE200128	09/19/2020
			DE210003	09/19/2020
	Office of the Assistant Secretary for International Affairs.	Senior Advisor	DE200200	09/29/2020
	Office of Artificial Intelligence and Technology.	Chief of Staff	DE200145	09/19/2020
	Office of Cybersecurity, Energy Security and Emergency Response.	Chief of Staff	DE200197	09/24/2020
	Office of Management	Special Assistant	DE200202	09/30/2020
	Office of Public Affairs	Press Secretary	DE200129	09/24/2020
	Office of the Secretary	Special Assistant	DE200196	09/24/2020
		White House Liaison	DE200198	09/24/2020
	Office of the Secretary of Energy Advisory Board.	Deputy Director	DE200171	09/19/2020
ENVIRONMENTAL PROTECTION AGENCY.	Office of Public Affairs	Special Advisor for Digital Media	EP200100	09/24/2020
	Office of Public Engagement and Environmental Education.	Deputy Associate Administrator for the Office of Public Engagement and Environmental Education.	EP200114	09/24/2020
	Office of the Administrator	Special Advisor for Logistics	EP200066	09/16/2020
	Office of the Assistant Administrator for Land and Emergency Management.	Senior Policy Advisor	EP200110	09/26/2020
	Office of the Associate Administrator for Congressional and Intergovernmental Relations.	Special Advisor	EP200068	09/24/2020
GENERAL SERVICES ADMINISTRATION.	Office of the Administrator	Deputy White House Liaison and Senior Advisor.	GS200045	09/29/2020

Agency name	Organization name	Position title	Authorization No.	Effective date
DEPARTMENT OF HEALTH AND HUMAN SERVICES.	Office of the Secretary	Special Assistant	DH200175	09/19/2020
DEPARTMENT OF HOMELAND SECURITY.	Countering Weapons of Mass Destruction Office.	Senior Advisor	DM200353	09/17/2020
	United States Customs and Border Protection.	Deputy Press Secretary	DM200396	09/25/2020
	Office of Strategy, Policy, and Plans.	Senior Advisor, National and Transnational Threats.	DM200381	09/30/2020
DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT.	Office of the Deputy Secretary	Special Assistant	DU200153	09/03/2020
DEPARTMENT OF THE INTERIOR	Office of the Assistant Secretary—Indian Affairs.	Assistant for Indian Affairs	DI200115	09/15/2020
	Bureau of Land Management	Senior Advisor, Bureau of Land Management.	DI200062	09/15/2020
	Office of Congressional and Legislative Affairs.	Senior Advisor	DI190078	09/03/2020
	Office of the Deputy Secretary	Advisor	DI200057	09/14/2020
	Secretary's Immediate Office	Advance Representative (2)	DI200058	09/03/2020
			DI200118	09/25/2020
		Special Assistant	DI200116	09/14/2020
		Press Assistant	DI200114	09/15/2020
	Office of United States Fish and Wildlife Service.	Senior Advisor	DI200059	09/03/2020
DEPARTMENT OF JUSTICE	Office of Civil Rights Division	Senior Counsel	DJ200148	09/10/2020
	Office of Justice Programs	Policy Advisor	DJ200130	09/25/2020
DEPARTMENT OF LABOR	Office of the Solicitor	Counsel	DL200164	09/03/2020
	Office of Mine Safety and Health Administration.	Chief of Staff	DL200173	09/10/2020
	Office of Wage and Hour Division	Special Assistant	DL200175	09/10/2020
OFFICE OF NATIONAL DRUG CONTROL POLICY.	Office of the Director	Special Adviser	QQ200009	09/24/2020
		White House Liaison and Advisor	QQ200010	09/30/2020
SMALL BUSINESS ADMINISTRATION.	Office of the Administrator	White House Liaison	SB200043	09/26/2020
DEPARTMENT OF TRANSPORTATION.	Office of the Assistant Secretary for Governmental Affairs.	Senior Advisor for Intergovernmental Affairs.	DT200148	09/24/2020
		Governmental Affairs Officer	DT200134	09/26/2020
	Office of the Assistant Secretary for Transportation Policy.	Public Liaison	DT200149	09/24/2020
	Office of the Deputy Secretary	Special Assistant for Advance Operations.	DT200130	09/24/2020
	Office of the Secretary	White House Liaison	DT200151	09/26/2020
DEPARTMENT OF VETERANS AFFAIRS.	Office of Public Affairs	Press Secretary	DV200095	09/29/2020
	Office of the General Counsel	Special Assistant (Attorney Advisor).	DV200104	09/30/2020

There were no Schedule C appointing authorities revoked during September 2020.

Authority: 5 U.S.C. 3301 and 3302; E.O. 10577, 3 CFR, 1954–1958 Comp., p. 218.

Office of Personnel Management.

Alexys Stanley,

Regulatory Affairs Analyst.

[FR Doc. 2020–28506 Filed 12–23–20; 8:45 am]

BILLING CODE 6325–39–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2021–50 and CP2021–52]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* December 30, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505

(Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

1. Docket No(s).: MC2021–50 and CP2021–52; Filing Title: USPS Request to Add Priority Mail Contract 685 to Competitive Product List and Notice of Filing Materials Under Seal; Filing Acceptance Date: December 18, 2020; Filing Authority: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; Public Representative: Christopher C. Mohr; Comments Due: December 30, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–28580 Filed 12–23–20; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

International Product Change—International Priority Airmail, International Surface Air Lift, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreement: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add an International Priority Airmail, International Surface Air Lift, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: *Date of notice:* December 28, 2020.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268–7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on December 15, 2020, it filed with the Postal Regulatory Commission a *USPS Request to Add International Priority Airmail, International Surface Air Lift, Commercial ePacket, Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 1 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2021–47 and CP2021–49.

Ruth Stevenson,

Chief Counsel, Federal Compliance.

[FR Doc. 2020–28573 Filed 12–23–20; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90734; File No. SR–FINRA–2020–030]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1 and Order Instituting Proceedings To Determine Whether To Approve or Disapprove the Proposed Rule Change, as Modified by Amendment No. 1, To Amend the Codes of Arbitration Procedure Relating To Requests To Expunge Customer Dispute Information, Including Creating a Special Arbitrator Roster To Decide Certain Expungement Requests

December 18, 2020.

I. Introduction

On September 22, 2020, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change SR–FINRA–2020–030 (''Proposed Rule Change'') pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4[2] thereunder to modify the current process relating to the expungement of customer dispute information.[3] The Proposed Rule Change was published for public comment in the **Federal Register** on October 1, 2020.[4] On November 12, 2020, FINRA consented to an extension of the time period in which the Commission must approve the Proposed Rule Change, disapprove the Proposed Rule Change, or institute proceedings to determine whether to approve or disapprove the Proposed Rule Change to December 30, 2020.[5] On December 18, 2020, FINRA responded to the comment letters received in response to the Notice and filed an amendment to modify the Proposed Rule Change (''Amendment No. 1'').[6] The Commission is publishing this order pursuant to Section 19(b)(2)(B) of the Exchange Act[7] to solicit comments on Amendment No. 1 from interested persons and to institute proceedings to determine whether to approve or disapprove the Proposed Rule Change, as modified by Amendment No. 1.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

FINRA is proposing to amend the Code of Arbitration Procedure for Customer Disputes (''Customer Code'') and the Code of Arbitration Procedure for Industry Disputes (''Industry Code'') (together, ''Codes'') to modify the current process relating to the expungement of customer dispute information. Specifically, the Proposed Rule Change would amend the Codes to: (1) Impose requirements on expungement requests (a) filed during an investment-related, customer initiated arbitration (''customer arbitration'') by an associated person, or by a party to the customer arbitration on-behalf-of an associated person, or (b) filed by an associated person separate from a customer arbitration (''straight-in request''); (2) establish a roster of arbitrators with enhanced training and experience from which a three-person

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See infra* note 4.

[4] Exchange Act Release No. 90000, (Sep. 25, 2020), 85 FR 62142 (Oct. 1, 2020) (File No. SR–FINRA–2020–030) (''Notice'').

[5] *See* letter from Mignon McLemore, Assistant General Counsel, Office of General Counsel, FINRA, to Lourdes Gonzalez, Assistant Chief Counsel, Division of Trading and Markets, Commission, dated November 12, 2020.

[6] *See* letter from Mignon McLemore, Assistant General Counsel, Office of General Counsel, FINRA, to Vanessa Countryman, Secretary, Commission, dated December 18, 2020.

[7] 15 U.S.C. 78s(b)(2)(B).

panel would be randomly selected to decide straight-in requests; (3) establish procedural requirements for expungement hearings; and (4) codify and update the best practices of the Notice to Arbitrators and Parties on Expanded Expungement Guidance (''Guidance'') that arbitrators and parties must follow.[8] In addition, the Proposed Rule Change would amend the Customer Code to specify procedures for requesting expungement of customer dispute information arising from simplified arbitrations. The Proposed Rule Change would also amend the Codes to establish requirements for notifying state securities regulators and customers of expungement requests.

III. Proceedings To Determine Whether To Approve or Disapprove File No. SR–FINRA–2020–030 and Grounds for Disapproval Under Consideration

The Commission is instituting proceedings pursuant to Section 19(b)(2)(B) of the Exchange Act to determine whether the Proposed Rule Change, as modified by Amendment No.1, should be approved or disapproved.[9] Institution of proceedings is appropriate at this time in view of the legal and policy issues raised by the Proposed Rule Change, as modified by Amendment No.1. Institution of proceedings does not indicate that the Commission has reached any conclusions with respect to the Proposed Rule Change, as modified by Amendment No.1.

Pursuant to Section 19(b)(2)(B) of the Exchange Act,[10] the Commission is providing notice of the grounds for disapproval under consideration. The Commission is instituting proceedings to allow for additional analysis and input concerning whether the Proposed Rule Change, as modified by Amendment No.1, is consistent with the Exchange Act and the rules thereunder.

IV. Request for Written Comments

The Commission requests that interested persons provide written submissions of their views, data, and arguments with respect to the issues identified above, as well as any other concerns they may have with the Proposed Rule Change, as modified by Amendment No. 1. In particular, the Commission invites the written views of interested persons concerning whether the Proposed Rule Change, as modified by Amendment No. 1, is consistent with the Exchange Act and the rules thereunder.

Although there do not appear to be any issues relevant to approval or disapproval that would be facilitated by an oral presentation of views, data, and arguments, the Commission will consider, pursuant to Rule 19b–4, any request for an opportunity to make an oral presentation.[11]

Interested persons are invited to submit written data, views, and arguments regarding whether the Proposed Rule Change, as modified by Amendment No. 1, should be approved or disapproved by January 19, 2021. Any person who wishes to file a rebuttal to any other person's submission must file that rebuttal by February 1, 2021.

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–FINRA–2020–030 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR- FINRA–2020–030. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the Proposed Rule Change, as modified by Amendment No. 1, that are filed with the Commission, and all written communications relating to the Proposed Rule Change, as modified by Amendment No. 1, between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street, NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA.

All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly.

All submissions should refer to File No. SR–FINRA–2020–030 and should be submitted on or before January 19, 2021. If comments are received, any rebuttal comments should be submitted on or before February 1, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28509 Filed 12–23–20; 8:45 am]

BILLING CODE 8011–01–P

[8] *See* Guidance, available at *https://www.finra.org/arbitration-and-mediation/notice-arbitrators-and-parties-expanded-expungement-guidance.*

[9] 15 U.S.C. 78s(b)(2)(B).

[10] *Id.*

[11] Section 19(b)(2) of the Act, as amended by the Securities Acts Amendments of 1975, Pub. L. 94–29, 89 Stat. 97 (1975), grants the Commission flexibility to determine what type of proceeding—either oral or notice and opportunity for written comments—is appropriate for consideration of a particular proposal by a self-regulatory organization. *See* Securities Acts Amendments of 1975, Report of the Senate Committee on Banking, Housing and Urban Affairs to Accompany S. 249, S. Rep. No. 75, 94th Cong., 1st Sess. 30 (1975).

[12] 17 CFR 200.30–3(a)(12); 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34143; File No. 813–00397]

Citadel Enterprise Americas LLC (formerly Citadel LLC) and CEIF LLC; Notice of Application

December 18, 2020.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of application for an order under sections 6(b) and 6(e) of the Investment Company Act of 1940 (the ''Act'') granting an exemption from all provisions of the Act, except section 9 and sections 36 through 53 and the rules and regulations under those sections. With respect to sections 17 and 30 of the Act, and the rules and regulations thereunder, and rule 38a-1 under the Act, the exemption is limited as set forth in the application.

SUMMARY OF APPLICATION: Applicants request a superseding order under sections 6(b) and 6(e) of the Act that amends and restates an existing order (''Existing Order'') [1] to exempt certain limited liability companies, limited partnerships, companies and other

[1] *Citadel LLC and CEIF LLC,* Investment Company Act Release Nos. 30589 (July 3, 2013) (notice) and 30637 (July 30, 2013) (order).

investment vehicles formed for the benefit of eligible employees of Citadel Enterprise Americas LLC and its affiliates (''ESC Funds'') from certain provisions of the Act. Each ESC Fund will be an ''employees' securities company,'' as defined in section 2(a)(13) of the Act. The requested order would (i) reflect general, clarifying updates to the incentive program pursuant to which Eligible Employees (defined below) are issued unvested membership interests, (ii) to permit voluntary capital contributions by Eligible Employees to certain ESC Funds, and (iii) to clarify that Eligible Employees may continue to be issued interests and/or make capital contributions to the ESC Fund in which it is invested after such Eligible Employee's employment with Citadel has terminated. The terms and conditions of the application are materially the same as the terms and conditions of the Existing Order.

APPLICANTS: Citadel Enterprise Americas LLC and CEIF LLC (''CEIF'').

FILING DATES: The application was filed on December 13, 2019, and amended on May 7, 2020, July 10, 2020, and October 15, 2020.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on January 12, 2021, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary.

ADDRESSES: The Commission: *Secretarys-Office@sec.gov.* Applicants: c/o David Form, by email to *dform@sidley.com.*

FOR FURTHER INFORMATION CONTACT: Joseph Toner, Senior Counsel, at (202) 551–7595, or David Nicolardi, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or an applicant using the Company's name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants' Representations:

1. Citadel is a global financial institution with a diverse business platform which includes two separate and distinct unites: (i) A global investment firm and (ii) a global market maker. Citadel Enterprise Americas LLC, a Delaware limited liability company, and its ''Affiliates,'' as defined in rule 12b–2 under the Securities Exchange Act of 1934 (''Exchange Act'') other than an ESC Fund are referred to collectively as ''Citadel'' or ''Citadel Entities.''

2. Citadel has established CEIF, a Delaware limited liability company, and will establish any other ESC Funds (collectively with CEIF, the ''ESC Funds'' and each, an ''ESC Fund'') for the benefit of Eligible Employees (defined below) as part of a program to create capital building opportunities that are competitive with those at other financial services firms and to facilitate the recruitment and retention of high caliber professionals. Each of the ESC Funds will be a limited liability company, limited partnership, corporation, business trust or other entity organized under the laws of the state of Delaware or another U.S. jurisdiction. Each ESC Fund will be identical in all material respects (other than investment objectives and strategies, vesting terms, form of organization and related structural and operative provisions contained in the constitutive documents of such ESC Funds). Each ESC Fund is or will be an ''employees' security company'' as such term is defined in section 2(a)(13) of the Act and will operate as a diversified or non-diversified management investment company. Citadel will control the ESC Funds within the meaning of section 2(a)(9) of the Act.

3. The Managing Member [2] of each ESC Fund will be an Affiliate of Citadel Enterprise Americas LLC. Any member or partner of, or other investor in, an ESC Fund is a ''Member.'' The Managing Member of each ESC Fund will manage, operate and control such ESC Fund, however, it will be authorized to delegate investment management responsibility with respect to the acquisition, management and disposition of Portfolio Investments (defined below) to a Citadel Entity. Any Citadel Entity that is delegated the responsibility of making investment decisions for an ESC Fund will be registered as an investment adviser under the Investment Advisers Act of 1940 (the ''Advisers Act''), if required under applicable law.

4. The Managing Member, a Member, Citadel or any employees of the Managing Member or Citadel will be eligible to receive any compensation, or any performance-based fee or profits allocation (such as a ''carried interest'' [3]). All ESC Fund investments (which may be made directly or through a Citadel Third Party Fund [4]) are referred to as ''Portfolio Investments.''

5. Interests in an ESC Fund will be issued without registration in transactions under a claim of exemption pursuant to section 4(a)(2) of the Securities Act of 1933 (the ''Securities Act''), Regulation D and/or Regulation S [5] and may be acquired only by (i) ''Eligible Employees'' or (ii) at the request of Eligible Employees and in the discretion of the Managing Member of an ESC Fund, by Qualified Participants (defined below) of such Eligible Employees. Prior to issuing Interests (defined below) to an Eligible Employee or a Qualified Investment Vehicle (defined below) or prior to permitting an Eligible Employee or a Qualified Investment Vehicle to make an additional capital contribution, the Managing Member must reasonably believe that each Eligible Employee (or the Eligible Employee relating to the Qualified Investment Vehicle) is a sophisticated investor capable of understanding and evaluating the risks of participation in an ESC Fund (or class thereof) without the benefit of regulatory safeguards.

6. An ''Eligible Employee'' is an individual who is (i) a current or former employee, officer or partner of Citadel or a director of Citadel that is an ''interested person'' (as defined in Section 2(a)(19) of the Act) of Citadel

[2] ''Managing Member'' means an Affiliate of Citadel Enterprise Americas LLC that is a managing member or manager of an ESC Fund (there being no distinction between the obligations of a managing member versus a manager of an ESC Fund) or acts in a similar capacity and is the functional equivalent of the ESC Funds' board of directors.

[3] A ''carried interest'' is a fee paid or allocation made to the Managing Member, a Member or the Citadel Entity acting as the investment adviser to an ESC Fund based on net gains in addition to the amount allocable to such entity in proportion to its invested capital. A Managing Member, Member or Citadel Entity that is registered as an investment adviser under the Advisers Act may be paid or allocated carried interest only if permitted by rule 205–3 under the Advisers Act.

[4] ''Citadel Third Party Fund'' means an investment fund or separate account, organized in part for the benefit of investors who are not Affiliates of Citadel, over which a Citadel Affiliate exercises investment discretion.

[5] An offer may be made pursuant to Regulation S to Eligible Employees who are not U.S. residents.

and (ii) meets the standards of an ''accredited investor'' under rule 501(a)(5) or (6) of Regulation D (''Accredited Investor''). A ''Qualified Participant'' is an entity that (i) is a Qualified Investment Vehicle and (ii) if such entity is purchasing an Interest directly from an ESC Fund, comes within one of the categories of an ''accredited investor'' under rule 501(a) of Regulation D. A ''Qualified Investment Vehicle'' is (a) a trust of which the trustee, grantor and/or beneficiary is an Eligible Employee and over which the Eligible Employee or their designee exercises investment discretion, or (b) a partnership, corporation or other entity controlled by an Eligible Employee. Eligible Employees and/or their Qualified Investment Vehicle that are not accredited investors will not be permitted to invest in an ESC Fund.

7. The terms of an ESC Fund will be fully disclosed to each Eligible Employee and, if applicable, a Qualified Participant, prior to the time such Eligible Employee is admitted to the ESC Fund. Each Eligible Employee and Qualified Participant will be furnished with the offering documents, including a copy of the operating agreement or other organizational documents (''Operating Agreement'') for the relevant ESC Fund. The Managing Member of each ESC Fund will send to each person who was a Member having an Interest in the ESC Fund at any time during the fiscal year then ended (except for the first year of operations of an ESC Fund if no investment activities took place in such fiscal year), audited financial statements with respect to those ESC Funds in which the Member held Interests within 120 days after the end of the fiscal year, or as soon as practicable thereafter. For purposes of this requirement ''audit'' shall have the meaning defined in rule 1–02(d) of Regulation S–X. In addition, as soon as practicable after the end of each tax year of an ESC Fund, a report will be transmitted to each Member showing such Member's share of income, gains, losses, credits, deductions, and other tax items for U.S. federal income tax purposes, resulting from such ESC Fund's operations during that year.

8. Interests in each ESC Fund will be non-transferable except (i) to the extent cancelled or (ii) with the prior written consent of the Managing Member, and, in any event, no person or entity will be admitted into an ESC Fund as a Member unless such person or entity is (a) an Eligible Employee, (b) a Qualified Participant of an Eligible Employee, or (c) a Citadel Entity, including Citadel Enterprise Americas LLC. Interests in these ESC Funds will be issued without a sales load or similar fee.

9. Ownership interests (''Interests'') in an ESC Fund may be acquired on a voluntary basis or through an incentive program pursuant to which incentive awards of cash and/or unvested membership interests are issued to Eligible Employees (the ''Program''). Interests in a ''Program ESC Fund'' may be acquired (i) through the Program or (ii) to the extent permitted by the Managing Member, by voluntary capital contributions from an Eligible Employee. Pursuant to the Program, Eligible Employees may be issued incentive awards on the basis of, among other things, personal performance and/or firm-wide or relevant team performance results. An Eligible Employee may voluntarily acquire an Interest in a non-Program ESC Fund or, to the extent permitted by the Managing Member, in a Program ESC Fund. To the extent permitted by the Managing Member, an Eligible Employee and/or its Qualified Participant may be issued additional Interests (whether vested or unvested) and/or may make additional capital contributions to the ESC Fund in which it is invested after such Eligible Employee's employment with Citadel has terminated.

10. Both Program ESC Funds and non-Program ESC Funds may be offered as part of an investment program that includes vesting and cancellation provisions. In such circumstances, some or all of an Eligible Employee's Interest at the commencement of the investment program will be treated as being ''unvested,'' and ''vesting'' will occur only as certain conditions are satisfied under the terms of the investment program. The portion of an Eligible Employee's Interest that is ''unvested'' at the time of termination of such Eligible Employee's employment by Citadel may be subject to (a) cancellation and/or (b) the imposition of different terms and conditions, which would be described in the Operating Agreement and/or offering documents of the relevant ESC Fund and/or in other written correspondence issued to such Eligible Employee.

11. With respect to Program ESC Funds, a Member will become vested in his/her unvested membership interests if (a) he/she remains employed by Citadel through a specified date (the ''Determination Date'') and he/she has satisfied, among other things, all of the certain applicable conditions (including non-competition, non-solicitation, non-disclosure and notice conditions) imposed on him/her throughout his/her employment up to the specified date or (b) in the case of certain specified Eligible Employees, he/she ceases to be employed by Citadel prior to the specified date but he/she has satisfied, among other things, all of the conditions, if any, imposed on him/her during his/her employment with Citadel and through any applicable post-employment period and affirms his/her compliance with the conditions, as applicable. Non-Program ESC Funds may or may not provide for vesting provisions. An Eligible Employee that purchases an Interest in a non-Program ESC Fund or makes a voluntary capital contribution to a Program ESC Fund will immediately vest in the portion of the Interest in such ESC Fund attributable to such purchase or contribution.

12. With respect to a non-Program ESC Fund that does not provide for vesting provisions, an Eligible Employee's entire Interest may be subject to repurchase by the Managing Member and/or the imposition of different terms and conditions upon termination of such Eligible Employee's employment by Citadel, as described in the Operating Agreement and/or offering documents related to the relevant ESC Fund and/or in other written correspondence issued to such Eligible Employee. Upon any repurchase of an Eligible Employee's vested membership interest, the Managing Member will at a minimum pay to the Eligible Employee the lesser of (a) the amount actually paid by the Eligible Employee to acquire the vested membership interest plus interest, provided that any prior distributions are subtracted from such combined amount, and (b) the fair market value of such vested membership interest as determined at the time of repurchase by the Managing Member in accordance with the relevant ESC Fund's valuation policies and procedures. The terms of any repurchase or cancellation of Interests will apply equally to any Eligible Employee and any Qualified Participant of such Eligible Employee.

13. With respect to Program ESC Funds, a Member who remains employed by Citadel may make a request to defer redemption of its unvested membership interests from the relevant Program ESC Fund beyond the relevant Determination Date, subject to approval by Citadel. If a Member does not make such a request, or Citadel does not approve such request, that portion of a Member's Interest attributable to such unvested membership interests will be mandatorily redeemed as soon as reasonably practicable following the

relevant Determination Date.[6] Citadel will endeavor to treat Members consistently in making the determination to approve such requests. A vested membership interest in a Program ESC Fund (including a vested membership interest received in respect of a voluntary capital contribution to such Program ESC Fund by an Eligible Employee) may be redeemed as of any calendar quarter-end upon not less than seventy days' prior written notice or according to such other terms as may be described in such Program ESC Fund's Operating Agreement and/or offering documents or election form, subject to the availability of liquidity (including suspensions on withdrawals) in respect of the Citadel Third Party Funds in which the relevant Participation Points ESC Fund is invested.

14. Subject to the terms of the applicable Operating Agreement and/or offering documents, an ESC Fund will be permitted to enter into transactions involving (i) a Citadel Entity, (ii) any Member or person or entity affiliated with a Member or (iii) a Citadel Third Party Fund. Prior to entering into any of these transactions, the Managing Member will make the findings required in Condition 1 below. A Citadel Entity (including the Managing Member) also may provide a full range of financial, asset management or other services, and may also provide financing in the form of debt, equity or other financial instruments, and receive fees or other compensation and expense reimbursement in connection therewith, from entities in which an ESC Fund (directly or indirectly) makes an investment, from competitors of such entities or from other unaffiliated persons or entities.

15. The investment objective of each ESC Fund and whether it will operate as a diversified or non-diversified and open-end or closed-end registered investment vehicle may vary from ESC Fund to ESC Fund, and will be set forth in the offering documents relating to the specific ESC Funds. Each ESC Fund (directly or indirectly through its investments in Citadel Third Party Funds) may engage in various investment strategies implemented by Citadel in markets around the world. An ESC Fund may invest directly in securities (including exchange-traded funds, mutual funds and index funds) and similar investments and/or may invest all or substantially all of its assets in Citadel Third Party Funds.[7] An ESC Fund will not acquire any security issued by a registered investment company if immediately after the acquisition such ESC Fund will own more than 3% of the outstanding voting stock of the registered investment company.

16. The offering documents will set forth, if applicable, whether the Managing Manager or a Citadel Entity will make any capital contributions or loans to such ESC Fund, and, if so, the terms applicable to the Managing Member's or the Citadel Entity's investment in such ESC Fund or its extension of credit to such ESC Fund, provided that the interest rate applicable to any such loan made to an ESC Fund will be no less favorable to such ESC Fund than the rate obtainable in an arm's-length transaction, provided, further, that any indebtedness of such ESC Fund will be the debt of such ESC Fund and without recourse to the Members. An Eligible Employee will not borrow from any person if such borrowing would cause any person not named in section 2(a)(13) of the Act to own outstanding securities of an ESC Fund (other than short-term paper). No ESC Fund will borrow from any person if the borrowing would cause any person not named in section 2(a)(13) of the Act to own outstanding securities of the ESC Fund (other than short-term paper).

APPLICANTS' LEGAL ANALYSIS: 1. Section 6(b) of the Act provides, in part, that the Commission will exempt employees' securities companies from the provisions of the Act to the extent that the exemption is consistent with the protection of investors. Section 6(b) provides that the Commission will consider, in determining the provisions of the Act from which the employees' securities companies should be exempt, the company's form of organization and capital structure, the persons owning and controlling its securities, the price of the company's securities and the amount of any sales load, how the company's funds are invested, and the relationship between the company and the issuers of the securities in which it invests. Section 2(a)(13) defines an employees' securities company, in relevant part, as any investment company all of whose securities (other than short-term paper) are beneficially owned (a) by current or former employees, or persons on retainer, of one or more affiliated employers, (b) by immediate family members of such persons, or (c) by such employer or employers together with any of the persons in (a) or (b).

2. Section 7 of the Act generally prohibits investment companies that are not registered under section 8 of the Act from selling or redeeming their securities. Section 6(e) of the Act provides that the Commission may determine as necessary or appropriate in the public interest or for the protection of investors that, in connection with any order exempting an investment company from section 7 of the Act, certain provisions of the Act will be applicable to such investment company and to other persons in their transactions and relations with such investment company, as though such investment company were a registered investment company. Applicants request an order under sections 6(b) and 6(e) of the Act that amends and restates the Existing Order exempting the Applicants and any ESC Funds from all provisions of the Act, except section 9 and sections 36 through 53, and the rules and regulations under the Act. With respect to sections 17 and 30 of the Act, and the rules and regulations thereunder, and rule 38a-1 under the Act, the exemption is limited as set forth in the application.

3. Section 17(a) of the Act, among other things, generally prohibits any affiliated person of a registered investment company, or any affiliated person of an affiliated person, acting as principal, from knowingly selling or purchasing any security or other property to or from the investment company. Applicants request an exemption from section 17(a) to the extent necessary to: (a) Permit a Citadel Entity or a Citadel Third Party Fund (or any affiliated person of such Citadel Entity or Citadel Third Party Fund), or any affiliated person of an ESC Fund (or affiliated persons of such persons) acting as principal, to engage in any transaction directly or indirectly with any ESC Fund or any company controlled by such ESC Fund; and (b) permit any ESC Fund to invest in or engage in any transaction with any Citadel Entity or Citadel Third Party Fund, acting as principal: (i) in which such ESC Fund, any company controlled by such ESC Fund or any Citadel Entity or Citadel Third Party Fund has invested or will invest; or (ii) with which such ESC Fund, any company controlled by such ESC Fund or any Citadel Entity or Citadel Third

[6] In the event of such a mandatory redemption, subject to the availability of liquidity (including suspensions on withdrawals) in respect of the Citadel Third Party Funds in which the relevant Program ESC Fund is invested, the balance of such Member's capital account in such Program ESC Fund relating to such redeemed Interest, as adjusted through the date of such redemption, will be distributed to such Member.

[7] Applicants are not requesting any exemption from any provision of the Act or any rule thereunder that may govern the eligibility of an ESC Fund to invest in an entity relying on section 3(c)(1) or 3(c)(7) of the Act or any such entity's status under the Act.

Party Fund is or will otherwise become affiliated.

4. Applicants submit that an exemption from section 17(a) is consistent with the purposes of each ESC Fund and the protection of investors, and is necessary to promote the basic purpose of such ESC Fund. Applicants state that the Members of each ESC Fund will be fully informed of the possible extent of such ESC Fund's dealings with Citadel and of the potential conflicts of interest that may exist, and, as professionals with experience in investing, financial planning, securities brokerage, investment banking, asset management, business operations, banking, cash management or trust services or other similar areas, or in administrative, financial, tax, legal, accounting or operational activities related thereto, will be able to understand and evaluate the attendant risks. Applicants assert that the community of interest among the Members in each ESC Fund and Citadel is the best insurance against any risk of abuse.

5. Section 17(d) of the Act and rule 17d–1 under the Act prohibit any affiliated person of a registered investment company, or any affiliated person of such person, acting as principal, from participating in any joint enterprise or joint arrangement with the company unless authorized by the Commission. Applicants request relief to the extent necessary to permit affiliated persons of each ESC Fund (including the Managing Member, Citadel, and/or a Citadel Third Party Fund), or affiliated persons of any of these persons to participate in, or effect any transaction in connection with, any joint enterprise or other joint arrangement or profit-sharing plan in which an ESC Fund or a company controlled by such ESC Fund is a participant.

6. Applicants assert that compliance with section 17(d) would cause an ESC Fund to forego investment opportunities simply because a Member in an ESC Fund or any other affiliated person of such ESC Fund (or any affiliate of such a person) also had, or contemplated making, a similar investment. Applicants also submit that co-investment opportunities with Citadel are advantageous to Eligible Employees because (a) the resources of Citadel enable it to analyze investment opportunities to an extent that Eligible Employees would have neither the time nor resources to duplicate, (b) investments made by Citadel will not be generally available to investors even if the financial status of the Eligible Employees would enable them to otherwise participate in such opportunities, and (c) Eligible Employees will be able to pool their resources in co-investments, thus achieving greater diversification of their individual portfolios. Applicants note that each ESC Fund will primarily be organized for the benefit of Eligible Employees as an incentive for them to remain with Citadel and for the generation and maintenance of goodwill through an investment in Citadel Third Party Funds. Applicants assert that the flexibility to structure co-investments and joint investments as described in the application will not involve abuses of the type section 17(d) and rule 17d–1 were designed to prevent.

7. All side-by-side investments held by Citadel Entities will be subject to the restrictions contained in Condition 3 except for side-by-side investments held by a Citadel Third Party Fund, or by a Citadel Entity in a transaction in which the Citadel investment was made pursuant to a contractual obligation to a Citadel Third Party Fund.[8] Applicants note that Citadel is likely to invest a portion of its own capital in Citadel Third Party Fund investments or on a side-by-side basis (which Citadel investments will be subject to substantially the same terms as those applicable to such Citadel Third Party Fund, except as otherwise disclosed in the offering documents and/or Operating Agreement of the relevant ESC Fund). In addition, applicants assert that the relationship of an ESC Fund to a Citadel Third Party Fund is fundamentally different from such ESC Fund's relationship to Citadel. Applicants contend that the focus of, and the rationale for, the protections contained in the requested relief are to protect the ESC Funds from any overreaching by Citadel in the employer/employee context, whereas the same concerns are not present with respect to the ESC Funds vis-à-vis the investors in a Citadel Third Party Fund.

8. Section 17(f) of the Act designates the entities that may act as investment company custodians, and rule 17f–1 under the Act imposes certain requirements when the custodian is a member of a national securities exchange. Applicants request an exemption from section 17(f) and rule 17f–1 to the extent necessary to permit a Citadel Entity to act as custodian without a written contract because there will be such a close association between each ESC Fund and Citadel that requiring a detailed written contract would expose the ESC Funds to unnecessary burden and expense. Applicants also request an exemption from the rule 17f–1(b)(4) requirement that an independent accountant periodically verify the assets held by the custodian as Applicants do not believe the expense of such verifications is warranted given the community of interest of all the parties involved and the existing requirement for an independent audit, compliance with the rule's requirement would be unnecessary. Except as requested, each ESC Fund will otherwise comply with the provisions of rule 17f–1.

9. Applicants also request an exemption from section 17(f) and rule 17f–2 to permit the following exceptions from the requirements of rule 17f–2: (a) An ESC Fund's investments may be kept in the locked files of the Managing Member (or a Citadel Entity) for purposes of paragraph (b) of the rule; (b) for purposes of paragraph (d) of the rule, (i) employees of the Managing Member (or a Citadel Entity) will be deemed to be employees of the ESC Funds, (ii) officers or managers of the Managing Member of an ESC Fund (or a Citadel Entity) will be deemed to be officers of the ESC Fund, and (iii) the Managing Member will be deemed to be the board of directors of the ESC Fund; and (c) in place of the verification procedure under paragraph (f) of the rule, verification will be effected quarterly by two high level employees of the Managing Member (or another Citadel Entity), each of whom is a member of the administrative, legal, and/or compliance function for Citadel and has specific knowledge of the custody requirements, policies, and procedures of the ESC Funds. Applicants expect that with respect to certain ESC Funds, most of their investments may be evidenced only by partnership agreements, participation agreements or similar documents, rather than by negotiable certificates that could be misappropriated. Applicants believe that, for such an ESC Fund, these instruments are most suitably kept in the locked files of the Managing Member (or a Citadel Entity), where they can be referred to as necessary. Applicants will comply with all other provisions of rule 17f–2, including the recordkeeping requirements of paragraph (e).

10. Section 17(g) of the Act and rule 17g–1 under the Act generally require the bonding of officers and employees of a registered investment company who have access to its securities or funds. Rule 17g–1 requires that a majority of directors who are not interested persons

[8] Such Citadel investment will only be exempt from Condition 3 to the extent that the investment was necessitated by the contractual obligation to the Citadel Third Party Fund.

take certain actions and give certain approvals relating to fidelity bonding. Applicants request an exemption to permit the Managing Member, regardless of whether it is deemed an interested person of the ESC Funds, to take actions and make determinations set forth in the rule. Applicants state that the ESC Funds are unable to comply with Rule 17g-1 because the ESC Funds will not have boards of directors and the Managing Member of the ESC Fund will be an interested person of the ESC Funds. Applicants also state that the ESC Funds will comply with all other requirements of rule 17g-1, except that the Applicants request an exemption from the requirements of paragraphs (g) and (h) of rule 17g–1 (relating to the filing of copies of fidelity bonds and related information with the Commission and relating to the provision of notices to the board of directors), and an exemption from the requirements of paragraph (j)(3) of rule 17g–1 that the ESCs comply with the fund governance standards defined in rule 0–1(a)(7).

11. Section 17(j) of the Act and paragraph (b) of rule 17j–1 under the Act make it unlawful for certain enumerated persons to engage in fraudulent or deceptive practices in connection with the purchase or sale of a security held or to be acquired by a registered investment company. Rule 17j–1 also requires that every registered investment company adopt a written code of ethics and that every access person of a registered investment company report personal securities transactions. Applicants request an exemption from the provisions of rule 17j–1, except for the anti-fraud provisions of paragraph (b), because they are unnecessary and burdensome as applied to the ESC Funds.

12. Applicants request an exemption from the requirements in sections 30(a), 30(b), and 30(e) of the Act, and the rules under those sections, that registered investment companies prepare and file with the Commission and mail to their shareholders certain periodic reports and financial statements. Applicants contend that the forms prescribed by the Commission for periodic reports have little relevance to an ESC Fund and would entail administrative and legal costs that outweigh any benefit to the Members of such ESC Fund. Applicants request exemptive relief to the extent necessary to permit each ESC Fund to report annually to its Members. Applicants also request an exemption from section 30(h) of the Act to the extent necessary to exempt the Managing Member of each ESC Fund, directors and officers of the Managing Member and any other persons who may be deemed to be members of an advisory board or an investment adviser (and affiliated persons thereof) of such ESC Fund from filing Forms 3, 4, and 5 under section 16 of the Exchange Act with respect to such ESC Fund. Applicants assert that, because there will be no trading market and the transfers of Interests will be severely restricted, these filings are unnecessary for the protection of investors and burdensome to those required to make them.

13. Rule 38a–1 requires investment companies to adopt, implement and periodically review written policies and procedures reasonably designed to prevent violation of the federal securities laws and to appoint a chief compliance officer. Each ESC Fund will comply will rule 38a-1(a), (c) and (d), except that (a) because the ESC Funds do not have a board of directors, the Managing Member will fulfill the responsibilities assigned to a board of directors under the rule, (b) because the Managing Member does not have any disinterested members, approval by a majority of the disinterested board members required by rule 38a-1 will not be obtained, and (c) because the ESC Funds do not have any independent directors, the ESC Funds will comply with the requirement in rule 38a-1(a)(4)(iv) that the chief compliance officer meet with the independent directors by having the chief compliance officer meet with the Managing Member. Each ESC Fund has adopted written policies and procedures reasonably designed to prevent violations of the terms and conditions of the application and appointed a chief compliance officer.

APPLICANTS' CONDITIONS: Applicants agree that any order granting the requested relief will be subject to the following conditions:

1. Each proposed Section 17 Transaction [9] will be effected only if the Managing Member determines that:

(a) the terms of the Section 17 Transaction, including the consideration to be paid or received, are fair and reasonable to the Members of the ESC Fund and do not involve overreaching of the ESC Fund or its Members on the part of any person concerned; and

(b) the Section 17 Transaction is consistent with the interests of the Members of the ESC Fund, the ESC Fund's organizational documents and the ESC Fund's reports to its Members.

(b) the Section 17 Transaction is consistent with the interests of the Memberws of the ESC Fund, the ESC Fund's organizational documents and the ESC Fund's reports to its Members.

In addition, the Managing Member will record and will preserve a description of all Section 17 Transactions, the Managing Member's findings, the information or materials upon which the findings are based and the basis for the findings. All such records will be maintained for the life of the ESC Fund and at least six years thereafter, and will be subject to examination by the Commission and its staff. Each ESC Fund will preserve the accounts, books and other documents required to be maintained in an easily accessible place for at least the first two years.

2. The Managing Member will adopt, and periodically review and update, procedures designed to ensure that reasonable inquiry is made, prior to the consummation of any Section 17 Transaction, with respect to the possible involvement in the transaction of any affiliated person or promoter of or principal underwriter for any ESC Fund, or any ''affiliated person'' of such an ''affiliated person,'' promoter or principal underwriter.

3. The Managing Member of each ESC Fund will not cause any of the funds of the ESC Fund to be invested in any investment in which a Co-Investor [10] has acquired or proposes to acquire the same class of securities of the same issuer and where the investment involves a joint enterprise or other joint arrangement within the meaning of rule 17d-1 in which the ESC Fund and the Co-Investor are participants, unless prior to such investment any such Co-Investor, prior to disposing of all or part of its investment: agrees to (a) give the Managing Member sufficient, but not less than one day's notice of its intent to dispose of its investment; and (b) refrain from disposing of its investment unless the ESC Fund has the opportunity to dispose of its investment prior to or concurrently with, and on the same terms as, and *pro rata* with, the Co-Investor.

The restrictions contained in this condition, however, shall not be

[9] ''Section 17 Transaction'' means a transaction that is otherwise prohibited by section 17(a), section 17(d) and/or rule 17d–1 under the Act to which an ESC Fund is a party.

[10] ''Co-Investor'' means with respect to any ESC Fund, any person who is: (a) An ''affiliated person'' (as defined in section 2(a)(3) of the Act) of the ESC Fund (other than a Citadel Third Party Fund); (b) a Citadel Entity; (c) an officer, director or partner of a Citadel Entity; or (d) an entity (other than a Citadel Third Party Fund) for which the Managing Member or an Affiliate acts as a managing member or in a similar capacity so as to control the sale or other disposition of the entity's investments.

deemed to limit or prevent the disposition of an investment by a Co-Investor:

(a) To its direct or indirect wholly-owned subsidiary, to a Parent [11] of which the Co-Investor is a direct or indirect wholly-owned subsidiary or to a direct or indirect wholly-owned subsidiary of such Parent;

(b) to immediate family members of the Co-Investor or to a trust or other investment vehicle established for any such family member; and

(c) when the investment is comprised of securities that are (i) listed on any exchange registered as a national exchange under section 6 of the Exchange Act; (ii) NMS stocks, pursuant to section 11A(a)(2) of the Exchange Act and rule 600(a) of Regulation NMS thereunder; (iii) government securities as defined in section 2(a)(16) of the Act, or (iv) listed or traded on any foreign securities exchange or board of trade that satisfies regulatory requirements under the law of the jurisdiction in which such foreign securities exchange or board of trade is organized similar to those that apply to a national securities exchange or a national market system for securities.

4. Each ESC Fund and its Managing Member will maintain and preserve, for the life of such ESC Fund and at least six years thereafter, such accounts, books, and other documents as constitute the record forming the basis for the audited financial statements that are to be provided to the Members of such ESC Fund, and each annual report of such ESC Fund required to be sent to such Members, and agree that all such records will be subject to examination by the Commission and its staff. Each ESC Fund will preserve the accounts, books and other documents required to be maintained in an easily accessible place for the first two years after the life of such ESC Fund.

5. Within 120 days after the end of the fiscal year of each ESC Fund, or as soon as practicable thereafter, the Managing Member of each ESC Fund will send to each person who was a Member having an Interest in the ESC Fund at any time during the fiscal year then ended (except for the first fiscal year of operations of an ESC Fund if no investment activities took place in such fiscal year), audited financial statements with respect to those ESC Funds in which the Member held Interests. At the end of each fiscal year, the Managing Member will make a valuation or have a valuation made of all of the assets of the ESC Fund as of such fiscal year end in a manner consistent with customary practice with respect to the valuation of assets of the kind held by the ESC Fund. In addition, within 120 days after the end of each fiscal year of each ESC Fund or as soon as practicable thereafter, the Managing Member will send a report to each person who was a Member at any time during the fiscal year then ended, setting forth such tax information as shall be necessary for the preparation by the Member of his, her or its U.S. federal and state income tax returns and a report of the investment activities of the ESC Fund during that fiscal year.

6. If an ESC Fund makes purchases from, or sales to, an entity affiliated with the ESC Fund by reason of an officer, director or employee of Citadel (a) serving as an officer, director, managing member, general partner or investment adviser of the entity, or (b) having a 5% or more investment in the entity, such individual will not participate in the ESC Fund's determination of whether or not to effect the purchase or sale.

For the Commission, by the Division of Investment Management, under delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

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BILLING CODE 8011–01–P

[11] ''Parent'' means any company of which an entity is a direct or indirect wholly-owned subsidiary.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90735; File No. SR–BOX–2020–14]

Self-Regulatory Organizations; BOX Exchange LLC; Order Disapproving Proposed Rule Change, as Modified by Amendment No. 1, To Adopt Rules Governing the Trading of Equity Securities on the Exchange Through a Facility of the Exchange Known as the Boston Security Token Exchange LLC

December 18, 2020.

Introduction

On May 21, 2020, BOX Exchange LLC (''Exchange'' or ''BOX'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt rules governing the listing and trading of equity securities that would be National Market System (''NMS'') stocks on the Exchange through a facility of the Exchange known as the Boston Security Token Exchange LLC (''BSTX''). The proposed rule change was published for comment in the **Federal Register** on June 1, 2020.[3] On July 16, 2020, pursuant to Section 19(b)(2) of the Exchange Act,[4] the Commission designated a longer period within which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5]

On July 31, 2020, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change as originally filed.[6] On August 12, 2020, the Commission published the proposed rule change, as modified by Amendment No. 1, for notice and comment and instituted proceedings to determine whether to approve or disapprove the proposed rule change, as modified by Amendment No. 1.[7] On November 24, 2020, pursuant to Section 19(b)(2) of the Exchange Act, the Commission

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 88946 (May 26, 2020), 85 FR 33454 (June 1, 2020) (SR–BOX–2020–14) (''Notice''). Comments received on the proposed rule change are available at: *https://www.sec.gov/comments/sr-box-2020-14/srbox202014.htm.*

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 89328 (July 16, 2020), 85 FR 44338 (July 22, 2020). The Commission designated August 30, 2020, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[6] In Amendment No. 1, the Exchange revised the proposal to: (i) Change the name used to refer to BSTX-listed securities from ''security tokens'' to ''Securities''; (ii) eliminate the proposed requirement for trades on the Exchange to settle one business day after the trade date (''T+1''), which is not the settlement cycle for NMS stock; (iii) add proposed rule text that the Exchange describes as containing measures to ensure the accuracy of end-of-day Security balance reports; (iv) add proposed rule text specifying that the time by which Exchange members must report end-of-day Security balances to the Exchange will be set forth by the Exchange via regulatory circular; (v) provide additional description of several aspects of the proposal, including end-of-day Security balance reporting and implications of the trading of BSTX-listed Securities on other national securities exchanges on the end-of-day reporting process; and (vi) make technical and conforming changes. Amendment No. 1 is available on the Commission's website at: *https://www.sec.gov/comments/sr-box-2020-14/srbox202014-7570237-222233.pdf.* On July 31, 2020, the Exchange also submitted a letter to the Commission requesting that the Commission concur with the Exchange's conclusion that members that enter orders into BSTX's trading system satisfy the conditions of Rule 11a2–2(T) under the Exchange Act (17 CFR 240.11a2–2(T)). *See* Letter from Lisa Fall, President, BOX, to Vanessa Countryman, Secretary, Commission, and Tyler Raimo, Assistant Director, Division of Trading and Markets, Commission (July 31, 2020), *available at https://www.sec.gov/comments/sr-box-2020-14/srbox202014-7506169-221931.pdf.*

[7] *See* Securities Exchange Act Release No. 89536 (August 12, 2020), 85 FR 51250 (August 19, 2020) (''Order Instituting Proceedings'' or ''OIP'').

designated a longer period within which to issue an order approving or disapproving the proposed rule change, as modified by Amendment No. 1.[8]

In Amendment No. 1 to the proposed rule change, the Exchange states that the proposed rule change was previously filed with the Commission as SR–BOX–2019–19, which the Exchange amended twice, and that the current proposed rule change, SR–BOX–2020–14, is ''substantively identical'' to previously-filed proposed rule change, SR–BOX–2019–19, as modified by Amendment No. 2 thereto.[9] SR–BOX–2019–19, as modified by Amendment No. 2 thereto, was published for comment in the **Federal Register** on March 6, 2020.[10] The Commission received comments on the substance of SR–BOX–2019–19, as well as responses submitted by BOX.[11] BOX withdrew proposed rule change SR–BOX–2019–19 on May 12, 2020.[12] As applicable and discussed below, the Commission considered comments submitted on SR–BOX–2019–19 and SR–BOX–2020–14 in its review of SR–BOX–2020–14.[13]

This order disapproves the proposed rule change, as modified by Amendment No. 1. The Exchange proposes to list and trade NMS stock that would be uncertificated securities that are issued, traded, and cleared like any other NMS stock. Unlike other NMS stock, however, the Exchange proposes to require issuers and members eligible to participate on the BSTX trading system (''BSTX Participants'') to comply with a protocol that would enable BSTX to record and publicly disseminate BSTX Participants' end-of-day securities ownership balances to the Ethereum blockchain [14] (such BSTX-listed stock to be referred to as ''Securities''). According to the Exchange, this information recorded on the Ethereum blockchain would be ''ancillary'' to the official ownership records maintained by participants at the securities depository and would not convey legal ownership of Securities. For each Security, the Ethereum blockchain would reflect the end-of-day balance for each BSTX Participant, along with a balance allocated to an ''omnibus'' wallet. The Exchange proposes to use the omnibus wallet to, among other things, record and publicly disseminate the aggregate balance of Securities held by non-BSTX Participants, as well as to account for other discrepancies between the total balance reported by BSTX Participants and the total number of Securities outstanding. As discussed in further detail below, this Order finds that that the Exchange has not met its burden to demonstrate that the proposal is consistent with Sections 6(b)(1), 6(b)(5), and 6(b)(8) of the Exchange Act.

Specifically, the Commission examines in Section III.B how the Exchange's proposal would result in inaccurate BSTX-listed Security ownership balances being publicly disseminated on the Ethereum blockchain. As explained in more detail below, there are several ways in which inaccurate information from BSTX would be publicly available on the Ethereum blockchain, including: (i) Security balances published to the Ethereum blockchain would be inaccurate to the extent that BSTX Participants report inaccurate information or are late in reporting; (ii) Security balances would be stale because they would represent a snapshot of a BSTX Participant's depository account balance at the end of the last trading day and thus fail to reflect transactions that have not yet settled; (iii) the omnibus wallet would include Security balances that cannot be attributed to the respective BSTX Participant due to such inaccurate or late reporting as well as the holdings of non-BSTX Participants; and (iv) BSTX Participants' short and long positions, both of which would be reported, would be indistinguishable when represented on the Ethereum blockchain, and thereby would provide an economically inaccurate picture of Security balances. Accordingly, as the Exchange concedes, there are a variety of circumstances in which the publicly disseminated information reflected on the Ethereum blockchain would not represent true holdings. Furthermore, exacerbating the inaccuracy of the information that the Exchange would publicly disseminate on the Ethereum blockchain, the Exchange has not demonstrated whether or how it would surveil for, reconcile, or address these inaccuracies. The Commission finds, based on the significant risk that this inaccurate information would confuse and mislead investors, that the Exchange has not met its burden to demonstrate that the proposed rule change is consistent with the protection of investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act. The Commission separately finds that, based on the significant risk that investors will use this inaccurate public information about Security ownership in their investment decisions, the Exchange has not met its burden to demonstrate that the proposed rule change is consistent with the protection of investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act.

In addition, the Commission examines in Section III.C significant operational aspects of the Exchange's proposal that the Exchange has not sufficiently explained, thereby making it difficult for potential BSTX Participants and other market participants to understand the obligations that the Exchange would impose. The Commission examines below several aspects of the Exchange's proposal, including: (i) The Exchange's proposed procedures relating to the recording and dissemination of end-of-day Security ownership balances; (ii) the costs or other burdens that would be imposed on market participants to comply with the proposed requirement to report end-of-day Security ownership balances; (iii) the Exchange's standard or procedures to suspend the end-of-day Security reporting requirements; and (iv) the requirements the Exchange would place on listed companies, and in particular,

[8] *See* Securities Exchange Act Release No. 90512 (Nov. 24, 2020), 85 FR 77327 (Dec. 1, 2020).

[9] *See* OIP, *supra* note 7, 85 FR at 51251, n.14.

[10] *See* Securities Exchange Act Release No. 88300 (February 28, 2020), 85 FR 13242 (March 6, 2020) (Notice of Filing of Amendment No. 2 to Proposed Rule Change). *See also* Securities Exchange Act Release Nos. 87287 (October 11, 2019), 84 FR 56022 (October 18, 2019) (Notice of Filing of Proposed Rule Change) (noticing SR–BOX–2019–19 as originally filed); and 88002 (January 16, 2020), 85 FR 4040 (January 23, 2020) (Notice of Filing of Amendment No. 1 and Order Instituting Proceedings) (noticing Amendment No. 1 to SR–BOX–2019–19 and instituting proceedings to determine whether to disapprove the proposed rule change as modified by Amendment No. 1). The only differences between SR–BOX–2019–19, as modified by Amendment No. 2, and SR–BOX–2020–14 relate to: Removal of references to Amendment No. 2; modification of a reference to Exhibit 5 to the filing; modification of the description of BSTX ownership interests to reflect the addition of a small percentage (less than 10%) of non-voting economic interest-holders; updating a reference to a related filing (SR–BOX–2019–37, which was also withdrawn and refiled as SR–BOX–2020–16); corrections to citations; and grammatical corrections.

[11] Comments on SR–BOX–2019–19 can be found at: *https://www.sec.gov/comments/sr-box-2019-19/srbox201919.htm.* These comments also include response letters from the Exchange.

[12] *See* Securities Exchange Act Release No. 89018 (June 4, 2020), 85 FR 35458 (June 10, 2020) (Notice of Withdrawal of a Proposed Rule Change).

[13] With respect to comments received on SR–BOX–2019–19 that are discussed below, the Commission notes that the aspects of the proposal that were the subject of commenters' concerns remain the same in the current proposal, SR–BOX–2020–14.

[14] A ''blockchain'' is a type of distributed ledger, or peer-to-peer database spread across a network, that records all transactions in the network in digitally-recorded data packages called blocks. The ''Ethereum blockchain'' is an open, or permissionless, blockchain that is a record of events resulting from the execution of code (smart contracts) on the blockchain. *See generally, Report of Investigation Pursuant to Section 21(a) of the Securities Exchange Act of 1934: The DAO,* Release No. 81207, 2017 WL 7184670, at *1-*2 & n.6 (July 25, 2017) (''The DAO Report'').

how trading might be impacted between two classes of securities of an issuer—one listed on BSTX and one listed on another national securities exchange—where the only distinction may be that one has the necessary smart contracts to comply with BSTX's requirements. The Commission finds, due to the lack of information about BSTX's intended operations, that the Exchange has not met its burden to demonstrate that its proposed rule change would prevent fraudulent and manipulative acts and practices, facilitate transactions in securities, remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest, and is not designed to permit unfair discrimination, consistent with Section 6(b)(5) of the Exchange Act. The Commission also finds, due to a lack of explanation about how the Exchange would carry out these functions and fulfill its obligation to be organized and be able to carry out the purposes of the Exchange Act, and to comply and enforce compliance by its members with its own rules, that the Exchange has not met its burden to show that its proposed rule change is consistent with Section 6(b)(1) of the Exchange Act.

Lastly, the Commission examines in Section III.D how another national securities exchange could provide end-of-day Security ownership balance reporting functionality for its members. The Commission finds, due to the lack of explanation of how another national securities exchange that seeks to extend unlisted trading privileges (''UTP'') to a BSTX-listed Security could feasibly provide an end-of-day Security ownership balance reporting functionality to its members, that the Exchange has not met its burden to demonstrate that its rules do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act, as required by Section 6(b)(8) of the Exchange Act. Specifically, the Exchange has not sufficiently addressed its control over the end-of-day reporting process or the feasibility of another national securities exchange setting up its own parallel process for end-of-day reporting. Without a sufficient understanding of the burdens on competition, the Commission cannot determine if these burdens are necessary or appropriate in furtherance of the Exchange Act.

Although the Commission is disapproving this proposed rule change, the Commission emphasizes that it encourages and supports innovation and the application of beneficial technologies in our securities markets, and its disapproval of this proposed rule change does not rest on an evaluation of whether blockchain technology has utility or value as an innovation, generally or as applied to the functions of a national securities exchange. The Commission believes that there is value in distributed ledger technology and related innovation, which offers the ability to share information, transfer value, and record transactions in a distributed digital environment. However, the public dissemination of information known to be inaccurate or misleading, as here, irrespective of whether it takes place through a public blockchain, a public database, a public website, or a published circular, is problematic.

Description of the Proposed Rule Change

As described in the OIP,[15] the Exchange proposes to adopt listing standards for certain NMS stocks that the Exchange refers to as ''Securities.'' For each class of ''Securities'' listed by BOX, the Exchange would employ a functionality to record and publicly disseminate on the Ethereum blockchain end-of-day ownership balances reported to the Exchange by BSTX Participants.[16] The Exchange is also proposing rules governing the trading of these NMS stocks through a facility of the Exchange known as BSTX, which would operate a fully automated, price-time priority execution system (''BSTX System'').[17] According to the Exchange, the end-of-day Security ownership balance information would constitute ''ancillary'' or supplemental records of end-of-day ownership balances and legal ownership would be separately established and evidenced by operation of commercial law. The Exchange contends that the official records of security ownership would be maintained by participants at The Depository Trust Company (''DTC''), and attribution of a ''Security'' to a particular wallet address on the Ethereum blockchain would not convey ownership of shareholder equity in the issuer of the NMS stock.[18]

According to the Exchange, the Exchange would record Security ownership balances on the Ethereum blockchain using a protocol standard determined by BSTX that each security admitted to trading on BSTX would be required to follow (the ''BSTX Protocol'').[19] The Exchange proposes that each BSTX Participant would be required to establish, either directly or through a carrying firm, what the Exchange calls a ''whitelisted'' wallet address (hereinafter ''allowlisted'') to which its end-of-day Security ownership balances may be recorded.[20] The Exchange proposes that, each business day, each BSTX Participant would be required to report to BSTX certain end-of-day Security ownership balances in a manner and form acceptable to BSTX.[21] The Exchange would then provide this information to a Wallet Manager[22] to update the Ethereum blockchain to reflect changes in ownership of Securities and publicly disseminate the ownership balance for each wallet address.[23] The Exchange proposes that a BSTX Participant shall promptly send a corrected end-of-day Security balance report to the Exchange upon the BSTX Participant's discovery that it submitted an inaccurate end-of-day report that has not already been corrected or superseded.[24] If the Exchange has reason to believe that Security balances reported by one or

[15] *See* OIP, *supra* note 7.

[16] *See* OIP, *supra* note 7, 85 FR at 51250–51. A ''BSTX Participant'' would be a participant that is authorized to trade Securities on the Exchange. *See* proposed BSTX Rule 17000(a)(11).

[17] *See* OIP, *supra* note 7, 85 FR at 51250. Pursuant to a separate proposed rule change, the Exchange proposes to establish BSTX as a facility of the Exchange that will operate a market for the trading of securities (''BSTX Market'') and adopt the BSTX Second Amended and Restated LLC Agreement. *See* Securities Exchange Act Release No. 89537 (August 12, 2020), 85 FR 50850 (August 18, 2020) (SR–BOX–2020–16) (Notice of Filing of Amendment No. 1 and Order Instituting Proceedings to Determine Whether to Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, in Connection with the Proposed Establishment of the Boston Security Token Exchange LLC as a Facility of the Exchange) (''Amended BSTX Governance Proposal''). *See also* Securities Exchange Act Release No. 88949 (May 26, 2020), 85 FR 33258 (June 1, 2020) (''BSTX Governance Proposal''). Among other things, the Amended BSTX Governance Proposal sets forth the proposed ownership structure for BSTX. The Exchange states that without Commission approval of the trading rules, the Exchange would not permit BSTX to commence operations of the BSTX Market, and that the Exchange's regulatory oversight responsibilities with respect to BSTX would not be triggered unless SR–BOX–2020–16 is approved by the Commission. *See* Amended BSTX Governance Proposal, 85 FR at 50850.

[18] *See* OIP, *supra* note 7, 85 FR at 51253, 51257.

[19] *See* OIP, *supra* note 7, 85 FR at 51254–56.

[20] *See* OIP, *supra* note 7, 85 FR at 51256–57. According to the Exchange, an allowlisted wallet address would be a permissioned number associated with a particular market participant to which Securities may be sent. *See id.* at 51255–56.

[21] *See* OIP, *supra* note 7, 85 FR at 51258. The Exchange states that BSTX Participants who fail to comply with the end-of-day ownership reporting requirement may be subject to disciplinary action. *See* OIP, *supra* note 7, 85 FR at 51259.

[22] The Exchange proposes to define a ''Wallet Manager'' as a party approved by BSTX to operate software compatible with the BSTX Protocol. *See* proposed BSTX Rule 17000(a)(31).

[23] *See* OIP, *supra* note 7, 85 FR at 51258–59.

[24] *See* OIP, *supra* note 7, 85 FR at 51260; proposed BSTX Rule 17020(e)(1).

more BSTX Participants may be inaccurate, the Exchange may request additional information regarding the applicable reports and balances from any BSTX Participant to which the BSTX Participant shall promptly respond.[25] Under the proposal, the Exchange would, in its discretion, be able to suspend the requirement that a BSTX Participant establish a wallet address and report its end-of-day ownership balance with respect to any BSTX Participant and/or with respect to one or more Securities, as applicable.[26] Non-BSTX Participants that may trade Securities would not be subject to the requirement to obtain an allowlisted wallet address or to report their end-of-day Security ownership balances, and would not be able to voluntarily report end-of-day Security ownership balances to BSTX.[27]

According to the Exchange, the Ethereum blockchain could contain an imprecise distribution of Securities among holders and display inaccurate information about Security ownership balances if BSTX Participants inaccurately report end-of-day Security balances to BSTX or if the number of reported Securities exceeds the number of outstanding Securities of a particular issuance.[28] To account for instances in which a BSTX Participant fails to report or inaccurately reports its end-of-day ownership balance, as well as for the Security positions of non-BSTX Participants who are not subject to the end-of-day ownership reporting requirement, the Exchange would provide information to the Wallet Manager to attribute all such unreported Security ownership balances for a given Security to a single omnibus wallet address.[29] The Exchange states that the Ethereum blockchain would publicly display Security balances that would reflect the end-of-day ownership balances reported to BSTX by BSTX Participants pursuant to proposed BSTX Rule 17020[30] and a balance allocated to the omnibus wallet address for any type of Security for which the sum of the reported positions is less than the number of Securities known by the Exchange to be issued and outstanding.[31] The Exchange acknowledges that there is a risk of situations in which it would be unable to communicate the end-of-day Security ownership balances to the Wallet Manager or the Wallet Manager would be unable to update the blockchain.[32] The Exchange states that it would not make public which BSTX Participant is associated with a particular wallet address or identify which address is the omnibus wallet address.[33]

The Exchange proposes that Securities would be eligible for trading on other national securities exchanges that extend unlisted trading privileges to them. According to the Exchange, the end-of-day Security ownership balance reporting by BSTX Participants and the public dissemination of the information on the Ethereum blockchain would not impact the ability of Securities to trade on other national securities exchanges or over-the-counter (''OTC'').[34]

The Exchange also proposes rules for participation on BSTX, business conduct for BSTX Participants, financial and operational provisions for BSTX Participants, supervision, trading practices, discipline, trading on the BSTX System, and market making.[35] In addition, the Exchange proposes listing standards that, according to the Exchange, are similar to the listing standards of NYSE American.[36] The Exchange proposes that these listing standards would also specify that all listed Securities comply with the BSTX Protocol.[37] The Exchange states that it is not proposing rules that would support its extension of UTP to NMS stock listed on other national securities exchanges.[38]

According to the Exchange, all transactions in Securities would clear and settle in accordance with the rules, policies, and procedures of registered clearing agencies.[39] The Exchange states that BSTX anticipates that DTC would serve as the securities depository for Securities and that confirmed trades in Securities on BSTX would be transmitted to National Securities Clearing Corporation (''NSCC'') for clearing.[40] The Exchange states that Security transactions occurring on BSTX would be cleared through NSCC using a T+2 settlement cycle, as is the case today for all other exchanges that facilitate trading in NMS stock.[41]

Discussion

Applicable Standard for Review

Under Section 19(b)(2)(C) of the Exchange Act, the Commission must approve the proposed rule change of a self-regulatory organization (''SRO'') if the Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the applicable rules and regulations thereunder; if it does not make such a finding, the Commission must disapprove the proposed rule change.[42] Additionally, under Rule 700(b)(3) of the Commission's Rules of Practice, the ''burden to demonstrate that a proposed rule change is consistent with the Exchange Act and the rules and regulations issued thereunder . . . is on the self-regulatory organization that proposed the rule change.'' [43] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must be sufficiently detailed and specific to support an affirmative Commission finding.[44] Any failure of an SRO to provide this information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Exchange Act and the applicable rules and regulations issued thereunder that are applicable to the SRO.[45] Moreover, ''unquestioning reliance'' on an SRO's representations in a proposed rule change is not sufficient to justify Commission approval of a proposed rule change.[46]

[25] *See* OIP, *supra* note 7, 85 FR at 51260; proposed BSTX Rule 17020(e)(2).

[26] *See* OIP, *supra* note 7, 85 FR at 51260; proposed BSTX Rule 17020(f).

[27] *See* OIP, *supra* note 7, 85 FR at 51257.

[28] *See* OIP, *supra* note 7, 85 FR at 51260. *See also* OIP, *supra* note 7, 85 FR at 51295 (''The Exchange acknowledges that, in certain circumstances, a BSTX Participant subject to the requirements of proposed Rule 17020 could fail to report end-of-day Security balances to BSTX in a timely manner, inaccurately report such balances, or fail to obtain a wallet address prior to acquiring a position in a Security. Such failures would impair the ability of the Exchange to report complete end-of-day Security balance information . . . to the Wallet Manager(s) who [would] update the Security balance information that is reflected on the Ethereum blockchain.'').

[29] *See* OIP, *supra* note 7, 85 FR at 51259; proposed BSTX Rule 17020(d).

[30] Proposed BSTX Rule 17020 sets forth the proposed end-of-day reporting requirements for BSTX Participants. *See* proposed BSTX Rule 17020.

[31] *See* OIP, *supra* note 7, 85 FR at 51259–60.

[32] *See* OIP, *supra* note 7, 85 FR at 51260, 51262.

[33] *See* OIP, *supra* note 7, 85 FR at 51261.

[34] *See* OIP, *supra* note 7, 85 FR at 51262.

[35] *See* OIP, *supra* note 7, 85 FR at 51264–77. The trading rules that the Exchange proposes include provisions for primary distributions of securities to be made through the Exchange, including using an auction process. *See id.* at 51270.

[36] *See* OIP, *supra* note 7, 85 FR at 51277.

[37] *See* OIP, *supra* note 7, 85 FR at 51278.

[38] *See* OIP, *supra* note 7, 85 FR at 51251. The Exchange also states that, therefore, it would only trade Securities listed on BSTX unless and until it proposes and receives Commission approval for rules that would support trading in other types of securities, including through the extension of UTP to other NMS stocks. *Id.*

[39] *See* OIP, *supra* note 7, 85 FR at 51253.

[40] *See* OIP, *supra* note 7, 85 FR at 51253.

[41] *See* OIP, *supra* note 7, 85 FR at 51254.

[42] *See* 15 U.S.C. 78s(b)(2)(C)(i).

[43] Rule 700(b)(3), Commission Rules of Practice, 17 CFR 201.700(b)(3).

[44] *See id.*

[45] *See id.*

[46] *Susquehanna Int'l Group, LLP* v. *Securities and Exchange Commission,* 866 F.3d 442, 447 (D.C. Cir. 2017).

In reviewing the proposed rule change, the Commission has analyzed information provided by the Exchange and issues raised by commenters. Based on the information before the Commission, for each of the reasons discussed below (whether viewed independently or in combination), the Commission is unable to find that the Exchange has met its burden to show that the proposed rule change is consistent with the Exchange Act and the applicable rules and regulations thereunder, including Exchange Act Sections 6(b)(1), 6(b)(5), and 6(b)(8), and is therefore unable to find that the proposal is consistent with the Exchange Act.

Whether BOX Has Met its Burden To Demonstrate That the Proposal Is Consistent With Section 6(b)(5) of the Exchange Act Notwithstanding the Risk That the Dissemination of Inaccurate Information About BSTX-Listed Securities Would Mislead Investors

Pursuant to the Exchange's proposal, the Exchange would disseminate inaccurate Security ownership balances to the public under many circumstances. The Commission has grave concerns when an SEC registrant, such as a national securities exchange that is an SRO, knowingly disseminates inaccurate information to the public, irrespective of whether it takes place through a public blockchain, a public database, a public website, or a published circular. As discussed below, the Exchange has failed to meet its burden to demonstrate that its proposal is consistent with protection of investors and the public interest, pursuant to Section 6(b)(5) of the Exchange Act, given that the publicly disseminated Security ownership balances could be inaccurate, which creates a significant risk of confusing and misleading investors. Furthermore, the Commission has concerns that the inaccurate Security ownership balance information disseminated to the public would impact investor decisions, and the Exchange has also failed to meet its burden to demonstrate how investors' use of inaccurate Security ownership balance information is consistent with the protection of investors and the public interest, pursuant to Section 6(b)(5) of the Exchange Act.

1. Exchange's Representations and Comments Received

The Exchange states that the proposed rules contemplate the use of smart contract [47] functionality to record end-of-day Security [48] position balance information to the Ethereum blockchain as an ''ancillary'' recordkeeping mechanism.[49] In the context of its proposal, the Exchange states that a Token [50] on the blockchain would be akin to a digital representation of shareholder equity in a legal entity that is organized under the authority of state or federal law and that meets BSTX's listing standards.[51] The Exchange further states that attribution of a Token to a particular wallet address would not convey ownership of shareholder equity in the issuer and that, instead, official records of ownership would be maintained at DTC.[52] The Exchange states that, pursuant to its proposal, ownership of Securities would be able to be transferred without regard to the blockchain-based recordkeeping functionality.[53]

The Exchange states that, for each Security, the Ethereum blockchain would reflect the end-of-day Security ownership balance associated with each BSTX Participant's wallet address, along with a balance allocated to an omnibus wallet address.[54] The Exchange states that it expects that each Security would have a designated omnibus wallet address.[55] The Exchange states that it would use an omnibus wallet address to account for instances in which a BSTX Participant fails to report or to accurately report its end-of-day Security ownership balance, as well as to account for the positions of Security holders that are not BSTX Participants and therefore not subject to the end-of-day Security ownership balance reporting requirement.[56] According to the Exchange, it would determine the number of Tokens (which represent Securities) to be allocated to the omnibus wallet address by subtracting the sum of the Security ownership balances reported for a particular Security by BSTX Participants from the total outstanding number of that particular Security.[57] The Exchange also recognizes that the omnibus wallet address would display the entire outstanding balance of a Security if only non-BSTX Participants hold the entire outstanding balance of a particular Security.[58]

According to the Exchange, Security ownership balance information reported to the Ethereum blockchain would be publicly available at the website Etherscan.io.[59] The Exchange states that, from Etherscan.io, an individual member of the public would be able to search for the name of a particular Security and see the holders of Tokens representing the Securities by wallet address and the quantity associated with each holder, along with other

[47] A ''smart contract'' has been defined as a computerized transaction protocol that executes terms of a contract with the general objectives to satisfy common contractual conditions (such as payment terms, liens, confidentiality, and even enforcement), minimize exceptions both malicious and accidental, and minimize the need for trusted intermediaries. *See* The DAO Report, *supra* note 13, at *2 & n.3.

[48] The Exchange defines ''Security'' as an ''NMS stock, as defined in Rule 600(b)(47) of the Exchange Act, trading on the BSTX System and for which ancillary blockchain records are maintained under these Rules.'' *See* proposed BSTX Rule 17000(a)(30). Exchange Act Rule 600(b)(47) defines ''NMS security'' as ''any security or class of securities for which transaction reports are collected, processed, and made available pursuant to an effective transaction reporting plan, or an effective national market system plan for reporting transactions in listed options.'' 17 CFR 242.600(b)(47). Exchange Act Rule 600(b)(48) then defines ''NMS stock'' as ''any NMS security other than an option.'' 17 CFR 242.600(b)(48). The Exchange states that it proposes to use the term ''Security'' to refer to BSTX-listed securities to distinguish them from other securities that are not designed to use blockchain technology as an ancillary recordkeeping mechanism. *See* OIP, *supra* note 7, 85 FR at 51251, n.15. For purposes of this Order, where discussing statements by commenters on previous versions of the proposal that used the term ''security token,'' which term the Exchange replaced with ''Security'' in Amendment No. 1, this Order will use the term ''Security.'' *See supra* note 6.

[49] *See* OIP, *supra* note 7, 85 FR at 51263. The Exchange uses the term ''tokens'' in its proposal to mean, in the context of blockchain technology, blockchain-based abstractions that can be owned and that represent assets, currency, or access rights. *See* OIP, *supra* note 7, 85 FR at 51255.

[50] This Order will use the term ''Token'' to refer more specifically to representations of Securities on a smart contract on the Ethereum blockchain that the Exchange would use to represent the reported end-of-day Security ownership balances for a particular Security. Securities listed and traded on BSTX would not be issued and/or transferred using distributed ledger or blockchain technology.

[51] *See* OIP, *supra* note 7, 85 FR at 51255. The Exchange states that this digital representation of a Security associated with a particular wallet address reflects an ancillary record of Security ownership based on data provided to BSTX by BSTX Participants. *See* OIP, *supra* note 7, 85 FR at 51255, n.52.

[52] *See* OIP, *supra* note 7, 85 FR at 51255. *See also id.* at 51261 (stating that the Security balance information as recorded on the Ethereum blockchain in Token form will not reflect legal ownership).

[53] *See* OIP, *supra* note 7, 85 FR at 51252 (also stating that Securities would trade, clear, and settle in the same manner as all other NMS stocks traded today).

[54] *See* OIP, *supra* note 7, 85 FR at 51261. The end-of-day Security ownership balance reported by a BSTX Participant or its carrying firm to the Exchange would reflect the total number of Securities for each class of Security that are credited to each account of the BSTX Participant at the securities depository (*i.e.,* DTC), or the total number of Securities for each class of Security that are credited to the BSTX Participant by its carrying firm. *See* proposed BSTX Rule 17020(b).

[55] *See* OIP, *supra* note 7, 85 FR at 51259.

[56] *See* OIP, *supra* note 7, 85 FR at 51259.

[57] *See* OIP, *supra* note 7, 85 FR at 51259. *See also* proposed BSTX Rule 17020(d).

[58] *See* OIP, *supra* note 7, 85 FR at 51260, n.80.

[59] *See* OIP, *supra* note 7, 85 FR at 51261.

information.[60] The observable quantity would reflect the last end-of-day Security ownership balances that the Exchange received from BSTX Participants and provided to the Wallet Manager to update the Ethereum blockchain.[61] The Exchange describes that a wallet address is essentially a string of numbers and characters.[62] The Exchange represents that it would not make public which wallet address is associated with a particular BSTX Participant or with the omnibus wallet address.[63] The Exchange states that an individual member of the public observing Security ownership balances would not be able to determine whether a particular wallet address represented, for example, a carrying firm reporting end-of-day Security ownership balances on behalf of multiple BSTX Participants, an individual BSTX Participant, or the omnibus wallet address.[64] In addition, the Exchange states that an individual member of the public would not to be able to tell whether a particular wallet address was long or short the shares.[65]

The Exchange recognizes that end-of-day Token balances (which represent Securities) ''may be inaccurate or unavailable.'' [66] The Exchange also acknowledges that there are many circumstances where the end-of-day Security ownership balances published on the Ethereum blockchain would not reflect the correct distribution of a Security among holders of the Security, or even among BSTX Participants holding the Security.[67] According to the Exchange, the Ethereum blockchain could reflect inaccurate information if BSTX Participants report inaccurate end-of-day Security balances.[68] The Exchange states that there could be situations where the number of reported Securities exceeds the number of outstanding Securities of a particular issuance.[69] The Exchange also states that there could be situations in which the Exchange is unable to communicate end-of-day Security ownership balances to the Wallet Manager or the Wallet Manager is unable to update the blockchain.[70] According to the Exchange, even if there were a disruption relating to the end-of-day Security balance reporting process, there would not be any impact on the ability to trade, clear, or settle Security transactions, because the end-of-day Security balance reporting process is solely an ''ancillary'' recordkeeping mechanism.[71]

The Exchange asserts that it does not believe that the records of Security ownership balance information published on the blockchain would be likely to cause investor confusion, because an individual member of the public observing the blockchain would not have any similar source of information with which to compare it.[72] According to the Exchange, the ownership balances related to Security ownership of BSTX Participants and other market participants are not available through another medium.[73] The Exchange also states that Security balance information recorded on the Ethereum blockchain would not reflect legal ownership of Securities, and the identities of BSTX Participants corresponding to each wallet address, as well as the identity of the omnibus wallet address, would not be made public.[74] The Exchange represents that it will not knowingly provide inaccurate end-of-day Security ownership balance information to the Wallet Manager.[75] Further, according to the Exchange, any reporting regime depends on the accuracy of the information reported to the reporting authority.[76]

In the context of SR–BOX–2019–19, two commenters raised concerns that the proposal would lead to investor confusion.[77] One commenter asserted that the proposal may confuse ''Main Street'' investors and that the difference between ''official'' and ''ancillary'' recordkeeping is inherently confusing.[78] This commenter stated that the proposal does not describe in detail how these two systems will interact or reconcile, and that this failing is likely to render the proposal confusing to market participants and investors.[79] Another

[60] *See* OIP, *supra* note 7, 85 FR at 51261 (stating that, for example, this other information may include transfers made as a result of the Wallet Manager's allocation process).

[61] *See* OIP, *supra* note 7, 85 FR at 51529. *See infra* Section III.C.2 for discussion of the process by which each BSTX Participant, directly or through its carrying firm, would report end-of-day Security ownership balances to BSTX and BSTX would provide this information, along with information pertaining to the balance to be allocated to the omnibus wallet address, to the Wallet Manager.

[62] *See* OIP, *supra* note 7, 85 FR at 51261.

[63] *See* OIP, *supra* note 7, 85 FR at 51261.

[64] *See* OIP, *supra* note 7, 85 FR at 51261. The Exchange further states that an individual member of the public would not be able to determine which underlying customers of a BSTX Participant held the Securities or whether the BSTX Participant owned the Securities proprietarily. *See id.* The Exchange asserts its belief that the Security ownership balance information that would be publicly available on the Ethereum blockchain would be sufficiently anonymous to address privacy concerns related to such information. *See id.* The Exchange further states that it believes that the use of anonymized wallet addresses to track end-of-day ownership balances may prevent fraudulent and manipulative acts and practices, because, according to the Exchange, obscuring the identities of the wallet address owners may make it difficult to misuse any private information associated with these wallet addresses. *See id.* at 51262.

[65] *See* OIP, *supra* note 7, 85 FR at 51261. The Exchange states that individual members of the public would not be able to know if a position is long or short because the reported end-of-day Security ownership balances would reflect balances as reported by DTC to BSTX Participants and their carrying firms. *See id.* at 51261, n.90. Therefore, according to the Exchange, if a BSTX Participant borrowed Securities and the borrowed Securities were moved to its DTC account (or the DTC account of its carrying firm on its behalf), the borrowed Securities would appear to be a long position in the Security, even if the BSTX Participant was taking a short position. *See id.*

[66] OIP, *supra* note 7, 85 FR at 51262. As discussed further below, the Exchange asserts that it believes that inaccuracies in the reported end-of-day Security ownership balances ''should not be routine'' and that the Exchange has adopted a number of mechanisms against potential inaccuracies. *Id.* at 51262, n.95. *See also infra* notes 116–120 and accompanying text. The Exchange states that it has described ''potential scenarios where potential inaccuracies could theoretically occur in the interest of full transparency.'' OIP, *supra* note 7, 85 FR at 51262, n.95.

[67] *See* OIP, *supra* note 7, 85 FR at 51260. The Exchange states that, while the ancillary recordkeeping mechanism will provide additional transparency into Securities holdings, there are limitations in what the Ethereum blockchain will reflect with regard to end-of-day Security ownership balances as an ancillary recordkeeping mechanism, given that all non-BSTX Participants' balances will be aggregated and reflected in an omnibus wallet address for each Security. *See id.* at 51261–62.

[68] *See* OIP, *supra* note 7, 85 FR at 51260.

[69] *See* OIP, *supra* note 7, 85 FR at 51260. The Exchange also gives examples of how the omnibus wallet address for each Security could have greater or fewer Tokens as a result of a misreport by a BSTX Participant, particularly if a Security is held entirely by BSTX Participants and a BSTX Participant over-reports. *See id.* In the case of an under-report by a BSTX Participant (*e.g.,* owns 100 of XYZ Securities, but reports only 90), the omnibus address for XYZ would have an additional 10 Tokens allocated to it; and in the case of an over-report (*e.g.,* owns 100 of XYZ Securities, but reports 110), the omnibus address for XYZ may have 10 additional Tokens allocated to it. *See* OIP, *supra* note 7, 85 FR at 51259–60, n.79.

[70] *See* OIP, *supra* note 7, 85 FR at 51260. *See infra* Sections III.C.1 and III.C.2 for discussion of the process by which BSTX would provide end-of-day Security balances to the Wallet Manager and the Wallet Manager would update the blockchain.

[71] *See* OIP, *supra* note 7, 85 FR at 51260–61. *See also id.* at 51262 (stating that, in the event of any disruption to the blockchain, the architecture of the Security (and its Token representation), or the end-of-day Security ownership balance reporting process, there would be no impact on the ability of market participants to trade Securities or on current balances of Securities held by each market participant through the facilities of DTC).

[72] *See* OIP, *supra* note 7, 85 FR at 51261.

[73] *See* OIP, *supra* note 7, 85 FR at 51261.

[74] *See* OIP, *supra* note 7, 85 FR at 51261.

[75] *See* OIP, *supra* note 7, 85 FR at 51262, n.95.

[76] *See* OIP, *supra* note 7, 85 FR at 51262, n.95 (stating that this includes reporting regimes administered by the Commission, such as large trader reporting, ATS quarterly transaction volume data reporting, and security-based swap reporting).

[77] *See* Letter from Benjamin Connault, Economist, Investors Exchange LLC (March 26, 2020) (''IEX Letter''), at 5; Letter from Joan C. Conley, Senior Vice President & Corporate Secretary, The Nasdaq Stock Market LLC (March 27, 2020) (''Nasdaq Letter''), at 3.

[78] *See* Nasdaq Letter, *supra* note 77, at 3.

[79] *See* Nasdaq Letter, *supra* note 77, at 3.

commenter asserted its belief that the Exchange has not sufficiently addressed the potential for confusion by investors and other participants because of a discrepancy between DTC ownership records and records maintained through the Exchange's proposed mechanism to record and disseminate on the Ethereum blockchain end-of-day Security ownership balances.[80] This commenter questioned whether there is some ''best-effort'' threshold around inaccurate or partial end-of-day Securities ownership balances on the Ethereum blockchain that would sufficiently address the risk of investor confusion.[81]

In a response submitted in connection with SR–BOX–2019–19, the Exchange stated that it is unclear what the commenter finds inherently confusing between official and ''ancillary'' records, and that ''official'' means that the record is authoritative, while ''ancillary'' means that the record is supplementary.[82] The Exchange also stated that the end-of-day Security balance information would constitute ''ancillary'' records of end-of-day ownership balances and that legal ownership would be separately established and evidenced by operation of commercial law.[83] According to the Exchange, what would appear on the Ethereum blockchain would be end-of-day Security ownership balances associated with an anonymous wallet address.[84] The Exchange stated that market participants would not have access to the full position records of DTC regarding Security ownership balances maintained by its participants, so it would not be possible for a market participant to see both sets of records and be confused by them.[85] Moreover, the Exchange stated that there is no possibility of an identifiable discrepancy between the DTC records and ''ancillary'' records, because aggregate records regarding DTC position balances are not available.[86]

In response to the commenter's question in the context of SR–BOX–2019–19 about whether there is a ''best-effort'' threshold, the Exchange stated that Section 19(g) of the Exchange Act requires the Exchange to comply with the Exchange Act, Commission rules, or its own rules.[87] The Exchange stated that this would require the Exchange to carry out its process for recording and disseminating end-of-day Security ownership balances as set forth in its rules and the proposal, or face a potential violation of Section 19(g) of the Exchange Act.[88] According to the Exchange, as described further below, in the event that these records become inaccurate, the Exchange would have the authority to suspend the reporting process with prompt notice to BSTX Participants and to the Commission.[89] The Exchange asserted, however, that even in the case of inaccurate ''ancillary'' records, there is no risk of investor confusion for the reasons it describes.[90]

Several commenters raised other questions, in the context of SR–BOX–2019–19, about differences between the end-of-day Security ownership balances on the blockchain and official records of legal ownership.[91] Two commenters asserted that the proposal is not clear regarding the differences between the records maintained by the Exchange, DTC, and NSCC and the end-of-day Security ownership balances.[92] Another commenter questioned whether the end-of-day Security ownership balances reported to the Ethereum blockchain would reflect the most recently completed transactions, or whether they would match DTC's records, including any reporting lags related to the T+2 settlement cycle.[93] This commenter questioned what type of information would be publicly observable from the end-of-day Security ownership balances and whether the public would be able to track the daily amount of stocks owned by a given BSTX Participant in its anonymized wallet address.[94] This commenter also asked how the Exchange's proposed recordkeeping mechanism would handle over-reporting of ownership balances,[95] and how short positions would be reflected in the end-of-day Security ownership balance recordkeeping mechanism.[96] Another commenter stated that the proposal does not describe all of the ''ancillary'' data and metadata that will be stored on the blockchain.[97] This commenter stated that the investor protection concerns that potentially flow from the creation of ''ancillary'' records need to be articulated and analyzed, including who benefits from the record, who will have access to the record, if the ''ancillary'' record would have any potential impact on the safeguarding of customer non-public information, and the utility of the Security for investors.[98]

In response, in the context of SR–BOX–2019–19, the Exchange stated that its proposed recordkeeping process using distributed ledger technology would be entirely separate from the trading, clearance, and settlement process for Securities, and that all Securities would be able to trade, clear, and settle in the same manner as any other NMS stock.[99] The Exchange stated that the only interaction between the existing market infrastructure and the Exchange's additional recordkeeping process would be that BSTX Participants, either directly or through their carrying firm, would be required to obtain end-of-day Security ownership

[80] *See* IEX Letter, *supra* note 77, at 5.

[81] *See* IEX Letter, *supra* note 77, at 5.

[82] *See* Letter from Lisa J. Fall, President, BOX Exchange LLC (April 9, 2020) (''BSTX Response Letter I''), at 6.

[83] *See* BSTX Response Letter I, *supra* note 82, at 6.

[84] *See* BSTX Response Letter I, *supra* note 82, at 6.

[85] *See* BSTX Response Letter I, *supra* note 82, at 6. *See also id.* at 11–12.

[86] *See* BSTX Response Letter I, *supra* note 82, at 8. According to the Exchange, although a BSTX Participant would be able to determine whether its own Security ownership balance as reported to the Exchange is ultimately reflected on the Ethereum blockchain, it is ''highly unlikely'' that the BSTX Participant, familiar with the Exchange and its process for recording and disseminating end-of-day Security ownership balances on the blockchain, would be confused as to which record is official and which record is ''ancillary.'' *See id.* at 8, n.36.

[87] *See* BSTX Response Letter I, *supra* note 82, at 8.

[88] *See* BSTX Response Letter I, *supra* note 82, at 8.

[89] *See* BSTX Response Letter I, *supra* note 82, at 8.

[90] *See* BSTX Response Letter I, *supra* note 82, at 8.

[91] *See* Letter from Holly H. Smith, Eversheds Sutherland (US) LLP (February 12, 2020) (''Eversheds Letter''), at 2; IEX Letter, *supra* note 77, at 6; Nasdaq Letter, *supra* note 77, at 3.

[92] *See* Nasdaq Letter, *supra* note 77, at 3; Eversheds Letter, *supra* note 91, at 2. One of these commenters stated that the proposal will require a Security to follow the BSTX Protocol as distributed by the Exchange via Regulatory Circular, but that currently there is no draft of the circular or other documentation that identifies the differences, if any, between the various types of records. *See* Eversheds Letter, *supra* note 91, at 2. The Commission notes that the Exchange filed a document described as a summary of the BSTX Protocol as Exhibit 3N to SR–BOX–2019–19, as modified by Amendment No. 2 and which was available on the Exchange's website, but, as discussed below, provides limited description of the protocol. This summary of the BSTX Protocol was refiled as Exhibit 3N to SR–BOX–2020–14, with minor revisions made in Amendment No. 1, and is available on the Commission's website at *https://www.sec.gov/rules/sro/box/2020/34-89536-ex3n.pdf* (''BSTX Protocol Summary Overview''). *See also infra* note 170 and accompanying text.

[93] *See* IEX Letter, *supra* note 77, at 6.

[94] *See* IEX Letter, *supra* note 77, at 5 (also asking whether BSTX Participants would be allowed to use multiple wallet addresses or change wallet addresses over time, including for the purpose of limiting the public's ability to track their positions).

[95] *See* IEX Letter, *supra* note 77, at 6. This commenter questioned whether, in the case of over-reporting, the total number of Securities for a given BSTX Security would fluctuate from one day to the next, with extra Securities being created and then destroyed when there is no longer over-reporting. *See id.*

[96] *See* IEX Letter, *supra* note 77, at 6.

[97] *See* Eversheds Letter, *supra* note 91, at 2.

[98] *See* Eversheds Letter, *supra* note 91, at 2.

[99] *See* BSTX Response Letter I, *supra* note 82, at 5.

balances available to them through DTC and report such balances to the Exchange.[100]

The Exchange also responded that the data appearing on the blockchain would only reflect end-of-day Security ownership balances associated with each BSTX Participant's anonymized address, as well as the omnibus address for unreported ownership balances.[101] With respect to whether the end-of-day Security ownership balances reflected on the Ethereum blockchain would reflect the most recent transactions or match DTC's records, the Exchange stated that the end-of-day Security ownership balances would represent a moment-in-time snapshot of each BSTX Participant's balance in each Security at the end of the day, either as credited to its DTC account or to its account at its carrying firm.[102] With respect to the potential for over-reporting, the Exchange stated that the total supply of Tokens associated with a particular issuance of a Security for purposes of the recordkeeping process on the blockchain would be fixed (subject to adjustment in the case of a corporate action that impacts the total supply) and would not fluctuate day-to-day.[103] The Exchange stated that it has proposed authority to suspend this recordkeeping process in its discretion, with prompt notice to BSTX Participants and to the Commission, which could include circumstances involving over-reporting.[104]

According to the Exchange, the Ethereum blockchain is public, so anyone would have access to the end-of-day Security ownership balances on the blockchain.[105] The Exchange stated that individual members of the public observing the Ethereum blockchain would not be able to view transaction-level or market participant-identifying detail, whether an ownership balance reflects proprietary or customer positions, whether a wallet address belongs to a carrying firm reporting on behalf of multiple BSTX Participants or a single BSTX Participant, or whether the reported long positions include borrowed shares.[106] The Exchange asserted that it has not proposed any limitation on the ability of BSTX Participants to establish multiple wallet addresses, and that the Exchange would discuss operational issues with BSTX Participants as appropriate.[107] The Exchange stated that, due to the lack of specific transaction-level details, the end-of-day Security ownership balances would contain only a small fraction of the records that the Exchange would retain with respect to transactions on its market.[108] According to the Exchange, it believes that DTC and NSCC's records would likely be extensively more detailed than the proposed end-of-day Security ownership balances, and likely contain transaction-level and market participant-identifying information.[109]

One commenter questioned, in the context of SR–BOX–2019–19, what the implications might be of making end-of-day Security ownership balance data publicly available.[110] This commenter stated that it would be unclear who would be responsible for ensuring the accuracy of this data.[111] This commenter also questioned whether the system for recording and disseminating end-of-day Security ownership balances could be gamed (*e.g.,* would a firm be able to publish a large holding to the blockchain that it does not actually hold, or vice versa).[112] The Exchange responds that knowingly reporting a false number of Securities to the Exchange would be a direct violation of proposed BSTX Rule 17020, violate just and equitable principles of trade, and cause a BSTX Participant to be subject to disciplinary action by the Exchange.[113] The Exchange states that if a BSTX Participant did try to ''game'' the end-of-day Security ownership balance recordkeeping process in the manner suggested, it would not have any impact on the ability of the Securities to trade, clear, or settle.[114] The Exchange also asserts that the balance information would not be useful to inform a market participant's trading in Securities because an individual member of the public observing the blockchain would not know which market participant is associated with each wallet address, whether a wallet address represents a DTC participant reporting on behalf of multiple Securities holders, whether the position is long or short, or whether the position represents a proprietary position or the position of customer of a BSTX Participant.[115]

In its notice of the proposal, the Exchange states that, to address the potential for inaccurate reporting by BSTX Participants, proposed BSTX Rule 17020(e) would provide that if a BSTX Participant discovers that it submitted an inaccurate end-of-day Security balance report that has not already been corrected or superseded, it must promptly send a corrected report to the Exchange.[116] In addition, if the Exchange has reason to believe that reported Security balances may be inaccurate, it may request additional information regarding the applicable reports and balances from any BSTX Participant.[117] The Exchange would consider a BSTX Participant's compliance with proposed BSTX Rule 17020(e) by promptly submitting a corrected report or responding to additional information requests from the Exchange in determining whether to

[100] *See* BSTX Response Letter I, *supra* note 82, at 5–6.

[101] *See* BSTX Response Letter I, *supra* note 82, at 13–14. *See also id.* at 15.

[102] *See* BSTX Response Letter I, *supra* note 82, at 10.

[103] *See* BSTX Response Letter I, *supra* note 82, at 11.

[104] *See* BSTX Response Letter I, *supra* note 82, at 11.

[105] *See* BSTX Response Letter I, *supra* note 82, at 14. *See also* Letter from Lisa J. Fall, President, BOX Exchange LLC (April 27, 2020) (''BSTX Response Letter II''), at 4, n.21 (stating that all market participants would have open access to the distributed ledger technology associated with BSTX, but also noting that market participants would not have the ability to modify the underlying source).

[106] *See* BSTX Response Letter I, *supra* note 82, at 10, 15. *See also* BSTX Response Letter II, *supra* note 105, at 21, n.22. The Exchange also stated that short positions would not be reflected, because the end-of-day Security ownership balances would include any borrowed shares. *See* BSTX Response Letter I, *supra* note 82, at 10.

[107] *See* BSTX Response Letter I, *supra* note 82, at 10.

[108] *See* BSTX Response Letter I, *supra* note 82, at 14.

[109] *See* BSTX Response Letter I, *supra* note 82, at 14.

[110] *See* Letter from Ellen Greene, Managing Director, Equities & Options Market Structure, & Thomas F. Price, Managing Director, Operations, Technology, Cyber & BCP, Securities Industry and Financial Markets Association (April 22, 2020) (''SIFMA Letter II''), at 5. This commenter stated that SR–BOX–2020–14 appears to be identical to Amendment No. 2 to SR–BOX–2019–19 and that, for that reason, SIFMA Letter II continues to apply to SR–BOX–2020–14. *See* Letter from Ellen Greene, Managing Director, Equities & Options Market Structure, & Thomas F. Price, Managing Director, Operations, Technology, Cyber & BCP, Securities Industry and Financial Markets Association (June 23, 2020) (''SIFMA Letter III''), at 1–2.

[111] *See* SIFMA Letter II, *supra* note 110, at 5.

[112] *See* SIFMA Letter II, *supra* note 110, at 5.

[113] *See* OIP, *supra* note 7, 85 FR at 51262, n.100. *See also* BSTX Response Letter II, *supra* note 105, at 4.

[114] *See* OIP, *supra* note 7, 85 FR at 51262, n.100. *See also* BSTX Response Letter II, *supra* note 105, at 4.

[115] *See* OIP, *supra* note 7, 85 FR at 51262, n.100 (stating that it is unclear what purpose or incentive there would be for a BSTX Participant to ''game'' the ancillary recordkeeping process, and noting that such an attempt would expose the BSTX Participant to disciplinary action).

[116] *See* OIP, *supra* note 7, 85 FR at 51260. *See also* proposed BSTX Rule 17020(e)(1).

[117] *See* OIP, *supra* note 7, 85 FR at 51260. The BSTX Participant must promptly respond to any additional information requests that the Exchange may make regarding its end-of-day Security balance reports. *See id.* (stating that these additional information requests may include asking the BSTX Participant to confirm its Security balances, or to provide a copy of the information the BSTX Participant used to provide its end-of-day Security ownership balance report, or other books and records of the BSTX Participant relating to its transactions in Securities). *See also* proposed BSTX Rule 17020(e)(2).

bring, or the appropriate consequences of, disciplinary action.[118] According to the Exchange, similar mechanisms to promote accurate reporting exist for a wide variety of different market participant obligations, such as the duty of the broker-dealer operator of an NMS stock alternative trading system to promptly correct material errors or omissions discovered in its Form ATS–N and the duty to correct trade reports submitted to the Financial Industry Regulatory Authority (''FINRA'').[119] The Exchange states that its proposed rule sets forth reasonable processes to help ensure that the Security position balances published as Token balances on the blockchain are accurate, and that ensuring the accuracy of this information will better facilitate all market participants' ability to evaluate the potential uses of blockchain technology in securities transactions.[120]

In the context of SR–BOX–2019–19, one commenter expressed concern over the uncertainty of whether surveillance of the end-of-day reporting requirement to make sure that a BSTX Participant accurately reports its Security ownership balances would be done by BSTX, or by FINRA pursuant to the Regulatory Services Agreement.[121] This commenter asked, in either case, what procedures would be used for surveillance and enforcement of the requirement.[122] Two commenters asserted that it is not clear how differences in reporting between the records maintained by the Exchange, DTC, and NSCC and the end-of-day Security ownership balances would be reconciled.[123] Another commenter questioned whether there would be any mechanism to ensure that ownership balances reported by a BSTX Participant accurately match DTC's records.[124]

The Exchange responded, in the context of SR–BOX–2019–19, that it has general authority under proposed BSTX Rule 20000 to request that a BSTX Participant provide the Exchange with copies of records related to its business.[125] According to the Exchange, its request to a BSTX Participant could include a request for the reports provided by DTC to the BSTX Participant that the BSTX Participant used to report end-of-day Security ownership balance information to the Exchange.[126]

Analysis

The Commission concludes that the Exchange has not met its burden to demonstrate that its proposal to publicly disseminate end-of-day Security ownership balances associated with certain wallet addresses by publishing these balances on the Ethereum blockchain on a daily basis is consistent with the protection of investors and the public interest, given that the disseminated balances could be inaccurate, which raises the significant risk that the publicly disseminated information may confuse and mislead investors. The Exchange acknowledges that, in a variety of circumstances the Security ownership balances published to the Ethereum blockchain would be inaccurate.[127] For example, if BSTX Participants report end-of-day Security ownership balances to BSTX that are not accurate, these inaccuracies would be reflected on the public Ethereum blockchain.[128] The publicly disseminated end-of-day Security ownership balances would also become inaccurate if a BSTX Participant is late in reporting or if the Exchange is unable to communicate updated ownership balances to the Wallet Manager or the Wallet Manager is unable to update the blockchain.[129] In addition, end-of-day Security ownership balances on the Ethereum blockchain would be stale because they would represent a snapshot of a BSTX Participant's DTC account balance at the end of the last trading day and would not reflect ownership balances that have changed due to transactions that settled during the day or that will change due to transactions that have not yet settled.[130] This latter variance may increase during the course of the trading day due to continued trading in the Securities. There is a significant risk that the reported balances of clearing firm BSTX Participants would create the misimpression of a large position because the reported balances would not indicate the beneficial owner, at least to the extent that the beneficial owner is not also a BSTX Participant.[131] In addition, BSTX concedes that its Participants' short and long positions, both of which would be reported, would be indistinguishable when represented on the Ethereum blockchain.[132] Given that these two types of transactions reflect opposite economic positions in the Security, the disseminated end-of-day Security ownership balances would provide an economically misleading picture. Moreover, while the Exchange represents that it believes inaccuracies in the end-of-day Security ownership balances ''should not be routine,'' [133] the Exchange does not explain what it would consider ''routine'' or further describe what it would consider to be an acceptable level of inaccuracy.

In addition, the end-of-day Security ownership balances would be incomplete in that they would be lacking in relevant detail, and thus there is a significant risk that the investing public would be confused or misled by the information presented. The Exchange has not explained how the public would be made aware of what information about Security ownership balances is actually reflected on the blockchain and the ways in which the true holdings of investors might be different than publicly disseminated balances.[134] The omnibus wallet address itself represents balances that cannot be attributed to a particular

[118] *See* OIP, *supra* note 7, 85 FR at 51260, n.83.

[119] *See* OIP, *supra* note 7, 85 FR at 51260 (citing 17 CFR 242.304(a)(2)(i)(C); FINRA, Trade Reporting FAQ, Section 311).

[120] *See* OIP, *supra* note 7, 85 FR at 51260. The Exchange states that, in addition to these controls and mechanisms, it may need to implement further measures in instances in which the ability to update the blockchain may be affected by exogenous factors, and points to proposed BSTX Rule 17020(f) as giving the Exchange the ability to suspend certain requirements related to end-of-day Security ownership reporting on the blockchain. *See id.* For further discussion of the proposed suspension provisions, see *infra* Section III.C.3.

[121] *See* IEX Letter, *supra* note 77, at 6.

[122] *See* IEX Letter, *supra* note 77, at 6.

[123] *See* Nasdaq Letter, *supra* note 77, at 3; Eversheds Letter, *supra* note 91, at 2.

[124] *See* IEX Letter, *supra* note 77, at 6.

[125] *See* BSTX Response Letter I, *supra* note 82, at 11, 16.

[126] *See* BSTX Response Letter I, *supra* note 82, at 11, 16.

[127] *See supra* notes 66–70 and accompanying text.

[128] *See supra* note 68 and accompanying text. The Exchange states that it is possible for BSTX Participants to over-report (*see supra* note 69 and accompanying text), but the Exchange does not explain how it would reconcile this over-reporting for purposes of updating the blockchain, given that the total supply of Tokens associated with a given Security is fixed (*see supra* note 103 and accompanying text).

[129] *See supra* note 70 and accompanying text.

[130] *See supra* notes 93, 102, and accompanying text.

[131] Moreover, the proposal is not clear regarding how BSTX Participants that are carrying firms will report Security ownership balances associated with their proprietary holdings versus Security ownership balances associated with other investors' holdings. The lack of clarity about how certain investors' Security ownership balances will be reported to BSTX and subsequently reflected on the Ethereum blockchain could impact the Security ownership balances that are viewable to the public.

[132] *See supra* notes 65, 106, and accompanying text. The Exchange states that end-of-day Security ownership balances may include borrowed shares in a DTC participant's account (*see supra* note 65), but the Exchange does not explain fully how borrowed shares may impact the end-of-day ownership balances of various types of participants. For example, the Exchange has not explained what might occur with respect to ownership balances on the blockchain in the case of a short sale with a failure to deliver.

[133] *See supra* note 66 and accompanying text.

[134] For example, the Exchange has not indicated whether it would be relying on issuers of Securities to inform potential investors about potential inaccuracies in the public Security ownership information or how that information would otherwise be conveyed to market participants.

holder, and would include balances that are unaccounted for because they represent the holdings of non-BSTX Participants, along with balances not associated with a BSTX Participant due to a failure to report on time or inaccurate reporting.[135] The Exchange has not explained its standard for how it will determine what to include and remove from the omnibus account, and this makes it unclear what the Security balance associated with the omnibus account will represent. The Exchange also has not proposed, for example, to identify within the omnibus account what Security ownership balances reflect errors, late reporting, or unaccounted for ownership because the shares are not owned by a BSTX Participant.

While the Exchange represents that it would not make public which wallet addresses are associated with particular BSTX Participants or the omnibus account and asserts that the publicly available information would be sufficiently anonymous to address privacy concerns,[136] the lack of identification of which Security holder is associated with a particular wallet address itself presents a significant risk of confusion for investors, potential investors, and other market participants. In particular, with respect to the omnibus account, a large associated Security balance could create the misimpression that there is a significant holder in the Security, when in fact the omnibus account for a Security reflects the combined holdings of several holders. As discussed above, if a carrying firm BSTX Participant reports a large Security ownership balance that represents the positions of many beneficial owners, the reported balance could create a similar misimpression.[137] Furthermore, the inability to disaggregate short and long positions is inherent in the proposed reporting scheme and would confuse and mislead investors. The Exchange does not describe any measures to mitigate these inherent inaccuracies.

Exacerbating the inaccuracy of the information that the Exchange would publicly disseminate on the Ethereum blockchain, the Exchange has not demonstrated whether or how it would surveil for or reconcile inaccurate reporting of end-of-day Security ownership balances by BSTX Participants, or otherwise address inaccurate information displayed on the Ethereum blockchain. The lack of a demonstrated ability of the Exchange to ensure the integrity of the end-of-day Security ownership balances that would be publicly disseminated by the Exchange increases the likelihood that these records would be inaccurate.[138] The Exchange would impose a unique obligation on BSTX Participants to obtain an allowlisted wallet address and report end-of-day Security ownership balances. BSTX Participants that fail to comply with these requirements may be subject to disciplinary actions.[139] However, the record does not demonstrate how the Exchange will perform surveillance for BSTX Participant compliance, particularly with respect to the end-of-day Security ownership balance reporting requirement.

Proposed BSTX Rule 17020(e) provides that the Exchange may request additional information from a BSTX Participant if the Exchange has ''reason to believe'' that its reported end-of-day Security ownership balances are inaccurate.[140] Yet the Exchange provides no evidence that it would take any affirmative steps to surveil for inaccurate end-of-day Security ownership balances, including where there are discrepancies between these reported ownership balances and official records of legal ownership. Rather, the Exchange would rely on BSTX Participants' self-reporting of the end-of-day Security ownership balances and on whether those reported balances reveal any apparent errors on their face, which the Commission finds to be insufficient to mitigate these inaccuracies. Moreover, the Exchange does not address what steps, if any, it will take after finding an inaccuracy. The proposed requirement that a BSTX Participant must respond to a request from the Exchange for information about its reported end-of-day Security ownership balances merely reinforces the Exchange's general regulatory authority.[141] While the Exchange has the authority to request records from a BSTX Participant, including the reports that the BSTX Participant received from DTC and used to determine its end-of-day Security ownership balance, the Exchange does not represent that it would request such records on a routine basis or use such requests to affirmatively identify inaccuracies in the reported end-of-day Security ownership balances, as opposed to using them as a tool to investigate suspected inaccuracies. And the Exchange does not describe alternative means that it might use to determine whether a BSTX Participant has accurately reported its end-of-day Security ownership balances, or how it might surveil for and correct against late reporting by BSTX Participants.

The Exchange compares its proposal to other reporting regimes and asserts that other reporting regimes, including reporting regimes administered by the Commission, depend on the accuracy of the information reported or explicitly direct their participants to correct inaccurate reports.[142] But this assertion does not alleviate the Commission's concern that the lack of a process for the Exchange to monitor or address the inaccuracy of end-of-day Security ownership information would exacerbate the inaccuracy of the publicly disseminated information, and that disseminating inaccurate information would not be consistent with the protection of investors and the public interest, as required by Section 6(b)(5) of the Exchange Act. For example, the Commission does not rely solely on trust to assure the integrity of its reporting regime, but rather also conducts surveillance of its regulated entities, and also relies on the presence of SROs that surveil these entities.[143] Moreover, provisions in other reporting regimes directing participants to correct inaccurate reports exist within a regulatory framework that includes

[135] *See supra* notes 56–57 and accompanying text.

[136] *See supra* notes 63–64 and accompanying text.

[137] *See supra* note 64 and accompanying text.

[138] *See also supra* notes 110–112 and accompanying text (commenter questioning the accuracy of the end-of-day Security ownership balances). It is also not clear from the record exactly what information would be publicly available. For example, it is not clear what ''other information'' beyond the end-of-day Security ownership balance information for BSTX Participants and the total balance attributed to the omnibus account, would be available to market participants. *See supra* note 60 and accompanying text. *See also supra* note 97 and accompanying text. Accordingly, this ''other information'' would not clear up the inaccuracies described herein, and the Exchange does not suggest otherwise.

[139] *See* OIP, *supra* note 7, at 51259. The Exchange states that BSTX Participants would be required to comply with applicable Exchange rules, including the requirement to report their end-of-day Security balances, and may be subject to disciplinary action for failing to comply with applicable rules pursuant to proposed BSTX Rule series 24000 (Discipline and Summary Suspension).

[140] *See supra* note 117 and accompanying text.

[141] *See supra* note 117. *See also supra* notes 125–126 and accompanying text.

[142] *See supra* notes 76, 119, and accompanying text.

[143] *See* Securities Exchange Act Release No. 40760 (December 8, 1998), 63 FR 70844, 70908 (December 22, 1998) (File No. S7–12–98) (Regulation of Exchanges and Alternative Trading Systems) (''As broker-dealers, alternative trading systems will be inspected on a regular basis by any SRO of which they are a member, and by the Commission only on an intermittent basis.''). *See also id.* at 70848 (''the Commission intends to work with the self-regulatory organizations ('SROs') to ensure that they can operate ongoing, real-time surveillance for market manipulation and fraud and develop surveillance and examination procedures specifically targeted to alternative trading systems they oversee'').

other affirmative surveillance measures.[144] Therefore, this comparison between other reporting regimes and the obligations on BSTX Participants to accurately report end-of-day Security balances to the Exchange and to correct inaccurate reports does not demonstrate that, without taking reasonable affirmative steps to monitor whether BSTX Participants have reported accurate information, the Exchange would be able to mitigate against the dissemination of inaccurate Security ownership information.

The Exchange's proposed use of an omnibus account to cover unattributed Security ownership balances arising from inaccurate or late reporting by BSTX Participants, and discretionary authority to suspend the end-of-day reporting obligation with respect to a particular BSTX Participant or a Security, suggest that the Exchange may rely on one or both of these measures, even though there is a significant risk that these measures would leave inaccurate information on the Ethereum blockchain, rather than taking steps to resolve certain inaccuracies or inconsistencies.[145] And the Exchange does not describe any procedures for correcting the end-of-day Security ownership balances beyond a proposed requirement that a BSTX Participant correct an inaccurate report, which would have an insufficient mitigating effect because BSTX Participants also have a duty to submit accurate reports.[146] Therefore, the Exchange has not demonstrated in the proposal how the Exchange would ensure the integrity of information that the Exchange seeks to publicly disseminate.

The Exchange asserts that it does not believe that the end-of-day Security balances on the Ethereum blockchain would cause investor confusion because there is no similar source of information with which an individual member of the public could make a comparison to the information disseminated on the blockchain and become confused.[147] The Commission concludes, however, that it would not be consistent with the protection of investors and the public interest for the Exchange to publicly disseminate inaccurate information about Securities ownership, even if the public is not able to make comparisons to identify discrepancies with official ownership records. While the lack of a comparable source of information may prevent the public from being aware of a discrepancy in ownership balances, the information the Exchange publishes would still be inaccurate.

The reliability of public securities records is important to the integrity of, and investor confidence in, the securities markets, and the Commission concludes that labeling records as ''ancillary'' does not minimize the need for such records of securities ownership publicly disseminated by a national securities exchange to be accurate. Where, as here, the very purpose of the Exchange's proposal is to publicize such securities ownership information,[148] the reliability and accuracy of that information is particularly important. Further, if a national securities exchange requires its members to report security ownership information that the exchange makes publicly available in some form, that exchange is obligated to take reasonable steps to surveil the reported information for accuracy, to prevent inaccuracies from misleading investors and other market participants. The Commission thus finds that the Exchange has not met its burden to demonstrate how its proposal is consistent with the requirements of Exchange Act Section 6(b)(5) that a national securities exchange's rules must be consistent with the protection of investors and the public interest.

Furthermore, once information about end-of-day Security ownership balances is put into the public domain, there is a significant risk that market participants, including investors, would interpret those public records and make use of this information. The Commission is not persuaded that the Exchange's designation of the end-of-day Security ownership balances publicly disseminated on the Ethereum blockchain as an ''ancillary'' record prevents market participants from making use of the information, including in connection with investment and trading decisions.[149] The Commission is also not persuaded by the Exchange's assertion, when responding to a commenter's concern that a BSTX Participant might try to ''game'' the system by reporting an inaccurate end-of-day Security ownership balance, that the balance information would not seem to be useful to inform a market participant's trading in a Security because of a lack of detail in the publicly disseminated information.[150] To the contrary, the Commission concludes that market participants put in place various investment strategies that at times use advantages in obtaining or analyzing information, and that it is reasonable to assume that some subset of market participants would try to analyze and make use of a new source of publicly available information concerning Security ownership, even if such information is incomplete.

For the reasons stated above, the Commission concludes that the public dissemination of inaccurate information about Security ownership has the significant potential to mislead investors, irrespective of whether the information is disseminated on the blockchain, the internet, or in print, and that the Exchange has not met its burden to demonstrate that its proposal is nonetheless consistent with the protection of investors and the public interest, pursuant to Section 6(b)(5) of the Exchange Act. The Commission also concludes that this misleading information creates a significant risk that investors make investment decisions based on misinterpretations of public information about Security ownership. Based on the consequences of the Exchange disseminating securities ownership information that is inaccurate, the Commission finds that the Exchange has failed to demonstrate that the proposal would protect investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act.

[144] For example, when discussing amendments to Form ATS recordkeeping requirements to cover Form ATS–N filers, the Commission stated that it believed that the amendments ''are necessary to create a meaningful audit trail of an ATS's current and previous written safeguards and procedures . . . and permit surveillance and examination staff to help ensure fair and orderly markets without imposing any undue burden on ATSs.'' Securities Exchange Act Release No. 83663 (July 18, 2018), 83 FR 38768, 38788, n.278 (August 7, 2018) (File No. S7–23–15) (Regulation of NMS Stock Alternative Trading Systems). Similarly, when approving amendments to FINRA's equity trade reporting rules, the Commission stated that these changes ''should enhance FINRA's audit trail and automated surveillance program, promote more consistent trade reporting by members, and aid in the detection of violations of FINRA trade reporting and other rules.'' Securities Exchange Act Release No. 71623 (February 27, 2014), 79 FR 12558, 12562 (March 5, 2014) (SR–FINRA–2013–050).

[145] *See supra* notes 56, 120, and accompanying text. *See also infra* note 262 and accompanying text.

[146] *See supra* note 116 and accompanying text. Further, this duty to update only applies if the erroneous report has not been corrected or superseded, and BSTX Participants must submit new end-of-day Security ownership balances at the end of each day. *See id.*

[147] *See supra* note 72 and accompanying text.

[148] *See* OIP, *supra* note 7, 85 FR at 51251.

[149] Although the Exchange states that any disruption to end-of-day Security ownership reporting would not impact the ability to trade, clear, or settle Security transactions (*see supra* notes 71, 114, and accompanying text), the ''ancillary'' nature of the blockchain-based records does not negate that these records could be viewed as a publicly available source of information regarding Security ownership.

[150] *See supra* note 115 and accompanying text.

C. Whether BOX Has Met Its Burden To Demonstrate That the Proposal Is Consistent With Sections 6(b)(1) and 6(b)(5) of the Exchange Act With Respect to the Operation of the Proposed Reporting of End-of-Day Security Ownership Balances

The Commission examines below whether the Exchange has met its burden to demonstrate that its proposal is consistent with Sections 6(b)(1) and 6(b)(5) of the Exchange Act with respect to additional aspects of the proposal. The Commission first considers whether the record explains sufficiently the processes by which a Wallet Manager will write to the Ethereum blockchain. As discussed below, the Commission concludes that the Exchange has not met its burden to demonstrate how the Exchange would, consistent with Section 6(b)(1) of the Exchange Act, be able to ensure compliance by the Exchange with its own rules, or that the Exchange's proposed rules would protect investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act.[151] Next, the Commission considers the processes by which BSTX Participants will obtain allowlisted wallet addresses, BSTX Participants will provide end-of-day Security ownership balances to BSTX, and BSTX will provide Security ownership balances to a Wallet Manager, as well as the costs or other burdens market participants would face as a result of the end-of-day Security ownership balance reporting requirements. As discussed below, the Commission concludes that the Exchange has not met its burden to demonstrate that the Exchange would be able to carry out its necessary functions or fulfill its obligations as an SRO to comply with its own rules, pursuant to Section 6(b)(1) of the Exchange Act; or that the Exchange's rules would facilitate transactions in securities, remove impediments to a free and open market and national market system, or protect investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act.[152]

The Commission examines how the Exchange might use its proposed discretion to suspend the requirements for BSTX Participants to obtain allowlisted wallet addresses and report end-of-day Security ownership balances as to a particular BSTX Participant or Security. As discussed below, the Commission concludes that the Exchange has not met its burden to demonstrate that it would be able to carry out its necessary functions, in accordance with Section 6(b)(1) of the Exchange Act; and that the Exchange's rules are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, as required by Section 6(b)(5) of the Exchange Act.[153]

The Commission then examines specific issues presented by the Exchange's proposed listing of Securities—specifically, the lack of fungibility between a BSTX-listed Security and other classes of securities of the same issuer, whether the Exchange has sufficiently addressed issues posed by potential listings by the Exchange or its affiliate, and its proposed continued listing requirement that all BSTX-listed Securities remain compliant with the BSTX Protocol. As discussed below, the Commission concludes that the Exchange has not met its burden to demonstrate that (1) notwithstanding the described lack of fungibility, the Exchange's rules would prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to a free and open market and national market system, or protect investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act; [154] and (2) based on a lack of explanation about issuer compliance with the BSTX Protocol, that the proposal is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, and is not designed to permit unfair discrimination between issuers, as required under Section 6(b)(5) of the Exchange Act.[155]

1. Wallet Manager Writing to Blockchain

(a) Exchange's Representations and Comments Received

According to the Exchange, it will enter into a contractual arrangement with a Wallet Manager as a third-party service provider for the Exchange that will establish wallet addresses for BSTX Participants and update the Ethereum blockchain with Security ownership balances.[156] The Exchange states that it intends to evaluate each potential Wallet Manager's capability to receive information from BSTX related to BSTX Participants' end-of-day Security balances and its ability to update the Ethereum blockchain.[157]

The Exchange states that, initially, it expects to contract with only one Wallet Manager, tZERO, who would also be a 50% owner of BSTX.[158] According to the Exchange, following the end of a trading day, BSTX Participants (or their carrying firms) would be required to send Security balance information to BSTX, and BSTX would deliver that information to the Wallet Manager (or Wallet Managers) who would be responsible for updating the Security ownership balances on the Ethereum blockchain ''by allocating balances among the wallet addresses of BSTX Participants and the omnibus address.'' [159] The Exchange states that the Ethereum blockchain would not reflect any particular transactions, but would instead record allocations of end-of-day Security balances that may result from, among other things, trading and lending activity.[160]

Specifically, the Exchange states that the Wallet Manager would make updates to the balances associated with wallet addresses by reallocating Tokens (which represent Securities) between wallet addresses, including the omnibus wallet address, so that, according to the Exchange, after each trading day the wallet address account balances reflect the new Security ownership balances reported to BSTX pursuant to BSTX Rule 17020. The Exchange also states that these reallocations based on end-of-day Security ownership balance reports from BSTX Participants are not designed to reflect actual transactions that occurred during the trading day, but that instead, the reallocation process focuses on having the correct number of

[151] *See infra* Section III.C.1.

[152] *See infra* Section III.C.2.

[153] *See infra* Section III.C.3.

[154] *See infra* Section III.C.4(a).

[155] *See infra* Section III.C.4(b).

[156] *See* OIP, *supra* note 7, 85 FR at 51257. The Exchange states that it believes that the Wallet Manager's functions do not meet the definition of ''facility'' under Section 3(a)(2) of the Exchange Act. *See id.*

[157] *See* OIP, *supra* note 7, 85 FR at 51258. The Exchange also describes that it intends to perform due diligence on potential Wallet Managers and that it will require in its service agreements with Wallet Managers that they agree to comply with applicable securities laws. The Exchange states its belief that its listed criteria for evaluating potential Wallet Managers may prevent fraudulent and manipulative act and practices, consistent with Section 6(b)(5) of the Exchange Act. *See id.*

[158] *See* OIP, *supra* note 7, 85 FR at 51258, n.68. The Exchange also states that there is nothing to preclude the use of another Wallet Manager capable of operating software that is compatible with the BSTX Protocol. *See id.*

[159] OIP, *supra* note 7, 85 FR at 51257. *See also* proposed BSTX Rule 17020(d). The Exchange also states that pursuant to the Exchange's agreement with the Wallet Manager (or Wallet Managers), the Wallet Manager would be required to record balances to the Ethereum blockchain following each trading day. Thus, Tokens representing Security balances of BSTX Participants would be updated each trading day, but not on non-trading days. *See* OIP, *supra* note 7, 85 FR at 51258, n.69.

[160] *See* OIP, *supra* note 7, 85 FR at 51257. *See also supra* note 65 discussing how short sales and borrowed shares would appear in the end-of-day Security ownership balances.

Tokens attributed to each wallet address based on the end-of-day Security ownership balance reports.[161]

The Exchange states that, to create a new Token on the Ethereum blockchain for purposes of facilitating the recording and dissemination of Security ownership balances, the issuer of the securities must create a new smart contract that is configured to detail, among other things, the name of the issuer and total supply of the Tokens that correspond to the BSTX-listed Security.[162] According to the Exchange, the recording of Security ownership balances would not commence until the conclusion of the first day of Security trading on BSTX.[163] As discussed above, the Exchange states that, using Etherscan.io, an individual member of the public would be able to see holders of Tokens representing the Securities and the associated quantity, as well as ''other information (*e.g.,* transfers made as a result of the Wallet Manager(s) reallocation process).'' [164] In describing how the term ''smart contract'' is commonly used, the Exchange asserts that in the context of Tokens representing Securities, smart contracts generally may have three components: (i) Functions, (ii) configurations; (iii) and events; and that ''events'' are the functions of a smart contract that, when executed, result in a log or record being recorded to the Ethereum blockchain, such as ''the transfer of tokenized assets from one address to another.'' [165] The Exchange also states that with a Token ''transfer'' no transaction is actually sent to the recipient of the ''Token.'' [166] The Exchange explains that a transaction ''transferring'' a Token to an address only changes the state of the Token contract, and that, instead of a wallet address being full of ''Tokens,'' it is the Token smart contact that contains the wallet addresses and associated balances.[167] Additionally, the Exchange states that in the context of the BSTX Protocol, a ''transfer'' of a Token refers to a reallocation of the digital representation of a Security on the Ethereum blockchain as an ''ancillary'' recordkeeping mechanism to reflect corresponding changes in ownership of the Security.[168]

The Exchange states that, in connection with the operation of BSTX, it proposes to use a series of ''new forms'' to facilitate becoming a BSTX Participant and for issuers to list their Securities,[169] and includes as one of these what it refers to as an overview of the BSTX Protocol.[170] Pursuant to the proposed BSTX Protocol Summary Overview, it is the Asset Smart Contract that will contain the balances of Tokens associated with each wallet address and carry out the functions necessary to effect changes in ownership for ''ancillary'' recordkeeping purposes.[171] Specifically, the proposed BSTX Protocol Summary Overview states that the Asset Smart Contract defines and creates the maximum number of Tokens available for a particular issuance for purposes of recording and disseminating end-of-day Security ownership balances on the Ethereum blockchain and records a list of each ''BSTX Participant or non-BSTX Participant broker-dealer address[ ]'' and the Tokens held at each address.[172] Pursuant to the proposed BSTX Protocol Summary Overview, the Asset Smart Contract includes the function ''Transfer,'' which allows for the transfer of Tokens to other specified, allowlisted addresses, and requires two parameters: The receiver address and the amount of Tokens being sent.[173] Also, one of the Asset Smart Contract's events, which generates a record on the Ethereum blockchain that is publicly viewable, will be ''Transfer.'' According to the proposed BSTX Protocol Summary Overview, this event records the details of the movement of the digital Token representation of a BSTX-listed Security from one address to another, as recorded in the ledger of the Asset Smart Contract.[174]

With respect to the role of Wallet Managers under the proposal, in the context of SR–BOX–2019–19, one commenter stated that further clarification is warranted for, among other things, ''rules regarding 'Wallet Managers.' '' [175] This commenter also stated that it is unclear ''why a 'Wallet Manager' would improve rather than complicate current market structure.'' [176] Another commenter stated that the Exchange should address why BSTX will act as an intermediary between BSTX Participants and Wallet Managers in the reporting of end-of-day Security ownership balances instead of

[161] *See* OIP, *supra* note 7, 85 FR at 51259, n.76. The Exchange gives as an example that if there were only two transactions in the entire marketplace during the trading day—a sale of 100 Securities from BSTX Participant A to BSTX Participant B and a subsequent sale of 100 Securities from BSTX Participant B to BSTX Participant C—the end-of-day reallocation process would result in a reallocation of 100 Tokens from BSTX Participant A to BSTX Participant C, and would consequently not reflect any actual transactions. *See id.*

[162] *See* OIP, *supra* note 7, 85 FR at 51255. The Exchange states that the BSTX Protocol would require a BSTX-listed company to use three related smart contracts as follows: (1) The ''Asset Smart Contract'' would define and establish the ''Tokens,'' such as setting the maximum number of Tokens available for a particular issuance, and record a list of market participant wallet addresses and the Tokens associated with each address; (2) the ''Registry Smart Contract'' would define the permissions available to different types of market participants to perform certain functions and contain the list of allowlisted wallet addresses and additional information associated with each address; and (3) the ''Compliance Smart Contract'' would contain a set of rules that could be configured to abide by and ensure compliance with applicable laws and regulations, such as by restricting a movement of Securities to a wallet address that has not been added to the Registry Smart Contract. *See* OIP, *supra* note 7, 85 FR at 51256–57.

[163] *See* OIP, *supra* note 7, 85 FR at 51253. According to the Exchange, all offerings of securities that are intended to be listed as Securities on BSTX would be conducted in the same general manner as offerings of exchange-listed equity securities are conducted today under the federal securities laws. *See id.* The Exchange states that an issuer would enter into a firm commitment or best efforts underwriting agreement with a sole underwriter or underwriting syndicate, the underwriter or underwriters would market the securities and distribute them to purchasers, and secondary trading in the securities (that are intended to trade on BSTX as Securities) would thereafter commence on BSTX. *See id.*

[164] *See* OIP, *supra* note 7, 85 FR at 51261. *See also supra* note 60 and accompanying text (discussing the Exchange's assertions regarding what would be publicly available on Etherscan.io).

[165] *See* OIP, *supra* note 7, 85 FR at 51255. The Exchange states that in the context of Tokens representing Securities and the ability to query a particular address to determine the quantity of Tokens that belong to that address, the term ''address'' refers to a number that is associated with a particular market participant that can be updated to ''reflect changes in ownership of tokenized assets.'' *See* OIP, *supra* note 7, 85 FR at 51256, ns.49–50 and accompanying text.

[166] *See* OIP, *supra* note 7, 85 FR at 51256.

[167] *See id.*

[168] *See* OIP, *supra* note 7, 85 FR at 51256, n.54. *See supra* Section III.B.1 (discussing the Exchange's use of the term ''ancillary'').

[169] *See* OIP, *supra* note 7, 85 FR at 51283.

[170] *See* OIP, *supra* note 7, 85 FR at 51286. The Exchange filed the BSTX Protocol Summary Overview as Exhibit 3N. *See supra* note 92.

[171] *See* BSTX Protocol Summary Overview, *supra* note 92, at 344; OIP, *supra* note 7, 85 FR at 51256. The Exchange states that the Asset Smart Contract defines and creates the Tokens (*e.g.,* the maximum number of Tokens available for a particular issuance) for purposes of the Ethereum blockchain ancillary recordkeeping function and records a list of each BSTX Participant or non-BSTX Participant broker-dealer addresses and the Tokens held at each address. *See* BSTX Protocol Summary Overview, *supra* note 92, at 344; OIP, *supra* note 7, 85 FR at 51255. The Exchange also states that the smart contracts of a Security cannot run on their own, but rather lie dormant until a transaction triggers them to carry out a specified operation, and that a ''transaction'' in this context is an operation triggering a smart contract to carry out its specified function, which must ultimately originate from a human source. *See* BSTX Protocol Summary Overview, *supra* note 92, at 342; OIP, *supra* note 7, 85 FR at 51256.

[172] *See* BSTX Protocol Summary Overview, *supra* note 92, at 344.

[173] *See id.* at 346.

[174] *See id.* at 347.

[175] *See* Letter from David A. Schrader, Partner, Paykin Krieg & Adams, LLP (February 25, 2020) (''PKA Law Letter''), at 1.

[176] PKA Law Letter, *supra* note 175, at 1–2.

allowing direct reporting from BSTX Participants to Wallet Managers.[177]

In response, the Exchange contended in the context of SR–BOX–2019–19 that it added more information regarding Wallet Managers in Amendment No. 2, and reiterated its discussion from the proposal without further elaboration.[178] The Exchange also stated that the Exchange has determined to have BSTX act as an intermediary between BSTX Participants and Wallet Managers ''for several reasons,'' including that the Exchange contends that it is less burdensome for a BSTX Participant to report to BSTX rather than establish a new relationship with a Wallet Manager.[179] The Exchange stated that it may consider other models in the future, which would be subject to the rule filing requirements of Section 19 of the Exchange Act.[180]

(b) Analysis

The Commission believes that the Exchange's proposed rules for using third-party service providers to act as Wallet Managers to perform the function of recording and updating Security ownership balance information on the Ethereum blockchain lacks clarity, and agrees with commenters that further clarification is warranted with respect to Wallet Managers.[181] This lack of clarity prevents the Commission from assessing whether the publicly available information about end-of-day Security ownership balances on the Ethereum blockchain will be inaccurate and misleading, and therefore whether the proposal would be consistent with the protection of investors and the public interest pursuant to Section 6(b)(5) of the Exchange Act, and how the Exchange would enforce compliance with its own rules, pursuant to Section 6(b)(1) of the Exchange Act. The areas needing clarification include how Wallet Managers will update BSTX Participants' account balances and how the smart contracts will be triggered to effectuate changes in the end-of-day ownership balances that are recorded using Tokens on the Ethereum blockchain. In addition, as described further below, the Wallet Manager's process of updating end-of-day Security ownership balances on the Ethereum blockchain will result in transfers between wallet addresses being publicly visible on the Ethereum blockchain, where these transfers may reflect the Wallet Manager's reallocation process but not correspond to actual transactions between the particular Securities holders associated with those specific wallet addresses.

While the Exchange states that it would provide end-of-day Security ownership balances to Wallet Mangers to update the Ethereum blockchain, neither the proposed rules nor the Exchange's description in the proposal explain how the balances will be updated by the Wallet Managers, including what procedures the Wallet Manger must follow to update the account balances of BSTX Participants on the blockchain. Among other things, the Exchange does not describe in its proposal many aspects of the proposed BSTX Protocol Summary Overview, such as the ''Transfer'' function and the ''Transfer'' event aspects of the Asset Smart Contract component of the protocol set forth in the BSTX Protocol Summary Overview, including what would be ''publicly viewable'' as a result. Additionally, the Exchange does not explain how the Asset Smart Contract, Registry Smart Contract, and Compliance Smart Contract interact, and what roles and authorities BSTX, the Exchange, the Wallet Manager or Wallet Managers, or other market participants would have with respect to each of the smart contracts, and whether and how those roles or authorities may change over time. For example, while the Exchange states that the process of reallocating Token balances among different wallet addresses is a function that will be performed by the Exchange ''in coordination with the Wallet Manager(s),'' [182] the Exchange does not specify when the Exchange will direct the Wallet Manager, and when the Wallet Manager will act according to its discretion. Furthermore, the proposed BSTX Protocol Summary Overview states that the Asset Smart Contract will record a list of each non-BSTX Participant broker-dealer wallet address and the Tokens held at each wallet address; however, non-BSTX Participants are neither required to, nor may they voluntarily, report their end-of-day Security ownership balances to the Exchange for recording to the Ethereum blockchain.[183]

As discussed above, the proposal is unclear as to what information will be publicly observable on the Ethereum blockchain, including what details beyond the wallet addresses of holders of Securities and associated quantities may be observable, but the Exchange has indicated that such information may include transfers made as a result of the Wallet Manager's reallocation process.[184] Given that BSTX Participants will not report individual transactions and will only update their end-of-day Security ownership balances at the end of each trading day, it is unclear how a transfer would work and whether issues could arise that might prevent the Wallet Manager from allocating the same number of Tokens representing Securities to a BSTX Participant's wallet address as the number of Securities that the BSTX Participant reports to the Exchange. The Commission believes that the proposal does not clearly address, for example, what the role of the Wallet Manager would be and the procedures the Wallet Manager would follow to reallocate the end-of-day balances if the total of the Security ownership balances reported were to exceed the total issuance.[185] Also, while the Exchange gives examples of what may be viewable as a result of a reallocation,[186] the Exchange does not describe whether the public would be able to view ''transfers'' between specific accounts for the purpose of reallocating Tokens to

[177] *See* IEX Letter, *supra* note 77, at 5.

[178] *See* BSTX Response Letter I, *supra* note 82, at 18. *See also* OIP, *supra* note 7, 85 FR at 51257–58.

[179] *See* BSTX Response Letter I, *supra* note 82, at 18. The Commission notes that the Exchange did not provide any other reasons in its response.

[180] *See id.*

[181] *See supra* notes 175–177 and accompanying text.

[182] *See infra* note 217. The Exchange states that the process of reallocating Token balances among different wallets addresses is a function performed by the Exchange in coordination with the Wallet Manager, and that the proposed use of blockchain technology is ''almost passive'' for BSTX Participants, but for obtaining a wallet address and the end-of-day reporting of balances. The Exchange also states that the Exchange would be responsible for maintaining wallet addresses for the entire life cycle of a Security and the associated Token and life cycle of participants' accounts. *See* OIP, *supra* note 7, 85 FR at 51257, n.58.

[183] *See supra* note 27 and accompanying text. The proposal also does not explain how the updating of the Ethereum blockchain will be achieved if there is a separate Wallet Manager used by another trading center, such as a national securities exchange trading Securities pursuant to UTP or an alternative trading center trading Securities OTC. *See infra* Section III.D for discussion about other trading centers' ability to trade BSTX-listed Securities.

[184] *See supra* note 60 and accompanying text. *See also supra* Section III.B.2.

[185] *See supra* note 69 and accompanying text (discussing the Exchange's assertion that the Ethereum blockchain may not reflect the precise distribution of Securities among holders and the possibility that the number of reported Securities may exceed the number of outstanding Securities of a particular issuance) and *infra* note 253 and accompanying text (discussing the lack of clarity around whether in the case of over-reporting of an end-of-day ownership balance by a BSTX Participant to BSTX the Exchange would suspend the end-of-day reporting process or whether the Exchange would handle allocations in such a circumstance some other way). *See also supra* note 128 (providing an example of the possibility of over-reporting by a BSTX Participant) and note 172 and accompanying text (discussing how the Smart Contract will, among other things, define and create the maximum number of Tokens available for a particular issuance).

[186] *See supra* note 161.

achieve the updated end-of-day balances associated with each wallet address. The lack of clarity concerning how the Wallet Manager would update the Ethereum blockchain, and what information may be available on the Ethereum blockchain that is generated by the Wallet Manager's actions, is an additional aspect that contributes to the Commission's concerns regarding the public dissemination of inaccurate or misleading information and inhibits the Commission's ability to find that the information to be recorded to the blockchain pursuant to the proposal is consistent with the protection of investors and the public interest. For example, if the publicly available information indicates that transactions have occurred between the holders of certain wallet addresses, when instead the Wallet Manager reallocated Securities from one wallet address to another wallet address to arrive at the reported end-of-day Security ownership balances without regard to what underlying transactions occurred, this would result in the appearance of false transactions, seriously risk misleading investors, and potentially affect investors' investment decisions.[187] Other market participants, such as BSTX Participants, could similarly be confused if, for example, the publicly disseminated information indicates Securities being reallocated between their wallet address and only one other wallet address, if in actuality their new balance is attributable to transactions with multiple counterparties.

The Commission cannot conclude that the proposal is consistent with the protection of investors and the public interest because the Exchange has failed to sufficiently describe both the process for Wallet Managers to produce updates in end-of-day ownership balances to the Ethereum blockchain and the public information resulting from these updates. In the absence of clarification about these processes and the resulting public information, the Commission cannot assess the extent to which the information on the Ethereum blockchain may be inaccurate or misleading, and therefore whether the dissemination of that information would be consistent with the protection of investors and the public interest.[188] For these reasons, the Commission finds that the Exchange has not met its burden to demonstrate that the Exchange's proposed rules would protect investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act.

Further, the proposal lacks information regarding the roles and authorities BSTX, the Exchange, the Wallet Manager or Wallet Managers, or other market participants would have with respect to smart contracts, as well as the possibility that these roles or authorities may change over time. Without such information, the Commission cannot assess how the Exchange would, consistent with Section 6(b)(1) of the Exchange Act, ensure compliance by the Exchange with its own rules requiring BSTX to provide end-of-day Security balance information to the Wallet Manager or Wallet Managers, and the updating of the blockchain by the Wallet Manager or Wallet Managers to reflect the end-of-day balance information reported to BSTX by BSTX Participants.

Allowlisting and End-of-Day Reporting

(a) Exchange's Representations and Comments Received

According to the Exchange, a BSTX Participant must obtain an allowlisted wallet address and report certain end-of-day Security ownership balance information to BSTX.[189] Specifically, proposed BSTX Rule 17020(a) states that each BSTX Participant, either directly or through its carrying firm acting on its behalf, must contact BSTX to establish a wallet address to which its end-of-day Security balances may be recorded. Furthermore, a BSTX Participant must obtain this wallet address within five business days after the Exchange approves its application.[190] The Exchange states that the process of obtaining a wallet address will generally occur contemporaneously with the application to become a BSTX Participant, but states that if a BSTX Participant is unable to obtain a wallet address within the five day period, the BSTX Participant's end-of-day Security ownership balances would be attributed to the omnibus wallet address until the BSTX Participant obtains a wallet address.[191] The Exchange proposes not to require a BSTX Participant to have a separate wallet address for each Security issuance that it trades, because multiple Security issuances can be attributed to a BSTX Participant's wallet address.[192] The Exchange states that the requirement for BSTX Participants to obtain a wallet address is not discriminatory because all BSTX Participants must do so, and the Exchange will not propose to charge a fee for obtaining a wallet address.[193] Finally, the Exchange states that once the Exchange assigns a BSTX Participant a wallet address, the only further obligation of the BSTX Participant is to report its end-of-day Security ownership balances to BSTX.[194]

In the proposal, the Exchange describes the process for BSTX Participants reporting end-of-day Security ownership balances. The Exchange proposes to require each BSTX Participant, either directly or through its carrying firm, to report each business day to BSTX, in a manner and form acceptable to BSTX, the total number of Securities for each class of Security credited to either the BSTX Participant's DTC account or the BSTX Participant by its carrying firm.[195] The Exchange states that it would require BSTX Participants to provide the end-of-day Security ownership balance report to the Exchange each business day when DTC is open for business after such time as DTC has completed its end-of-day settlement process.[196] The Exchange represents that DTC typically makes end-of-day security position reports available to participants at approximately 7:30 p.m. Eastern time, and that it would notify BSTX Participants, via Regulatory Circular, of

[187] *See supra* note 161 discussing the Exchange's examples regarding how reallocations would be effectuated.

[188] While the Exchange asserts that its listed criteria for evaluating potential Wallet Managers may prevent fraudulent and manipulative acts and practices, consistent with Section 6(b)(5) of the Exchange Act (*see supra* note 157), it does not provide a basis for this assertion and therefore the Commission cannot determine whether it agrees with this conclusion.

[189] *See* OIP, *supra* note 7, 85 FR at 51256–57. According to the Exchange, an allowlisted wallet address is a permissioned wallet address associated with a market participant to which end-of-day Security ownership balances may be recorded. *See id.*

[190] *See* proposed BSTX Rule 17020(a).

[191] *See* OIP, *supra* note 7, 85 FR at 51257. The Exchange likens the requirement for BSTX Participants to obtain a wallet address to that of other exchanges requiring a market participant identifier (MPID), because it is establishing an identifier that can be attributed to a particular BSTX Participant for reporting requirements. *See id.*

[192] *See* OIP, *supra* note 7, 85 FR at 51257, n.59. In the context of SR–BOX–2019–19, in response to a commenter's question about whether the a BSTX Participant could use multiple wallets, (*see supra* note 94), the Exchange stated that, pursuant to proposed BSTX Rule 17020, BSTX Participants would be required to contact the Exchange as part of the allowlisting process, and the Exchange intends to discuss related operational issues with BSTX Participants as appropriate (*see supra* note 107 and accompanying text).

[193] *See* OIP, *supra* note 7, 85 FR at 51257.

[194] *See id.*

[195] *See* OIP, *supra* note 7, 85 FR at 51258. For BSTX Participants that are participants at DTC, the report to BSTX would consist of the total number of Securities for each class of Security that is credited to each DTC account of the BSTX Participant, and for those that are not participants at DTC, the report would consist of the total number of Securities that are credited to the BSTX Participant by its carrying firm. *See id.*

[196] *See* OIP, *supra* note 7, 85 FR at 51259. *See also* proposed BSTX Rule 17020(c).

the time after 7:30 p.m. Eastern time by which they must report end-of-day Security ownership balances to BSTX.[197] Furthermore, the Exchange represents that it would notify BSTX Participants of the precise manner in which Securities should be reported via a Regulatory Circular.[198] The Exchange states that, in general, the report would simply require certain identifying information regarding the BSTX Participant (*e.g.,* name, carrying firm, MPID) and a list of the end-of-day Security ownership balances of the BSTX Participant.[199] Furthermore, the Exchange states that BSTX Participants would be subject to potential disciplinary action for failing to comply with the requirement to report their end-of-day Security ownership balances.[200]

Once BSTX Participants have reported their end-of-day Security ownership balances to BSTX, BSTX would provide this information to the Wallet Manager (or Wallet Managers) to update the Ethereum blockchain with Security ownership balances.[201] Pursuant to proposed BSTX Rule 17020(d), the updates to the Ethereum blockchain would reflect updates in Security ownership balances in Token form.[202] The Exchange also represents that it would notify BSTX Participants via Regulatory Circular of the time by which BSTX would need to provide Security ownership balance information to the Wallet Manager so that the Wallet Manager would have sufficient time to update the Ethereum blockchain prior to the commencement of trading on BSTX the next trading day.[203] According to the Exchange, the result of the end-of-day Security ownership balance reporting requirement would be that the Ethereum blockchain, for each Security, would reflect the end-of-day ownership balance associated with each BSTX Participant's wallet address.[204] Furthermore, the Exchange states that the end-of-day Security balance reporting by BSTX Participants would ''reflect a relatively more robust use of the functionality of the smart contracts,'' than just the use of the omnibus wallet, and that ''[p]romoting this more robust use of the functionality of the smart contracts and their ability to allocate and re-allocate Security balances across multiple wallet addresses will enhance the ability of market participants, including the Exchange, to observe and evaluate the capabilities of blockchain technology as an ancillary recordkeeping mechanism.'' [205]

The Exchange asserts that imposing the end-of-day Security ownership balance reporting requirement on BSTX Participants would not be unfairly discriminatory or burden competition because all market participants would be free to choose whether or not to become a BSTX Participant.[206] The Exchange states that market participants that voluntarily choose to become BSTX Participants must comply with the rules of the Exchange, but remain free to become a member of another national securities exchange that supports trading of BSTX-listed Securities or to purchase BSTX-listed Securities OTC.[207]

In its notice of the proposal, the Exchange states that it currently functions as an exchange only for standardized options, and that equity securities would represent a new asset class for the Exchange.[208] According to the Exchange, in connection with the operation of BSTX, the Exchange would leverage many of the regulatory structures that it established to operate a national securities exchange in compliance with Section 6 of the Exchange Act.[209] The Exchange states that it will perform Security listing regulation, authorize BSTX Participants to trade on the BSTX System, and conduct surveillance of Security trading on the BSTX System.[210] In addition, the Exchange states that it will oversee the onboarding and application process for BSTX Participants and compliance by issuers of Securities with the applicable initial and continued listing requirements, including those pertaining to compliance with the BSTX Protocol.[211] As discussed in more detail above, the Exchange also proposes to address the potential for inaccurate reporting by BSTX Participants with proposed BSTX Rule 17020(e), which, among other things, provides that the Exchange may request additional information regarding applicable reports and balances from any BSTX Participant if the Exchange has reason to believe that reported Security balances may be inaccurate.[212]

With respect to the end-of-day reporting requirements, in the context of SR–BOX–2019–19, one commenter raised a concern that BSTX might place additional reporting requirements on market participants.[213] Another commenter questioned how a BSTX Participant would obtain an allowlisted address, how the permissioning would be determined for the allowlisted wallet, and who would control this permissioning.[214] This commenter also asked how allowlisting would be maintained for the entire life-cycle of a

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[197] *See* OIP, *supra* note 7, 85 FR at 51259. *See also* proposed BSTX Rule 17020(c).

[198] *See* OIP, *supra* note 7, 85 FR at 51261.

[199] *See id.* The Exchange likens the requirement of BSTX Participants to report end-of-day Security ownership balances to BSTX to other exchanges' ability to request that members or participants furnish to the exchange records pertaining to transactions executed on or through the exchange in a time and manner required by such exchange. *See id.*

[200] *See* OIP, *supra* note 7, 85 FR at 51262, n.95.

[201] *See* OIP, *supra* note 7, 85 FR at 51258–59. *See also* proposed BSTX Rule 17020(d).

[202] *See* proposed BSTX Rule 17020(d).

[203] *See* OIP, *supra* note 7, 85 FR at 51259.

[204] *See* OIP, *supra* note 7, 85 FR at 51261. As described in more detail above, the Exchange also states that as part of the end-of-day reporting process, the Exchange would provide information to the Wallet Manager(s) which would allow the Wallet Manager(s) to allocate Tokens (which represent Securities) among BSTX Participants consistent with their end-of-day Security balance reports, and to attribute the unreported Security balance for a given Security to an omnibus wallet address for each Security. *See* OIP, *supra* note 7, 85 FR at 51259. *See also supra* Sections III.B and III.C.1.

[205] OIP, *supra* note 7, 85 FR at 51261.

[206] *See* OIP, *supra* note 7, 85 FR at 51262, n.94.

[207] *See id.* The Exchange also asserts that the end-of-day Security ownership balance reporting process would not impose a substantial burden on BSTX Participants, because it would not require them to expend significant resources or time. *See id. See also* Letter from Lisa J. Fall, President, BOX Exchange LLC (September 17, 2020) (''BSTX Response Letter III''), at 5.

[208] *See* OIP, *supra* note 7, 85 FR at 51252. The Exchange also states that while BSTX may eventually support a wider variety of securities, subject to Commission approval, at the time that BSTX commences operations it would only support trading in Securities that are equity securities. *See id.*

[209] *See* OIP, *supra* note 7, 85 FR at 51286. The Exchange states that it will extend its Regulatory Services Agreement with FINRA to cover BSTX Participants and trading on the BSTX System, and this Regulatory Services Agreement will govern many aspects of the regulation and discipline of BSTX Participants, similar to how it functions for options regulation. *See id.* The Exchange also states that, as is the case with the Exchange's options trading platform, the Exchange will supervise FINRA and continue to bear ultimate regulatory responsibility for BSTX. *See id.* The Exchange further states that it plans to join the Plan for the Allocation of Regulatory Responsibilities Regarding Regulation NMS and may choose to join certain Rule 17d–2 agreements such as the agreement allocating responsibility for insider trading rules. *See id.*

[210] *See* OIP, *supra* note 7, 85 FR at 51286. The Exchange states that it will perform automated surveillance of trading on BSTX for the purpose of maintaining a fair and orderly market at all times and monitor BSTX to identify unusual trading patterns and determine whether particular trading activity requires further regulatory investigation by FINRA. *See id.* at 51286–87. The Exchange also states that it will oversee the process for determining and implementing trade halts, identifying and responding to unusual market conductions, and administering the process for identifying and remediating ''clearly erroneous trades.'' *See id.* at 51287.

[211] *See* OIP, *supra* note 7, 85 FR at 51287.

[212] *See supra* notes 116–126 and accompanying text. *See also* OIP, *supra* note 7, 85 FR at 51260; proposed BSTX Rule 17020(e).

[213] *See* PKA Law Letter, *supra* note 175, at 1.

[214] *See* SIFMA Letter II, *supra* note 110, at 5.

Security and for the life-cycle of participant accounts.[215]

The Exchange responds that it would be the only source for obtaining wallet addresses and that the Exchange would be responsible for permissioning wallet addresses.[216] According to the Exchange, a BSTX Participant would not have the ability to move Tokens to or from its wallet address or otherwise ''control'' the wallet address, and the process of reallocating Token balances among different wallet addresses would be a function performed by the Exchange in coordination with a Wallet Manager.[217] The Exchange states that the use of the blockchain technology would be ''almost entirely passive'' for the BSTX Participants, excluding the obtaining of a wallet address and the end-of-day reporting of ownership balances.[218] Lastly, the Exchange responds that the Exchange would be responsible for maintenance of allowlisting for the entire life-cycle of the allowlisted wallet address and that an unlimited number of wallet addresses may be established for a Security and could be removed as necessary.[219]

A commenter asserted, in the context of SR–BOX–2019–19, that the proposed rule change did not explore in sufficient detail the costs or other impacts to firms associated with adopting systems to accommodate the infrastructure needed to manage the Securities' distributed ledger technology, including allowlisted wallet addresses and associated recordkeeping.[220] This commenter stated that although the Exchange suggests that firms could avoid these impacts by not becoming BSTX Participants, that would not be the case if the Securities start trading on other exchanges pursuant to UTP.[221] This commenter further stated that, in that scenario, firms would likely need to implement systems and other infrastructure to be able to submit reports of end-of-day Security ownership balances to the Exchange, assuming they determine that they need to become BSTX Participants.[222] In the context of SR–BOX–2020–14, this commenter noted its prior comment that if exchanges were to adopt different forms of distributed ledger technology to track ownership of equity securities, that could cause additional costs to market participants.[223]

Also in the context of SR–BOX–2020–14, this commenter noted that certain firms, by virtue of their business (such as order consolidation), may need to become BSTX Participants.[224] This commenter also stated that as a result of the Order Protection Rule under Regulation NMS,[225] trading centers such as OTC market makers and firms that internalize order flow may need to become BSTX Participants to satisfy their firms' policies and procedures reasonably designed to prevent trade-throughs. This commenter stated that firms in these lines of business would take on additional burdens if subject to the end-of-day Security ownership balance reporting obligations or potentially be subject to regulatory exposure from BSTX if they err in reporting end-of-day ownership balances.[226] This commenter stated that although the Exchange asserts, in response to its concerns, that the end-of-day Security ownership balance reporting obligations are no different than other reporting obligations imposed on firms, such as the large options positions reporting requirements adopted by the options exchanges and FINRA that obligate firms to report large options positions at the end of the day to the exchanges and FINRA, the end-of-day Security ownership balance reporting obligation is not related to any regulatory objectives.[227]

The Exchange states that, to the extent any market participant does not want to perform the end-of-day Security ownership reporting obligations, it could avoid these obligations by choosing not to become a BSTX Participant.[228] The Exchange also states that a BSTX Participant would only need to obtain a wallet address from the Exchange and comply with the end-of-day Security ownership balance reporting requirement.[229] According to the Exchange, the proposal would not require BSTX Participants to make a technological investment related to the use of distributed ledger technology,[230] and the Exchange does not propose any fees associated with the end-of-day Security ownership balance recordkeeping process.[231] In the context of SR–BOX–2019–19, the Exchange stated, however, that BSTX Participants would likely need to include in their policies and procedures a process for complying with the end-of-day Security ownership balance reporting requirement to promote compliance with the proposed BSTX rules.[232]

The Exchange also responded that no market participant would be forced to

[215] *See* SIFMA Letter II, *supra* note 110, at 5.

[216] *See* OIP, *supra* note 7, 85 FR at 51256–57, n.58. *See also* BSTX Response Letter II, *supra* note 105, at 5.

[217] *See* OIP, *supra* note 7, 85 FR at 51256–57, n.58. *See also* BSTX Response Letter II, *supra* note 105, at 5.

[218] *See* OIP, *supra* note 7, 85 FR at 51256–57, n.58. *See also* BSTX Response Letter II, *supra* note 105, at 5.

[219] *See* OIP, *supra* note 7, 85 FR at 51256–57, n.58. *See also* BSTX Response Letter II, *supra* note 105, at 5.

[220] *See* SIFMA Letter II, *supra* note 110, at 3. In the context of SR–BOX–2020–14, this commenter stated that it continues to believe that the Proposal contains novel aspects related to the current recordkeeping processes for equity securities that are potentially inconsistent with the Exchange Act, and that it continues to have some concerns about the proposal's ''ancillary'' recordkeeping requirements. *See* Letter from Ellen Greene, Managing Director, Equities & Options Market Structure, & Thomas F. Price, Managing Director, Operations, Technology, Cyber & BCP, Securities Industry and Financial Markets Association (September 10, 2020) (''SIFMA Letter IV''), at 3. This commenter also noted its previously stated concerns, citing its comments in the context of SR–BOX–2019–19. *See id.* at 4.

[221] *See* SIFMA Letter II, *supra* note 110, at 3.

[222] *See* SIFMA Letter II, *supra* note 110, at 3.

[223] *See* SIFMA Letter IV, *supra* note 220, at 4 (citing SIFMA Letter III).

[224] *See* SIFMA Letter IV, *supra* note 220, at 4–5. This commenter stated that, for example, order consolidators for other firms may need to become BSTX Participants if customers of those other firms trade BSTX-listed Securities. *See* SIFMA Letter IV, *supra* note 220, at 5.

[225] Rule 611 of Regulation NMS under the Exchange Act is also known as the ''Order Protection Rule'' or ''Trade-through Rule,'' and requires a trading center to implement policies and procedures that are reasonably designed to prevent trade-throughs on that trading center of protected quotations in NMS stocks that do not fall within one of certain specified exceptions. *See* 17 CFR 242.611.

[226] *See* SIFMA Letter IV, *supra* note 220, at 5. This commenter also stated that it is unclear from the Proposal whether a firm that is a member of other exchanges and is also a BSTX Participant would be subject to the end-of-day Security ownership balance reporting obligation in connection with effecting or clearing trades in Securities that are trading on other exchanges pursuant to UTP. *See id.*

[227] *See id.* This commenter stated that it has concerns when new processes and technology with wider implications for the equity market infrastructure are considered in the framework of a proposed rule change by a single exchange. *See* SIFMA Letter IV, *supra* note 220, at 5–6.

[228] *See* OIP, *supra* note 7, 85 FR at 51263.

[229] *See* OIP, *supra* note 7, 85 FR at 51263, n.106. Additionally, with respect to the ability of market participants to trade Securities OTC, the Exchange states its belief that the additional requirements of acquiring a wallet address and end-of-day Security balance reporting impose only a minimal burden on BSTX Participants and should not have any material or undue burden or impact on competition between BSTX Participants and non-BSTX Participants. *See* OIP, *supra* note 7, 85 FR at 51289. In response to comments in the context of SR–BOX–2019–19, the Exchange also stated that the end-of-day Security ownership balance reporting process would impose only a ''minimal'' reporting burden on BSTX Participants that would be similar to other reporting obligations currently required by SROs, such as large options position reporting. *See* BSTX Response Letter II, *supra* note 105, at 3. *See also* OIP, *supra* note 7, 85 FR at 51288 (analogizing the end-of-day reporting requirement to reporting of end-of-day large options position reporting); and *infra* note 347 (discussing the purpose of large options position reporting).

[230] *See* OIP, *supra* note 7, 85 FR at 51263, n.105.

[231] *See* OIP, *supra* note 7, 85 FR at 51287.

[232] *See* BSTX Response Letter II, *supra* note 105, at 3, n.13.

become a BSTX Participant as a result of the proposal, including if operating as a carrying firm or order consolidator; that the only potential circumstance in which a firm would be required to execute a trade in a Security on BSTX would be to comply with the Order Protection Rule, if the firm wanted to trade through on an away market a protected quotation on BSTX; and that even then the firm could choose to execute the trade through a BSTX Participant instead of becoming a BSTX Participant.[233] The Exchange further responded that the Exchange has addressed in the Proposal the issue of whether a market participant that trades Securities on multiple exchanges would be subject to the end-of-day Security ownership balance reporting obligation in connection with effecting or clearing trades in Securities that are trading on another exchange, and that a BSTX Participant would be required to report its end-of-day balance in Securities at DTC (or at its carrying firm) in the relevant Security pursuant to proposed BSTX Rule 17020(b).[234] In addition, the Exchange responded that it disagrees with a commenter's assertion that the end-of-day Security ownership balance reporting obligation is not related to any regulatory objective, citing its assertion in the proposal that the requirement will allow market participants to observe and increase their familiarity with the capabilities and potential benefits of blockchain technology in a context that advances and protects the public's interest.[235]

Additionally, the Exchange responded that it maintains its views expressed in the Proposal, including that the Exchange does not believe that imposing the end-of-day Security ownership balance reporting requirements on BSTX Participants is unfairly discriminatory or burdens competition, and that the end-of-day Security ownership balance reporting process would not impose a substantial burden on BSTX Participants.[236] While the Exchange stated that it recognizes a commenter's assertion that the Proposal may require market participants that wish to become BSTX Participants to bear certain costs, the Exchange contends that it is incorrect that the costs related to the end-of-day Security ownership balance reporting obligation will be significant.[237] The Exchange also stated that the Proposal is not inconsistent with the Exchange Act, ''simply because market participants might not want to take on the additional operational processes and minimal costs associated with'' the end-of-day Security ownership balance reporting obligation.[238]

(b) Analysis

The Commission concludes that the Exchange's proposed rules concerning the process for obtaining an allowlisted wallet address and reporting end-of-day Security ownership balances does not contain sufficient detail about how BSTX Participants must satisfy their obligations. The Commission also does not believe that the Exchange has addressed commenters' concerns regarding the costs or other burdens that would be imposed on market participants as a result of the end-of-day Security ownership balance reporting process.

The Exchange does not provide support for its assertion that BSTX Participants would not need to expend significant resources or time on the end-of-day Security ownership balance reporting process.[239] The Exchange concedes that market participants will have to bear costs from the Proposal, and then characterizes those costs as ''minimal,'' [240] but the Commission finds no support for that characterization. The Exchange acknowledges that BSTX Participants may need to add to their policies and procedures a process to comply with the end-of-day Security ownership balance reporting requirement,[241] but does not discuss the potential outlines of that process. The Exchange states that BSTX Participants would not need to make a technological investment related to the distributed ledger technology,[242] but does not discuss whether BSTX Participants would need to update their systems to facilitate the reporting of end-of-day Security ownership balances.[243] The Exchange states that a commenter's assertion that market participants might not want to take on the additional operational processes and minimal costs associated with the end-of-day Security ownership balance reporting obligation does not make the proposal inconsistent with the Exchange Act.[244] But the Exchange has not clarified what those processes and costs may be and why, in light of the additional burden, the proposed end-of-day Security ownership reporting obligations are consistent with the Exchange Act.[245] Also, pursuant to proposed BSTX Rule 17020(e), a BSTX Participant would be required to send a corrected end-of-day Security balance report to the Exchange upon the BSTX Participant's discovery that it submitted an inaccurate end-of-day report that has not already been corrected or superseded.[246] Yet the Exchange does not explain whether BSTX Participants would be obligated to monitor the end-of-day Security ownership balances on the blockchain associated with their assigned wallet addresses and whether the Exchange would provide any process by which BSTX Participants could contest or rectify discrepancies between their reported end-of-day Security ownership balances and the balances attributed to their addresses as observable on the blockchain.

The Exchange asserts that the end-of-day Security balance reporting by BSTX Participants and recording to the Ethereum blockchain will allow market participants to observe and increase their familiarity with the capabilities and potential benefits of blockchain technology in a context that advances and protects the public's interest,[247] but the fact that the information on the blockchain will not be accurate undercuts the benefit. Moreover, the

[233] *See* BSTX Response Letter III, *supra* note 207, at 2–3. The Exchange stated that a routing broker that chooses to become a BSTX Participant would be acting on an agency basis and would not have an end-of-day balance in Securities arising from this function, and that accordingly, reporting a zero end-of-day balance to the Exchange would not be burdensome. *See id.*

[234] *See id.*

[235] *See* BSTX Response Letter III, *supra* note 207, at 4. *See also infra* notes 330–331 and accompanying text.

[236] *See* BSTX Response Letter III, *supra* note 207, at 5–6. *See also supra* note 206.

[237] *See* BSTX Response Letter III, *supra* note 207, at 6.

[238] *Id.*

[239] *See supra* note 207.

[240] *Id.*

[241] *See supra* note 232 and accompanying text.

[242] *See supra* note 230 and accompanying text.

[243] *See supra* note 222 and accompanying text (commenter stating that firms would likely need to implement systems and other infrastructure to be able to submit reports of end-of-day Security ownership balances to the Exchange).

[244] *See supra* note 238 and accompanying text.

[245] The Exchange asserts that market participants can decide voluntarily whether to become a BSTX Participant (*see supra* notes 206–207 and accompanying text), and although the Exchange recognizes that a firm may need to execute a trade on BSTX to comply with the Order Protection Rule if BSTX is the protected quote, it further states that the firm could choose to execute the trade through a BSTX Participant instead of becoming a BSTX Participant. *See supra* note 233 and accompanying text. And a firm could also choose not to execute a trade that would trade through a protected quote on BSTX. However, the Exchange does not examine whether there may be additional factors for broker-dealer firms, including compliance with best-execution requirements, that might influence whether a broker-dealer firm decides to become a BSTX Participant. Also, as one commenter recognized, whether BSTX-listed Securities traded on other national securities exchanges pursuant to UTP may influence whether a broker-dealer firm would need to become a BSTX Participant. *See supra* notes 224–225 and accompanying text.

[246] *See supra* note 116 and accompanying text (discussing proposed BSTX Rule 17020(e)).

[247] *See supra* note 235 and accompanying text.

Exchange asserts that the balance information that will be publicly observable on the Ethereum blockchain would not be useful to inform a market participant's trading in Securities.[248] BOX does not explain how knowingly recording and disseminating to the public inaccurate information regarding BSTX Securities ownership on the blockchain is consistent with the purposes of the Exchange Act, or even with BOX's stated purposes of the proposed rule change.[249]

The Exchange also does not propose a standard for how the Exchange will determine what to include and remove from the omnibus account, beyond stating that the omnibus account will comprise the unreported Security balance for a given Security.[250] While the Exchange states that the Security ownership balance that it would allocate to the omnibus account would account for instances in which a BSTX Participant fails to report its end-of-day Security ownership balance or inaccurately reports such balance, and for the positions of Security holders that are not BSTX Participants,[251] the Exchange has not described how it will determine when a BSTX Participant's report is late or inaccurate, other than stating that it will provide additional information about the time, after 7:30 p.m. Eastern time, by which reports are due.

The Exchange also acknowledges that it is possible that, due to inaccurate reporting, the total of the Security ownership balances reported to BSTX could exceed the number of Securities actually issued,[252] but does not explain, given that it is not possible to over-allocate Token balances on the blockchain, how the Exchange would then determine how to allocate balances to wallet addresses.[253] For example, the Exchange does not address whether, in the case of over-reporting by BSTX Participants, it might assign a negative balance to the omnibus wallet address or take some other action. And the proposal does not indicate whether, if the BSTX Participants' wallet addresses account for the full balance of the Securities, the wallet address associated with the omnibus account would appear on the Ethereum blockchain with a balance of zero or the wallet address for the omnibus account would be omitted. This lack of information about how the Exchange will carry out its functions with respect to determining the Security balance to be associated with the omnibus account for a particular Security would impede the Commission from being able to carry out its obligations to ensure that the Exchange is complying with its own rules.

Further, the Commission concludes that the record does not demonstrate that the Exchange's proposed use of surveillance will enable the Exchange to carry out its necessary functions or enforce BSTX Participants' compliance with its rules. Specifically, while the Exchange states that it will extend its Regulatory Services Agreement with FINRA to BSTX Participants and trading in the BSTX Market,[254] the record does not demonstrate how the Exchange will perform surveillance regarding and enforce the unique obligations that it would impose on BSTX Participants to obtain an allowlisted wallet address and report end-of-day-Security ownership balances, including whether or how it would surveil for or reconcile inaccurate reporting of these end-of-day Security ownership balances.[255] For example, as discussed above, in response to commenters' concerns regarding surveillance and enforcement of the end-of day-reporting requirement to ensure that BSTX Participants accurately report their Security ownership balances,[256] as well as how differences in reporting between the records maintained by the Exchange, DTC, and NSCC and the end-of-day Security ownership balances would be reconciled,[257] the Exchange stated that it could use its general authority under BSTX rules to request from a BSTX Participant records related to its business, which could include the reports provided by DTC to the BSTX Participant that the BSTX Participant used to report end-of-day Security ownership balance information to the Exchange.[258] As the Commission stated above, the record does not, however, demonstrate how the Exchange will perform surveillance for BSTX Participant compliance, particularly with respect to the end-of-day Security ownership balance reporting requirement, such as whether it would request such records from BSTX Participants on a routine basis or use alternative means to determine whether a BSTX Participant has accurately reported its end-of-day Security ownership balances, and how it might surveil for and correct against late reporting by BSTX Participants.[259]

For these reasons, the Exchange has not provided sufficient information for the Commission to be able to find that the Exchange's rules would facilitate transactions in securities, remove impediments to a free and open market and national market system, or protect investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act. In the absence of information about, among other things, when and how a BSTX participant must obtain an allowlisted wallet address and the associated costs, as well as the time and manner by which a BSTX Participant must submit end-of-day Security balances to BSTX and the costs to comply with the reporting obligation, the Commission cannot evaluate whether imposing a burden on BSTX Participants to obtain an allowlisted wallet address and report end-of-day Security balance information to BSTX is reasonable in light of the intended purpose for recording end-of-day balances on the Ethereum blockchain. Particularly given that BSTX

[248] *See supra* note 115 and accompanying text.

[249] *See supra* Section III.B.

[250] *See supra* note 135. Pursuant to proposed BSTX Rule 17020(d), the Exchange would determine any difference between the Security position balance(s) reported to BSTX regarding a Security and the number of shares outstanding for the Security, and provide that information to the Wallet Manager(s) for allocation to an omnibus wallet address for the Security. *See* proposed BSTX Rule 17020(d).

[251] *See supra* notes 56–57 and accompanying text. As described above, BSTX Participants would report their Security ownership balances at the end of each trading day and the Wallet Manager would reallocate Tokens (representing Securities) as needed to reflect the reported balances, without regard to whether these transfers correspond with actual transactions. *See supra* Section III.C.1. Therefore, if a BSTX Participant fails to report its end-of-day Security ownership balance or inaccurately reports such balance, and the Exchange allocates Securities owned by such BSTX Participant to the omnibus account, or if a BSTX Participant that previously failed to report or inaccurately reported subsequently reports its end-of-day Security ownership balance, the Wallet Manager's reallocation of Tokens to reflect reported balances may not include a transfer between the wallet addresses associated with that BSTX Participant and the omnibus account.

[252] *See supra* note 69 and accompanying text.

[253] The Commission notes that, while in the case of over-reporting by BSTX Participants in a particular Security, the Exchange would have the ability to use its discretion, pursuant to proposed BSTX Rule 17020(f), to suspend the requirements regarding reporting of end-of-day Security balances for that Security, the Exchange has not indicated that it would necessarily do so in such circumstances. *See supra* note 104 and accompanying text; *infra* Section III.C.3. *See also* BSTX Response Letter I, *supra* note 82, at 11.

[254] *See supra* note 209.

[255] *See supra* Section III.B for additional discussion about whether or how the Exchange would surveil the end-of-day Security ownership balance reporting.

[256] *See supra* notes 121–122 and accompanying text.

[257] *See supra* notes 123–124 and accompanying text.

[258] *See supra* notes 125–126 and accompanying text. Pursuant to proposed BSTX Rule 17020(e), the Exchange may also request additional information regarding the applicable reports and balances from any BSTX Participant, if the Exchange has reason to believe that Security balances reported by one or more BSTX Participants may be inaccurate. *See supra* note 117 and accompanying text.

[259] *See supra* Section III.B.2.

Participants would be subject to disciplinary action if they fail to comply with either obligation, the Commission is not able to find that the obligations to obtain a wallet address and to report end-of-day Security balances are consistent with the requirements of Exchange Act Section 6(b)(5), and, in particular, the requirement that the rules of a national securities exchange be designed to remove impediments to and perfect the mechanism of a free and open market and a national market system.

Also, due to the lack of information discussed above regarding, among other things, anticipated timeframe regarding when BSTX must provide the reported information to the Wallet Manager, the way in which balances are allocated to the omnibus account, and the Exchange's infrastructure to surveil and enforce compliance by BSTX Participants to accurately report end-of-day Security ownership balances, the Commission cannot assess whether the Exchange would be able to carry out its responsibilities and enforce compliance by BSTX Participants with their obligations. Therefore, the Commission is not able to find that the Exchange would be able to carry out its necessary functions or fulfill its obligations as an SRO to comply with its own rules, pursuant to Section 6(b)(1) of the Exchange Act.

Suspension of Allowlisting and End-of-Day Reporting Requirements

(a) Exchange's Representations

The Exchange states that, in addition to controls and mechanisms for ensuring the accuracy of reported records,[260] the Exchange may need to implement further measures in situations where the ability to update blockchain records may be affected by ''exogenous factors,'' for example a disruption to the website through which ownership balances may be observed (*i.e.,* Etherscan.io), to the Ethereum blockchain itself that prevents the updating of end-of-day balances, or to the architecture or functioning of a particular Security.[261] To account for these situations, the Exchange proposes that the Exchange would, in its discretion, be able to suspend the allowlisting and end-of-day reporting requirements regarding any BSTX Participant and/or regarding one or more Securities.[262] The Exchange also proposes that in the case of such a suspension, the Exchange would be required to provide prompt notice, including the reasons for the suspension, to BSTX Participants, and must also notify the Commission within two hours.[263] The Exchange proposes that the suspension may not continue for more than thirty days unless the Exchange submits a proposed rule change to the Commission seeking approval of the suspension, in which case the suspension may continue until the Commission approves or disapproves the proposed rule change.[264] The Exchange states its belief that the proposal to allow for suspension of the allowlisting and end-of-day reporting requirements may foster coordination with persons processing information with respect to Securities and is not designed to permit unfair discrimination, because it will allow the Exchange to suspend certain rule requirements in events where there may be difficulty coordinating or sharing pertinent information with BSTX Participants or Wallet Managers.[265] The Exchange also states that its proposed suspension provision is designed to apply to all market participants equally, and to provide notice to affected participants and regulators of BSTX, in order to allow such individuals and entities to coordinate with the Exchange and react to potential issues as deemed necessary.[266]

(b) Analysis

The Commission concludes that the Exchange's proposal, which would give the Exchange discretion to suspend the requirements for obtaining an allowlisted wallet address or the end-of-day reporting requirements, is insufficient to support a finding that the Exchange's proposed rules are consistent with the Exchange Act, and with Section 6(b)(5) in particular. The Exchange failed to propose in its suspension provision a standard for the Exchange to suspend the allowlisting and end-of-day ownership reporting requirements. Under the proposal, the Exchange appears to retain complete discretion to suspend the allowlisting and end-of-day ownership balance reporting requirements as to some BSTX Participants or Securities but not others. The Exchange also appears to have discretion to suspend its own reporting of information to Wallet Managers to in turn update the Ethereum blockchain. Absent a standard for determining the suspension of allowlisting and end-of-day ownership reporting that would mitigate against the Exchange differently treating BSTX Participants or classes of Securities, the Commission has concerns about the potential for unfair discrimination among brokers-dealers, and also among issuers.

While the Exchange states that the proposed suspension provision is designed to apply to all market participants equally, and has listed several examples of when it may be appropriate to suspend the allowlisting or end-of-day ownership balance reporting requirements, the proposal does not provide any specificity regarding when the Exchange would be required to suspend these requirements or any conditions that must be met to warrant suspension.[267] Furthermore, while the Exchange states that it will provide prompt notice to market participants in the case of a suspension, the proposal does not describe who at BSTX is empowered to make the decision to suspend or the standard that would be applied when deciding whether to suspend. Specific information regarding the extent of the Exchange's discretion and standards that it would apply in determining when to suspend the allowlisting and end-of-day ownership balance reporting requirements is necessary for the Commission to assess whether the Exchange's rules are not designed to permit unfair discrimination between issuers and between brokers or dealers,

[260] *See supra* notes 116–120 and accompanying text.

[261] *See* OIP, *supra* note 7, 85 FR at 51260 and n.81.

[262] *See* proposed BSTX Rule 17020(f). The Exchange states that suspension of the ancillary recordkeeping process would not impact trading in a Security and that trading and clearance and settlement of Securities can operate entirely independently from the ''ancillary'' recordkeeping process. *See* OIP, *supra* note 7, 85 FR at 51258, n.67.

[263] *See id.*

[264] *See id.*

[265] *See* OIP, *supra* note 7, 85 FR at 51260, n.86.

[266] *See id.*

[267] For example, while the Exchange states that it may use its suspension authority in the case of over-reporting of end-of-day Security ownership balances, it does not state, and the proposed rule does not require, that it would necessarily do so. *See supra* note 253. The Exchange also does not explain how it would mitigate any potential conflicts of interest that may impact its discretionary use of its suspension authority with respect to an Affiliate Security. The Exchange would define ''Affiliate Security'' as ''any security or Security issued by an Exchange Affiliate or any Exchange-listed option on any such security.'' *See* proposed BSTX Rule 26140(a)(2). The Exchange would define ''Exchange Affiliate'' as ''the Exchange and any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the Exchange, where 'control' means that the one entity possesses, directly or indirectly, voting control of the other entity either through ownership of capital stock or equity securities or through majority representation on the board of directors or other managements body of such entity.'' *See* proposed BSTX Rule 26140(a)(1). The Exchange would define ''Exchange'' to mean ''BOX Exchange LLC and its facilities.'' *See* proposed BSTX Rule 17000(a)(20).

consistent with the requirements of Section 6(b)(5).

Due to the proposal's failure to explain how the Exchange's broad discretion to suspend requirements related to end-of-day reporting, which is the cornerstone of the Security as an NMS stock, is consistent with the Exchange Act, the Commission cannot find that the Exchange's rules are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers, as required by Section 6(b)(5) of the Exchange Act.[268] Further, due to the lack of information regarding how the Exchange will determine whether to suspend the requirements for allowlisting and end-of-day reporting, the Commission is not able to find that the Exchange would be able to carry out its necessary functions, in accordance with Section 6(b)(1) of the Exchange Act.

4. Listed Companies

The proposal contains proposed rules concerning the listing of Securities, and the Exchange states that its proposed listing rules are substantially similar to the listing rules of another national securities exchange, with certain additions or modifications to the rules that are specific to the Exchange's market.[269] The Commission considers the proposed lack of fungibility between BSTX-listed Securities and other classes of securities of the same issuer, and concludes that the Exchange has not sufficiently addressed the potential implications on the trading of these securities and how these securities would trade in a manner consistent with the Exchange Act. In addition, the Commission considers the Exchange's proposed rules requiring that a Security comply and continue to comply with the BSTX Protocol, and concludes that the record does not demonstrate how the Exchange will apply these provisions in a manner that is consistent with the Exchange Act.[270]

(a) Fungibility of BSTX-Listed Securities

Exchange's Representations and Comments Received

The Exchange states that potential issuers on BSTX could include (1) new issuers that do not currently have any class of securities registered on a national securities exchange; and (2) issuers who currently have securities registered on another national securities exchange, and who are seeking registration of a separate class of equity securities for listing on BSTX.[271] The Exchange also states that BSTX does not intend for Securities listed on BSTX to be fungible with any other class of securities from the same issuer.[272]

In the context of SR–BOX–2019–19, one commenter questioned why a class of BSTX-listed Securities would not be fungible with any other class of securities from the same issuer.[273] This commenter also questioned what implications a lack of fungibility would have for the overall equity market infrastructure.[274] In response, the Exchange stated that Securities would not be fungible with another class of securities of the same issuer, because no class of an issuer's securities would be fungible with a separate class of its securities, and that it was not proposing any changes to the existing framework for different classes of securities.[275] The Exchange gave as an example that two classes of shares of the same issuer, each of which have different ticker symbols, different rights (such as different voting rights), and different dividend rates, would not, according to the Exchange, be fungible with one another.[276]

(b) Analysis

The Exchange asserts that its proposed use of blockchain technology to record and disseminate end-of-day Security ownership balances would operate separately from the existing market infrastructure and would not have an impact on the trading, clearing, or settlement of BSTX-listed Securities.[277] For the Commission to make a finding that the rules of the Exchange are designed to, among other things, prevent fraudulent and manipulative practices, it is important for the Exchange to comprehensively analyze the potential relationship between a Security listed on BSTX and another class of securities from the same issuer that is listed on another national securities exchange. The Exchange asserts that, while issuers who have a class of securities listed on another national securities exchange may issue a separate class of securities to list on BSTX, the Securities listed on BSTX would not be fungible with any other class of securities from the same issuer.[278] However, the proposal does not address whether BSTX would require that there be any differences in the rights and obligations associated with two classes of securities from the same issuer, only one of which is a Security listed on BSTX, other than that the BSTX-listed Security would have to have associated smart contracts that are compliant with the BSTX Protocol and adhere to the associated obligations relating to allowlisting and end-of-day reporting, which according to the Exchange would not impact trading, clearing or settling of BSTX-listed Securities.

Moreover, as discussed above, the Exchange would be able to suspend the allowlisting and end-of-day reporting requirements for Securities listed on BSTX without an articulated standard in its rules.[279] The Exchange does not address the possibility that, if the Exchange suspended these requirements with respect to a particular BSTX-listed Security, there might not be any difference in the rights and obligations associated with two classes of securities, or whether this lack of different characteristics would impact the fungibility of the classes. The Exchange also does not explain whether there might be possibilities for arbitrage between the two classes of securities of same issuer, if, due to a suspension of the allowlisting and end-of-day reporting requirements for the particular BSTX-listed Security, there are no remaining differences between the rights and obligations of the two classes of securities. Further, the Exchange does not explain whether a lack of remaining differences between the two classes of securities would impact trading in the securities. For example, in the instance the Exchange suspends allowlisting, which could occur at any time and for any reason as proposed under the Exchange's rules, the Exchange does not explain whether it anticipates the two classes of securities would trade at the

[268] Additionally, the Exchange has not addressed how it would mitigate any potential conflicts of interest that could arise if Affiliate Securities were listed and traded on BSTX or if a broker-dealer affiliate of BSTX or the Exchange were to trade Securities as a BSTX Participant or otherwise, which could impact the Exchange's determination to use its suspension authority.

[269] *See* OIP, *supra* note 7, 85 FR at 51277 (citing Parts 1–12 of the NYSE American LLC Company Guide).

[270] The Commission's conclusions that the Exchange has not demonstrated that its proposal is consistent with the Exchange Act focus on these two specific aspects of the Exchange's proposed listing rules. The Commission does not reach a conclusion about whether other aspects of the Exchange's proposed listing rules are consistent with the Exchange Act.

[271] *See* OIP, *supra* note 7, 85 FR at 51253.

[272] *See* OIP, *supra* note 7, 85 FR at 51253.

[273] *See* SIFMA Letter II, *supra* note 110, at 5.

[274] *See* SIFMA Letter II, *supra* note 110, at 5.

[275] *See* OIP, *supra* note 7, 85 FR at 51253, n.34. *See also* BSTX Response Letter II, *supra* note 105, at 4.

[276] *See* BSTX Response Letter II, *supra* note 105, at 4, n.22.

[277] *See infra* note 339 and accompanying text. For a discussion of other trading centers' ability to trade BSTX-listed Securities, see *infra* Section III.D.

[278] *See supra* notes 271–272, 275–276, and accompanying text.

[279] *See supra* Section III.C.3 for discussion about the Exchange's ability to suspend the allowlisting and end-of-day reporting requirements.

same or different prices and why there might be a discrepancy in prices. The lack of clarity about differences between multiple classes of securities of the same issuer, particularly where only one is a Security with an associated Token representation and that Token representation for a Security is suspended by the Exchange, and how this may impact the fungibility of the classes or how they trade, prevents the Commission from determining whether the relationship between the classes might create the potential for fraudulent or manipulative trading practices. Due to the Exchange's failure to explain whether or how its proposed use of blockchain technology to record and disseminate end-of-day Security ownership balances could impact trading of the BSTX-listed Securities, the Commission cannot find that the Exchange's rules would prevent fraudulent and manipulative acts and practices, promote just and equitable principles of trade, remove impediments to a free and open market and national market system, or protect investors and the public interest, in accordance with Section 6(b)(5) of the Exchange Act.

(b) Compliance With BSTX Protocol

(1) Exchange's Representations

Proposed BSTX Rule 26230 would provide listing requirements relating to the architecture of a Security's associated smart contract that an issuer must satisfy to list and remain listed on the Exchange. The Exchange states that all listed companies' Securities must comply with the BSTX Protocol to ensure that all Securities are governed by the same set of specifications and controls that allow for their ownership to be recorded on the Ethereum blockchain using Tokens as an ''ancillary'' recordkeeping mechanism.[280] Prior to approving a Security for trading on the Exchange, the Exchange would conduct an audit of the Security's smart contract architecture to ensure compliance with the BSTX Protocol.[281] The Exchange states that the purpose of this initial listing requirement is to ensure that the design and structure of a prospective BSTX-listed company's Security smart contract is compatible with the BSTX Protocol, for purposes of facilitating updates to the blockchain as an ancillary recordkeeping mechanism.[282] The Exchange states that it may use third party service providers that have demonstrated sufficient technical expertise in blockchain technology and an understanding of the BSTX Protocol to conduct this audit on behalf of the Exchange.[283]

After being listed on the Exchange, as a continued listing requirement, a BSTX-listed company would remain responsible for ensuring that its Security smart contract remains compatible with the BSTX Protocol and accurately reflects the number of shares outstanding.[284] The Exchange states that it recognizes that there may be circumstances in which it becomes necessary to modify certain aspects of the smart contract corresponding to the Security.[285] The Exchange adds that, for example, in the case of a stock split, a BSTX-listed company may need to increase the total supply of Securities as programmed into its Security smart contract.[286] Under the proposal, the BSTX-listed company would be required to provide notice to the Exchange at least five days prior to implementing any modification that it would make to a smart contract corresponding to a Security (*e.g.,* to increase the total supply), to allow the Exchange to audit the proposed modification.[287] If additional time is needed to implement the modification, the Exchange would be able to exercise its authority to suspend the ancillary recordkeeping process relating to that Security pursuant to proposed BSTX Rule 17020(f).[288]

The Exchange asserts that the primary circumstances under which a modification to a smart contract corresponding to a Security may be necessary would be where there is a change to the total supply of the Security, which could occur in the case of a stock split, a reverse stock split, a buy-back, or a dividend in kind.[289] The Exchange states that any delay in the implementation of a change to a smart contract that corresponds to a Security would not impact the record date or ex-dividend date for any dividend, distribution, or other action.[290] According to the Exchange, it believes that proposed BSTX Rule 26230 facilitates end-of-day Security ownership balance reporting for BSTX-listed Securities, and that this reporting is a first step towards the potential integration of blockchain technology to securities transactions.[291] The Exchange states that, without ensuring that BSTX-listed companies' Securities are compatible with the BSTX Protocol, the use of blockchain technology as an ancillary recordkeeping mechanism could be impaired.[292]

(2) Analysis

The record fails to explain clearly how the Exchange will implement its proposed continued listing requirement that smart contracts associated with BSTX-listed Securities must remain in compliance with the BSTX Protocol. The proposal contemplates circumstances in which the smart contracts associated with Securities would need to be changed due to corporate actions by the BSTX-listed company that would change the outstanding number of Securities.[293] However, the record does not contain any discussion about the impact on a BSTX-listed company's obligations under circumstances in which the Exchange initiates changes to the BSTX Protocol. In such circumstances, proposed BSTX Rule 26230(b) would require an issuer to make changes to the smart contract associated with its Security so that its Security remains compliant with the BSTX Protocol.[294] Yet the proposal does not contain any discussion about what policies and procedures the Exchange would use to evaluate the ability of BSTX-listed companies to respond to changes in the BSTX Protocol initiated by the Exchange or resulting from changes to the Ethereum blockchain itself and to ensure that the BSTX-listed company's Securities continue to meet this continued listing requirement under BSTX's proposed rules. The lack of procedures increases the risk of the Exchange unfairly discriminating between issuers.

In particular, the proposal does not address whether any protections would be in place to ensure that the BSTX-

[280] *See* OIP, *supra* note 7, 85 FR at 51256. *See also* proposed BSTX Rule 26138.

[281] *See* proposed BSTX Rule 26230(a). In addition, an applicant that was denied initial listing pursuant to this section would be able to appeal the decision via the process outlined in the proposed BSTX Rule 27200 Series. *See id.*

[282] *See* OIP, *supra* note 7, 85 FR at 51278.

[283] *See* OIP, *supra* note 7, 85 FR at 51278. The Exchange states that it expects that some issuers may choose to use an outside vendor to help build their Security smart contract in a manner that complies with the BSTX Protocol, and that it understands that there are numerous technology companies that offer this service. *See id.* at 51278, n.300.

[284] *See* proposed BSTX Rule 26230(b).

[285] *See* OIP, *supra* note 7, 85 FR at 51278.

[286] *See* OIP, *supra* note 7, 85 FR at 51278.

[287] *See* proposed BSTX Rule 26230(b).

[288] *See* proposed BSTX Rule 26230(b). *See supra* Section III.C.3 for a discussion of suspension of the end-of-day ownership balance reporting requirement.

[289] *See* OIP, *supra* note 7, 85 FR at 51278.

[290] *See* OIP, *supra* note 7, 85 FR at 51278–79.

[291] *See* OIP, *supra* note 7, 85 FR at 51279.

[292] *See* OIP, *supra* note 7, 85 FR at 51279.

[293] *See supra* notes 284–287, 289, and accompanying text.

[294] *See supra* note 284 and accompanying text.

listed company has adequate notice of changes to the BSTX Protocol and has the technical capability to make any changes necessary to its Security smart contract to maintain its Security in compliance with the BSTX Protocol. Although a BSTX-listed company may hire an external vendor prior to initial listing to help it build its smart contracts,[295] assessing capabilities to comply with the BSTX Protocol prior to listing, when an issuer can decide whether to undertake the work necessary to ensure that its smart contracts comply with the BSTX Protocol, presents different concerns than what is needed to make changes to maintain compliance with the BSTX Protocol after listing, when the failure to comply can lead to the delisting of a listed and actively-traded security. In addition, it is unclear how a fork in the Ethereum blockchain might impact the BSTX Protocol and the steps necessary for a BSTX-listed company to maintain compliance. Moreover, the proposed rule provision concerning the Exchange's audit of the architecture of a Security's associated smart contract prior to listing states explicitly that an applicant denied listing pursuant to that provision would be able to appeal that decision via the process outlined in the proposed BSTX Rule 27200 Series,[296] but the proposal does not set forth procedures for appeal of a decision by the Exchange that a Security has fallen outside of compliance with the BSTX Protocol. To the extent that the general procedures in the proposed BSTX Rule 27000 Series (Suspension and Delisting) would apply, the Exchange has not demonstrated that these procedures are adequate for technical determinations about compliance with the BSTX Protocol.

For the Commission to conclude that the proposal is not designed to, among other things, impose continued listing requirements on issuers in an arbitrary manner or permit unfair discrimination between issuers, it is important for the Exchange to provide sufficient explanation about how the Exchange will implement its continued listing requirement that a BSTX-listed Security remain compliant with the BSTX Protocol, and how issuers will be able to ensure that their listed Securities remain compliant. Due to the lack of such information, the Commission is unable to find that the proposal is designed to remove impediments to and perfect the mechanism of a free and open market and a national market system, and is not designed to permit unfair discrimination between issuers, as required under Section 6(b)(5) of the Exchange Act.

D. Whether BOX Has Sufficiently Explained the Burden the Proposal Would Place on Other National Securities Exchanges' Ability To Trade BSTX-Listed Securities and Met its Burden To Demonstrate That the Proposal Is Consistent With Section 6(b)(8) of the Exchange Act

The Commission examines below whether the Exchange has met its burden to demonstrate that its rules do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act, as required by Section 6(b)(8) of the Exchange Act. As discussed further below, the Exchange has not sufficiently explained the burden that the proposal would place on national securities exchanges to provide end-of-day reporting of Security ownership balances for their members. Moreover, the Exchange has not adequately addressed the potential burden on competition that would result from the Exchange's control over the end-of-day reporting process or the burden on other national securities exchanges that seek to either participate in the end-of-day reporting process of the Exchange or develop their own. Accordingly, the Commission does not have sufficient information to assess whether the burden on competition imposed by the proposed end-of-day reporting functionality is necessary or appropriate in furtherance of the Exchange Act, in accordance with Section 6(b)(8) of the Exchange Act.

1. Exchange's Representations and Comments Received

The Exchange states that the end-of-day Security ownership balance reporting by BSTX Participants and the public dissemination of the end-of-day Security ownership balances on the blockchain does not impact the ability of Securities to trade on other national securities exchanges or OTC.[297] The Exchange states that Securities would be eligible for trading on other national security exchanges that extend UTP to them, and therefore Securities would be able to trade on other national securities exchanges and OTC in the same manner as other NMS stocks.[298] Specifically, the Exchange states that because Securities would trade, clear, and settle in the same manner as other NMS stock, other national securities exchanges could extend UTP to BSTX-listed Securities that are NMS stock in accordance with Commission rules.[299] Additionally, the Exchange states that a national securities exchange that chooses to extend UTP to Securities could trade them without any end-of-day or blockchain reporting structure.[300] Furthermore, the Exchange states that, with regard to other national securities exchanges extending UTP to Securities, the Exchange does not believe that the proposed BSTX Rules would impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act.[301]

The Exchange states that there are many ways another national securities exchange could adopt its own end-of-day Security ownership balance reporting requirement. The Exchange also states that it cannot predict whether another exchange would want to adopt its own reporting requirement, and if it did, what model it would choose, and how or whether that model would interact with the Exchange's end-of-day Security ownership reporting structure.[302] Further, the Exchange states that it is not proposing any limitation that would prevent another national securities exchange from participating in the Exchange's end-of-day Security ownership balance reporting process or establishing its own alternative or complementary process, and that it is not proposing to limit another exchange's ability to establish a similar, different, or integrated reporting structure.[303] If another exchange

[295] *See supra* note 283.

[296] *See supra* note 281.

[297] *See* OIP, *supra* note 7, 85 FR at 51262.

[298] *See* OIP, *supra* note 7, 85 FR at 51262.

[299] *See* OIP, *supra* note 7, 85 FR at 51289.

[300] *See* OIP, *supra* note 7, 85 FR at 51263.

[301] *See* OIP, *supra* note 7, 85 FR at 51289. *See infra* notes 328–331 and accompanying text (discussing the Exchange's assertions concerning the benefits of the proposal).

[302] *See* OIP, *supra* note 7, 85 FR at 51262–63. The Exchange gives as examples of potential alternatives that another national securities exchange could employ: Collecting end-of-day Security ownership balance information from its members and then relaying that information to BSTX to deliver to a Wallet Manager for recording to the Ethereum blockchain; trading BSTX-listed Securities without any end-of-day reporting requirement; engaging its own version of a wallet manager to communicate with BSTX's Wallet Manager(s) to facilitate updates to the Ethereum blockchain; or designing its own reporting process and technology, with no nexus to the BSTX end-of-day Security balance reporting structure. *See* OIP, *supra* note 7, 85 FR at 51263. In the case of a national securities exchange that determined to relay balance information from its members to BSTX, the Exchange states that no development of blockchain technology, smart contract functionality, or other similar technology would be required, because an exchange that adopts such a reporting structure would be in a position similar to a BSTX Participant, in that it would simply deliver end-of-day Security balance information to BSTX (or a Wallet Manager). *See* OIP, *supra* note 7, 85 FR at 51263, n.103 and accompanying text.

[303] *See* OIP, *supra* note 7, 85 FR at 51263.

decides to trade Securities, but not to use blockchain technology to record end-of-day ownership balances reported by its members, the Exchange states that the other exchange's process would not be able to leverage the smart contract functionality built into BSTX-listed issuers' Securities pursuant to the BSTX Protocol.[304] The Exchange states that in such a case, there would be separate sets of end-of-day ownership balance records—the balances of BSTX Participants would be recorded on the Ethereum blockchain and the balances of the other exchange's members would be separately reflected.[305]

One commenter questioned, in the context of SR–BOX–2019–19, whether other national securities exchanges would be in a position to extend UTP to BSTX-listed Securities.[306] This commenter asked if the distributed ledger technology proposed by BSTX would be exclusive to BSTX and if other national securities exchanges would have access to the technology or its source code.[307] This commenter asked if other national securities exchanges would have the ability currently to trade BSTX-listed Securities, and, if not, what changes they would need to make to be able to do so.[308] This commenter stated that, to the extent that other national securities exchanges adopt their own distributed ledger technology to track ownership of equity securities traded on their markets, complications may arise in the equities markets if varying forms of this technology are used.[309] Another commenter, in the context of SR–BOX–2019–19, stated its belief that the Exchange should address the implications in terms of burden on competition for other national securities exchanges that would like to extend UTP to BSTX-listed stocks.[310]

Also in the context of SR–BOX–2019–19, one commenter stated that the proposal appears to provide insufficient detail regarding the digital security infrastructure and how technology would pair with existing equities market infrastructure.[311] This commenter stated that to avail itself of the blockchain technology associated with the proposed Securities (which this commenter asserted is the only unique characteristic of the Securities), the purchaser must be a BSTX Participant.[312] This commenter further stated that the proposal is designed to provide an advantage to the Exchange as the exclusive provider of blockchain technology for Securities, because the Exchange will not accept end-of-day Security ownership balance reports from non-BSTX Participants.[313] This commenter asserted that, as such, the Exchange's proposal places an ''unreasonable'' burden on competition.[314] This commenter also stated it would be inappropriate, and perhaps beyond the scope of the Commission's authority, to allow NMS plans to be used for the ''specialized competitive purposes'' of an individual national securities exchange.[315]

In response, in the context of SR–BOX–2019–19, the Exchange asserted that the trading of Securities does not impose any additional burden compared to the trading of other NMS stocks.[316] The Exchange stated that end-of-day Security ownership balance reporting and the publication of such information on the Ethereum blockchain does not impact the ability of Securities to trade on other national securities exchanges or OTC, and that Securities are fully capable of trading on other national securities exchanges or OTC without an ''ancillary'' recordkeeping mechanism.[317] Therefore, according to the Exchange, if any other national securities exchange sought to extend UTP to a BSTX-listed Security, it could do so under the existing regulatory framework.[318]

The Exchange responded further that there is no limitation in its proposal that would prevent another national securities exchange from adopting its own process and requirements to record and disseminate end-of-day Security ownership balances.[319] The Exchange stated that it encourages other national securities exchanges to consider taking steps to promote the use of blockchain technology and help familiarize market participants with its potential uses and benefits.[320] The Exchange also stated that it proposes to use a ''common distributed ledger'' in the form of the public Ethereum blockchain that any other national securities exchange could use to implement its own recordkeeping process.[321] According to the Exchange, any other national securities exchange that wants to trade Securities would have access to the publicly available, open-source code from the BSTX Protocol, and also would be able to leverage the pre-established Security architecture to facilitate any similar end-of-day reporting requirements.[322] The Exchange stated that it would impose the end-of-day reporting requirement only on BSTX Participants because of the limits of its legal authority, and that while it would not initially accept voluntary reporting from non-BSTX Participants, it may consider accepting such voluntary reports in the future.[323]

[304] *See* OIP, *supra* note 7, 85 FR at 51263, n.105.

[305] *See id.*

[306] *See* SIFMA Letter II, *supra* note 110, at 6.

[307] *See* SIFMA Letter II, *supra* note 110, at 4. This commenter also asked, if the distributed ledger technology and its source code is exclusive to BSTX, what other national securities exchanges would have to do to gain access. *See id.* at 4–5.

[308] *See* SIFMA Letter II, *supra* note 110, at 6. This commenter also stated that it is unclear whether the Exchange could limit UTP trading in BSTX-listed Securities in the future. *See id.*

[309] *See* SIFMA Letter II, *supra* note 110, at 3. This commenter also questioned whether other market participants would have the ability to change the source code underlying the distributed ledger technology. *See id.* at 5.

[310] *See* IEX Letter, *supra* note 77, at 5.

[311] *See* Nasdaq Letter, *supra* note 77, at 1.

[312] *See* Nasdaq Letter, *supra* note 77, at 2.

[313] *See* Nasdaq Letter, *supra* note 77, at 3.

[314] *See* Nasdaq Letter, *supra* note 77, at 3.

[315] *See* Nasdaq Letter, *supra* note 77, at 3.

[316] *See* BSTX Response Letter I, *supra* note 82, at 3. Also, with respect to other exchanges extending UTP to Securities, the Exchange states that it does not believe that the proposal would impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act, in that Securities would trade, clear, and settle in the same manner as other NMS stock, and accordingly, other exchanges would be able to extend UTP to Securities in accordance with Commission rules. *See* OIP, *supra* note 7, 85 FR at 51289. *See also supra* notes 301, 303, and accompanying text (discussing the Exchange's statement regarding burden on competition in the context of other exchanges extending UTP).

[317] *See* OIP, *supra* note 7, 85 FR at 51262; BSTX Response Letter I, *supra* note 82, at 3. *See also id.* at 16 (stating that Securities are fully capable of trading on other national securities exchanges or OTC without an ''ancillary'' recordkeeping mechanism); BSTX Response Letter II, *supra* note 105, at 5 (same).

[318] *See* BSTX Response Letter I, *supra* note 82, at 3. *See also* BSTX Response Letter II, *supra* note 105, at 5 (stating that any national securities exchange would be free to extend UTP to Securities consistent with applicable regulatory requirements). The Exchange also states, in response to whether other exchanges would be able to access the distributed ledger technology that BSTX proposes to use, that use of Ethereum blockchain technology, which is an open source public blockchain that supports smart contract functionality, is not exclusive to BSTX, and thus, all market participants would have open access to the distributed ledger technology associated with the Exchange's proposal. *See* OIP, *supra* note 7, 85 FR at 51289, n.366.

[319] *See* OIP, *supra* note 7, 85 FR at 51290; BSTX Response Letter I, *supra* note 82, at 3, 4.

[320] *See* BSTX Response Letter I, *supra* note 82, at 4.

[321] *See* BSTX Response Letter I, *supra* note 82, at 4. *See also* BSTX Response Letter II, *supra* note 105, at 2–3 (reiterating that the distributed ledger technology that would be used is the Ethereum blockchain, which is not exclusive to BSTX, and is an open source public blockchain that supports smart contract functionality).

[322] *See* BSTX Response Letter I, *supra* note 82, at 4.

[323] *See* BSTX Response Letter I, *supra* note 82, at 4. *See also* OIP, *supra* note 7, 85 FR at 51257 (stating that the Exchange will not accept voluntary reports of end-of-day Security balances from non-BSTX Participants, but may consider doing so in the future, subject to any applicable or necessary rule filing requirements with the Commission); BSTX Response Letter III, *supra* note 207, at 3.

In response to comments on SR–BOX–2019–19, the Exchange stated its disagreement with a commenter's assertion that the Exchange is proposing to use UTP to promote trading that uniquely benefits the Exchange, and states that it is not ''using'' UTP in any manner.[324] The Exchange asserted its belief that its proposal would not impose any burden on competition because other national securities exchanges would be free to determine whether to extend UTP to Securities.[325] The Exchange further asserted that there is no mechanism by which one national securities exchange can force another national securities exchange to extend UTP to its listed securities, and therefore any national securities exchange would be free to extend UTP to BSTX-listed Securities consistent with applicable regulatory requirements.[326] The Exchange also stated that, if a national securities exchange were to choose to extend UTP to BSTX-listed Securities and adopt a recordkeeping process utilizing the blockchain, it could do so in a manner consistent with BSTX's proposed requirements and end-of-day reporting structure, or could develop and pursue another approach.[327]

With respect to the Exchange's stated purpose for recording and publicly disseminating Security ownership balances, the Exchange states that it believes that initially using blockchain technology as an ''ancillary'' recordkeeping mechanism, pursuant to which the Securities represented on the blockchain in Token form would not convey legal ownership, is the appropriate way to explore the potential benefits of blockchain technology consistent with the protection of investors and the public interest.[328] According to the Exchange, it believes that using blockchain technology to record and disseminate end-of-day Security ownership balances in parallel with the traditional trading, recordkeeping, and clearance and settlement structures that market participants are familiar with is an important first step toward exploring the potential uses and benefits of blockchain technology in securities transactions.[329] The Exchange further states that it believes that promoting the use of the functionality of smart contracts and their ability to allocate and re-allocate Securities balances in Token form across multiple wallet addresses in connection with end-of-day Security ownership balance information of BSTX Participants will allow market participants to observe and increase their familiarity with the ''capabilities and potential benefits'' of blockchain technology in a context that parallels the current equity market infrastructure.[330] Thereby, according to the Exchange, its proposal would advance and protect the public's interest in the use and development of new data processing techniques that may create opportunities for more efficient, effective, and safe securities markets.[331]

In the context of SR–BOX–2019–19, several commenters raised questions about the purpose of the Exchange's proposed use of blockchain technology to record and disseminate end-of-day Security ownership balances.[332] One commenter asserted that it is unclear what efficiencies or purposes an end-of-day Security ownership balance would provide or that Securities would offer to the global securities marketplace, and that the proposed structure would introduce potential burdens on market participants.[333] According to this commenter, it seemed likely that the introduction and use of Securities would create an undue burden on market participants, exchanges, custodians, clearing firms, and retail and institutional investors.[334] Another commenter asked what the purpose of the proposed end-of-day Security ownership balance reporting mechanism would be.[335] This commenter further asked, if the purpose was to gradually introduce blockchain technology, what the next steps would be.[336] Another commenter asserted that the proposal did not provide sufficient detail regarding the ultimate purpose of the records of end-of-day Security ownership balances and the specific content and design of such records, and that therefore the purpose and design of these records was unclear and could not be evaluated under the Exchange Act.[337] According to this commenter, a reader of the proposal could not identify and evaluate the ways in which the end-of-day Security ownership balance may benefit investors or add transactional, operational, and other types of risk.[338]

In response, in the context of SR–BOX–2019–19, the Exchange reiterated the purpose of the end-of-day Security ownership balances as previously stated and asserted its belief that the proposed ''ancillary'' recordkeeping process, which is designed to operate separate and apart from the existing market infrastructure and would not impact trading, clearance, or settlement of Securities, would not pose any transactional or operational risks.[339] According to the Exchange, it believed that its explanation about the purpose of the end-of-day Security ownership balances that it provided in SR–BOX–2019–19 as amended by Amendment No. 2 provided ''sufficient information for market participants to independently arrive at this same conclusion.'' [340] The Exchange stated that the record of end-of-day Security balances on the blockchain is for the public benefit.[341] The Exchange asserted its belief that blockchain technology may offer benefits to the trading of securities, and that the Exchange had proposed a

[324] *See* BSTX Response Letter I, *supra* note 82, at 4. The Exchange also stated that it was not proposing a fee related to the reporting of end-of-day ownership balances to the Ethereum blockchain, and therefore Securities trading on other national securities exchanges would not offer a unique benefit to the Exchange in this respect. *See id.* at 5.

[325] *See* BSTX Response Letter I, *supra* note 82, at 4, 5.

[326] *See* BSTX Response Letter I, *supra* note 82, at 4–5.

[327] *See* BSTX Response Letter I, *supra* note 82, at 5, 9–10. The Exchange also asserted its disagreement with a commenter's statement that it would be inappropriate to allow national market system plans to be used for the specialized competitive purposes of an individual national securities exchange, and stated that the point is not relevant because the Exchange had not proposed any national market system plan relating to its proposal. *See id.* at 4, n.15.

[328] *See* OIP, *supra* note 7, 85 FR at 51262. The Exchange also states that it believes that the public has an interest in exploring the use of new technology, such as blockchain technology, and that such technology may be able to help perfect the mechanism of a free and open market and a national market system. *See id.*

[329] *See* OIP, *supra* note 7, 85 FR at 51287. *See also id.* at 51262 (stating that the Exchange's contention that the proposal is reasonably designed to introduce blockchain technology in a gradual way, and in coordination and cooperation with the industry, the Commission, and the existing regulatory framework).

[330] *See* OIP, *supra* note 7, 85 FR at 51263.

[331] *See id. See also* BSTX Response Letter I, *supra* note 82, at 13. The Exchange also states that, while it believes that its proposal represents an introductory step in pairing the benefits of blockchain technology with the current equity market structure, other market participants and FINRA have recognized additional potential benefits to blockchain technology in various applications related to the securities markets. *See* OIP, *supra* note 7, 85 FR at 51263, n.110.

[332] *See* Eversheds Letter, *supra* note 91, at 1–2; IEX Letter, *supra* note 77, at 5; PKA Law Letter, *supra* note 175, at 1–2; SIFMA Letter II, *supra* note 110, at 3.

[333] *See* PKA Law Letter, *supra* note 175, at 1–2.

[334] *See* PKA Law Letter, *supra* note 175, at 2.

[335] *See* IEX Letter, *supra* note 77, at 5.

[336] *See* IEX Letter, *supra* note 77, at 5.

[337] *See* Eversheds Letter, *supra* note 91, at 1–2. *See also* IEX Letter, *supra* note 77, at 5, n.8 (agreeing with the concerns identified in the Eversheds Letter and stating that these concerns were not fully or clearly addressed by Amendment No. 2).

[338] *See* Eversheds Letter, *supra* note 91, at 2.

[339] *See* BSTX Response Letter I, *supra* note 82, at 13.

[340] BSTX Response Letter I, *supra* note 82, at 13.

[341] *See* BSTX Response Letter I, *supra* note 82, at 14.

limited use of the technology in the form of end-of-day Security ownership balances on the blockchain to help it evaluate whether such benefits might be realized.[342] The Exchange stated that it may consider a variety of next steps towards potential further integration of blockchain technology, any of which would be subject to the rule filing requirements, and public notice and comment, pursuant to Section 19 of the Exchange Act.[343]

Also in the context of SR–BOX–2019–19, one commenter asserted that the proposal's requirements with respect to maintaining end-of-day Security ownership balances on the blockchain are inconsistent with the requirement in Section 6(b)(5) of the Exchange Act that a national securities exchange's rules may not regulate matters not related to the purposes of this title or the administration of the exchange, because the maintenance of these records does not appear to be necessary for the clearance and settlement of the Securities, the fair and orderly trading of Securities, or any purpose regulated by the Exchange Act.[344] The Exchange responds that it believes that the proposal is not designed to regulate matters outside those contemplated and authorized by the Exchange Act.[345] The Exchange states that Section 2 of the Exchange Act sets forth the reasons for the Exchange Act, which include that '' transactions in securities as commonly conducted upon securities exchanges and over-the-counter markets are effected with a national public interest which makes it necessary to provide for regulation and control of such transactions *and of practices and matters related thereto,* including . . . *to require appropriate reports.*''' [346] According to the Exchange, the Exchange Act and the rules of SROs include reporting requirements that regulate and control matters and practices related to securities transactions conducted on national securities exchanges and in OTC markets.[347] As noted above, the Exchange also reasserts its belief that the end-of-day reporting requirements will allow market participants to observe and increase their familiarity with the capabilities and potential benefits of blockchain technology in a context that parallels current equity market infrastructure.[348]

In the context of SR–BOX–2019–19, one commenter stated that the Exchange appeared to be proposing a proprietary Ether-based distributed ledger technology to be used to track ownership on an ''ancillary'' basis for BSTX-listed Securities.[349] This commenter asserted that the Exchange is encouraging the adoption of this technology with the likely eventual goal of having it become a system for tracking equity security ownership outside of the current system maintained by DTC and broker-dealers.[350] This commenter further asserted that the end-of-day Security balance reporting ''appears to be nothing more than a way to force industry participants to sign up for the Exchange's blockchain service, adding cost while providing no apparent value to firms, institutional clients, or retail investors.'' [351] This commenter stated that while it supports adoption of new processes and technology to make the equity market infrastructure more efficient and robust and supports the use of technology to strengthen the security settlement system, it has concerns about the wider implications on the equity market infrastructure.[352] The Exchange responded that that proposal was designed to operate entirely within the existing equity market structure, including the requirements for clearance through NSCC and settlement through DTC, and that any future changes would be subject to the Commission's rule filing process under Section 19 of the Exchange Act.[353]

In the context of SR–BOX–2020–14, this commenter stated that it previously expressed concerns regarding the end-of-day Security balance reporting aspect of the Exchange's proposal, and that it had previously raised concerns about how other exchanges might trade Securities pursuant to UTP, whether they might be required to adopt BOX's proprietary technology, and how having exchanges adopt different forms of distributed ledger technology to track equity ownership of equity securities could cause additional costs to the industry.[354] This commenter stated that the end-of-day Securities balance reporting requirements would serve as a potential impediment for other exchanges to trade the Securities pursuant to UTP, and that other exchanges may be hesitant to trade Securities pursuant to UTP because of the lack of clarity around the implications of BSTX's end-of-day Security ownership balance reporting requirements for their members.[355]

In response to the commenter's concerns about ''how other exchanges might trade the Securities pursuant to UTP,'' the Exchange stated that no comments were submitted by any national securities exchanges following its filing of Amendment No. 1 to the proposal.[356] The Exchange also stated that a market participant that voluntarily chooses to become a BSTX Participant must comply with BSTX rules,[357] and that its proposal is clear that a BSTX Participant must report its end-of-day balance at DTC or its carrying firm in the relevant Security pursuant to proposed BSTX Rule 17020(b).[358] Additionally, the Exchange stated that, regarding costs associated with the end-of-day Security ownership balance reporting process, it does not believe that imposing the proposed requirement on BSTX Participants is unfairly discriminatory or burdens competition because all market

[342] *See* BSTX Response Letter I, *supra* note 82, at 14.

[343] *See* BSTX Response Letter I, *supra* note 82, at 9.

[344] *See* Eversheds Letter, *supra* note 91, at 3.

[345] *See also* OIP, *supra* note 7, 85 FR at 51288.

[346] *See* OIP, *supra* note 7, 85 FR at 51288 (quoting 15 U.S.C. 78(b) (emphasis in OIP)). *See also* BSTX Response Letter I, *supra* note 82, at 16.

[347] *See* OIP, *supra* note 7, 85 FR at 51288; BSTX Response Letter I, *supra* note 82, at 16–17. The Exchange states that, for example, all of the U.S. options exchanges and FINRA maintain rules approved by the Commission that require their member broker-dealers to prepare and submit daily large options position reports, and that these reports do not concern the trading or clearance and settlement of securities transactions themselves, but instead are reports relating to end-of day positions. The Exchange asserts that the requirements regarding the end-of-day Security ownership balance reporting process would similarly require BSTX Participants to provide reports regarding their end-of-day ownership balances in Securities. *See* OIP, *supra* note 7, 85 FR at 51288. *See also* BSTX Response Letter I, *supra* note 82, at 17.

[348] *See* OIP, *supra* note 7, 85 FR at 51288. *See also* BOX Response Letter I, *supra* note 82, at 13; OIP, *supra* note 7, 85 FR at 51289, n.371 and accompanying text. *See also supra* notes 328–331 and accompanying text.

[349] *See* SIFMA Letter II, *supra* note 110, at 3.

[350] *See* SIFMA Letter II, *supra* note 110, at 3.

[351] SIFMA Letter II, *supra* note 110, at 3.

[352] *See* SIFMA Letter II, *supra* note 110, at 3–4. This commenter suggested that the novel equity market infrastructure issues presented by the proposal are better suited for a concept release or other type of release by the Commission that is geared toward soliciting market-wide feedback, rather than an ad hoc proposal by a single national securities exchange. *See id.* at 4. *See also* SIFMA Letter IV, *supra* note 220, at 5–6 (stating continued concerns about new processes and technology with wider implications for the equity market structure infrastructure being considered in the framework of a proposed rule change by a single exchange without actively working with and soliciting input from the industry).

[353] *See* BSTX Response Letter II, *supra* note 105, at 3.

[354] *See* SIFMA Letter IV, *supra* note 220, at 4 (noting its prior comment).

[355] *See* SIFMA Letter IV, *supra* note 220, at 5.

[356] *See* BSTX Response Letter III, *supra* note 207, at 5, n.13.

[357] *See* BSTX Response Letter III, *supra* note 207, at 6.

[358] *See* BSTX Response Letter III, *supra* note 207, at 3.

participants are free to choose whether to become a BSTX Participant or not and there is no limitation imposed by the Exchange on the ability to trade Securities on other markets.[359] The Exchange also stated that its proposal represents an incremental change to incorporate blockchain technology within the current infrastructure and regulations for the equities market—including clearance and settlement—and that any future structural changes would be subject to the rule filing process pursuant to Section 19 of the Act.[360]

2. Analysis

As stated above, the Commission supports innovation in our securities markets, and its disapproval does not rest on an evaluation of the utility or value of blockchain technology as applied to the functions of a national securities exchange. Due to the Exchange's lack of analysis about the burden that other national securities exchanges would face to use an end-of-day Security ownership reporting mechanism in connection with the trading of Securities on their markets and the competitive impacts, however, the Commission cannot find that the proposal does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act, consistent with Section 6(b)(8). The Exchange asserts that it is not proposing any limitation that would prevent another national securities exchange from participating in the Exchange's end-of-day Security ownership balance reporting process or establishing its own alternative or complementary process, and that it is not proposing to limit another exchange's ability to establish a similar, different, or integrated reporting structure.

As discussed below, the Commission believes that the Exchange has not fully explained critical operational aspects of the end-of-day Security ownership reporting functionality, particularly with respect to how another national securities exchange may employ such functionality, on its own or in coordination with BSTX, and trade BSTX-listed NMS stock on its exchange.[361] Without this explanation, the Commission is unable to comprehensively assess the existence or scope of any burden resulting from the Exchange's proposed end-of-day Security ownership reporting functionality and concludes that the Exchange has not provided sufficient information to support a finding by the Commission that the proposed rules would not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the federal securities laws.

Although the Exchange asserts that BSTX-listed Securities trading on another national securities exchange could trade, clear, and settle in the same manner as other NMS stock,[362] the Exchange will not accept, at least initially, end-of-day Security ownership balance reports from non-BSTX Participants that transact on other trading centers.[363] The Exchange asserts that another national securities exchange that wants to trade BSTX-listed Securities would be able to leverage the Exchange's pre-established Security architecture to facilitate similar end-of-day reporting requirements, or could develop and pursue its own approach,[364] and provides some broad examples of how it believes another exchange could develop its own end-of-day reporting requirement or participate in BSTX's process.[365] However, the Exchange has not provided sufficient information for the Commission to determine whether it would be feasible, and the associated burden, for another national securities exchange that extends UTP to BSTX-listed Securities, or another trading center that trades BSTX-listed Securities, to implement a process that uses blockchain technology for end-of-day Security ownership balance reporting for its members. The Exchange has not explained, as proposed, how another national securities exchange would be able to participate in the Exchange's end-of-day Security ownership balance reporting mechanism without the Exchange's permission, and without complying with any conditions that the Exchange might place on access to this mechanism, including membership requirements. For example, only BOX would control the end-of-day reporting mechanism by requiring the issuer to set up the necessary smart contracts, contracting with the Wallet Manager, obtaining allowlisted wallet addresses for BSTX Participants, collecting end-of-day Security ownership balance reports from BSTX Participants, and instructing the Wallet Manager to update the Ethereum blockchain to reflect those ownership balances.[366] It is also unclear whether the Exchange would make its allowlisting and end-of-day reporting process available to other national securities exchanges or trading centers directly. For example, the Exchange provides as an example of how another exchange could adopt its own end-of-day reporting requirement, that the other exchange could choose to collect end-of-day Security ownership balance information from its members and then relay that information to BSTX to deliver to a Wallet Manager for recording to the Ethereum blockchain,[367] but it is unclear what that process would entail. While the Exchange suggests that the other exchange would be in a position similar to a BSTX Participant in such a case,[368] the Exchange also states that it would not accept voluntary reporting from non-BSTX Participants.[369] Further, the Exchange does not explain what would be necessary for the coordination of end-of-day reporting mechanisms.[370]

The Exchange also does not provide sufficient detail about how the end-of-day Security ownership balances of members of another national securities exchange could be included in the same smart contract on the Ethereum blockchain that is being used for BSTX Participants, and whether the Exchange's permission would be required. The Exchange states that other exchanges would be able to access the distributed ledger technology that BSTX proposes to use because Ethereum blockchain technology is an open source public blockchain that supports smart contract functionality and is not

[359] *See* BSTX Response Letter III, *supra* note 207, at 5–6.

[360] *See* BSTX Response Letter III, *supra* note 207, at 6–7.

[361] Commenters raised concerns about the Exchange being an exclusive provider of a process that would use blockchain technology to record and disseminate end-of-day Security ownership balances and that other national securities exchanges would be unable to compete on this basis. *See supra* notes 307–315 and accompanying text.

[362] *See supra* note 299 and accompanying text.

[363] *See supra* note 323.

[364] *See supra* notes 319–322, 327, and accompanying text.

[365] *See supra* note 302.

[366] *See supra* Section III.C.2 for additional discussion of the process for allowlisting and end-of-day reporting.

[367] *See supra* note 302.

[368] *See id.*

[369] *See supra* note 323. Although the Exchange states that it may determine to accept voluntary reporting from non-BSTX Participants in the future (*see supra* note 323 and accompanying text), the Commission must evaluate whether the current proposal is consistent with the Exchange Act.

[370] *See* OIP, *supra* note 7, 85 FR at 51264, n.104 (discussing the Exchange's lack of clarity as to whether it would be necessary for BSTX and another exchange that decides to trade Securities, establish an end-of-day balance reporting requirement for its members, and relay the balance information to BSTX for recording to the Ethereum blockchain to file an NMS plan with respect to coordinating end-of-day balance reporting mechanisms).

exclusive to BSTX.[371] However, the Exchange's proposal suggests that, for end-of-day Security ownership balances of trading centers' non-BSTX Participant members to be included in the same smart contract that contains the records for BSTX Participants, the non-BSTX Participants would need to obtain allowlisted wallet addresses, and that the Exchange would control the allowlisting process. In addition, either the other exchange or its non-BSTX Participant members would need to be allowed to provide end-of-day Securities ownership balances to the Exchange or its Wallet Manager, or if the other exchange was to work with another Wallet Manager, that Wallet Manager would need to have the necessary security permissions to write to the same smart contract.[372] Moreover, the Exchange does not explain the implications for the recordkeeping process of having more than one Wallet Manager, particularly if there is a Wallet Manager that does not have a direct relationship with the Exchange. And the Exchange does not explain how it would calculate the Securities ownership balance to attribute to the omnibus wallet address if non-BSTX Participants did not report their ownership balances to the Exchange, but these ownership balances were associated with non-BSTX Participants' wallet addresses in the smart contract on the Ethereum blockchain.[373]

The Exchange also does not explain, alternatively, the potential implications of having two separate smart contracts with digital representations of ownership interest in the same Security if a national securities exchange extending UTP to BSTX-listed Securities (or other trading center trading BSTX-listed Securities) were to create its own smart contracts, using a parallel process for end-of-day Securities ownership balance reporting that is either similar to or differs greatly from that developed by the Exchange.[374] For example, the existence of competing sets of records could be confusing for investors and other market participants. One potential source of confusion is that even if one smart contract represented end-of-day Security ownership balances for BSTX Participants and a separate smart contract represented end-of-day Security ownership balances for another trading center's members, there could be double-counting if some BSTX Participants were also members of the other trading center. And whereas an issuer of a BSTX-listed Security must create a smart contract compliant with BSTX Protocol as a condition of listing on the Exchange,[375] that issuer would not have a direct relationship with another national securities exchange that extends UTP to its Security (or other trading center that trades its Security). The Exchange does not explain the likelihood that an issuer would be willing to work with another national securities exchange that wishes to trade the same BSTX-listed Security to create a separate smart contract associated with its Security, or whether there would be any logistical impediments to doing so post-issuance.

These deficiencies in the Exchange's explanation about how another national securities exchange may be able to use the proposed end-of-day Security ownership reporting functionality leaves the Commission with significant concerns about whether it would be feasible for another national securities exchange to make use of this functionality or create its own parallel reporting functionality. The Commission finds that the Exchange has not met its obligation to explain any burden its proposed end-of-day Security ownership reporting functionality would place on competition between BSTX and other national securities exchanges. Without being able to assess this potential burden on competition, particularly in light of commenters' concerns that meaningful competition among national securities exchanges with respect to the use of the end-of-day Security ownership functionality may be foreclosed, the Commission is unable to assess the necessity or appropriateness of that burden on competition. Therefore the Commission does not need to reach the question of whether the Exchange's assertions about the purpose of its end-of-day Security ownership reporting functionality demonstrate that the burden on competition is necessary or appropriate in furtherance of the Exchange Act.[376] Accordingly, the Commission is unable to find that the Exchange's rules would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the federal securities laws, in accordance with Section 6(b)(8) of the Exchange Act.

For the reasons discussed above, considered independently or in combination, the Commission concludes that Exchange has not met its burden of demonstrating that the proposal is consistent with Exchange Act Sections 6(b)(1), 6(b)(5), or 6(b)(8),[377] and, accordingly, the Commission must disapprove the proposal.[378]

E. Other Aspects of the Exchange's Proposal and Comments Received

The Commission is disapproving the proposed rule change for the reasons discussed above. Therefore the Commission does not reach the question of whether other aspects of the Exchange's proposal, including proposed rules relating to participation on BSTX, business conduct for BSTX Participants, financial and operational provisions for BSTX Participants, supervision, trading practices, discipline, trading on the BSTX System, market making, and listing on the Exchange (with the exception of the specific topics discussed in Section III.C.4 above), are consistent with the Exchange Act. Other issues have been raised by commenters, in connection with SR–BOX–2019–19, including the settlement process for Securities; [379] what reporting facility would be used for trade reporting; [380] the process of trade confirmation reporting; [381] the

[371] *See supra* notes 318–322 and accompanying text.

[372] *See supra* Section III.C.1 for discussion of the process by which the Wallet Manager would write to the blockchain. For example, the Exchange indicated that one option might be for the other exchange to report its members' balances to BSTX's Wallet Manager or engage its own wallet manager to communicate with BSTX's Wallet Manager. However, the Exchange has not explained how that other exchange (or its wallet manager) could coordinate with BSTX's Wallet Manager, given that BOX has the contractual relationship with its Wallet Manager.

[373] *See supra* note 57 and accompanying text (stating that the Exchange would determine the number of Tokens to be allocated to the omnibus wallet address for a particular Security by subtracting the sum of the Security ownership balances reported by BSTX Participants from the total outstanding number).

[374] *See also supra* note 309 and accompanying text (commenter asserting that, to the extent that other national securities exchanges adopt their own distributed ledger technology and varying forms of technology are used, complications may arise in the equities markets).

[375] *See supra* Section III.C.4(b) for discussion of the obligations that companies have to comply with the BSTX Protocol as a condition of Exchange listing.

[376] *See supra* notes 328–360 and accompanying text. Moreover, the record does not contain any argument that the Exchange's proposed use of end-of-day Security ownership reporting functionality is necessary or appropriate in furtherance of the purposes of the Exchange Act, notwithstanding a significant burden imposed by such functionality on competition between national securities exchanges.

[377] 15 U.S.C. 78f(b)(1), (5), and (8).

[378] In disapproving the proposed rule change, the Commission has considered its impact on efficiency, competition, and capital formation. *See* U.S.C. 78c(f). For the reasons discussed throughout, the Commission is disapproving the proposed rule change because it does not find that the proposed rule change is consistent with the Exchange Act.

[379] *See* PKA Law Letter, *supra* note 175, at 1.

[380] *See* PKA Law Letter, *supra* note 175, at 1.

[381] *See* PKA Law Letter, *supra* note 175, at 1.

proposal's compatibility with DTC and NSCC infrastructure;[382] the liquidity of Securities;[383] how the end-of-day Security ownership balance reporting mechanism would affect short sales, including the locate process, clearing, settling, and market maker compliance with short sale rules;[384] how end-of-day Security ownership balances would affect the margin methodology for member self-calculation;[385] the potential liability of custodians for differences between DTC records and end-of-day Security ownership balances;[386] the proposed listing requirements' compliance with penny stock rules;[387] the proposal's compliance with the anti-fraud or customer protection provisions of the Exchange Act or other Commission regulations;[388] Security ownership verification, including for purposes of compliance with know-your-customer and anti-money laundering rules;[389] access to the end-of-day Security ownership balance records and the safeguarding of customer non-public information;[390] the requirements of Exchange Act Rule 12f-5 relating to the extension of UTP by other national securities exchanges to BSTX-listed Securities;[391] the relationship among tZERO, Overstock.com, Inc. (''Overstock''),[392] and entities related to the Exchange;[393] whether any registered broker-dealer has indicated its intention to become a BSTX Participant;[394] and whether the Exchange is still working with FINRA regarding end-of-day Security ownership balance reporting requirements for FINRA members.[395] Additional discussion on these topics is unnecessary, as they do not bear on the basis for the Commission's decision to disapprove this proposal.

IV. Conclusion

For the reasons set forth above, the Commission does not find, pursuant to Section 19(b)(2) of the Exchange Act, that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, with Sections 6(b)(1), 6(b)(5), and 6(b)(8) of the Exchange Act.[396]

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[397] that the proposed rule change (SR–BOX–2020–14), as modified by Amendment No. 1, be, and hereby is, disapproved.

By the Commission.

Vanessa A. Countryman,

Secretary.

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[382] *See* PKA Law Letter, *supra* note 175, at 2.

[383] *See* PKA Law Letter, *supra* note 175, at 1.

[384] *See* IEX Letter, *supra* note 77, at 6; PKA Law Letter, *supra* note 175, at 1.

[385] *See* Nasdaq Letter, *supra* note 77, at 3.

[386] *See* Eversheds Letter, *supra* note 91, at 2.

[387] *See* IEX Letter, *supra* note 77, at 6.

[388] *See* Eversheds Letter, *supra* note 91, at 2; Nasdaq Letter, *supra* note 77, at 3.

[389] *See* Nasdaq Letter, *supra* note 77, at 3; PKA Law Letter, *supra* note 175, at 1.

[390] *See* Eversheds Letter, *supra* note 91, at 2.

[391] *See* Eversheds Letter, *supra* note 91, at 2–3; IEX Letter, *supra* note 77, at 3–4. One commenter also discussed aspects of requirements might be placed on a national securities exchange extending UTP to BSTX-listed Securities that the Exchange modified in Amendment No. 2 to SR–BOX–2019–19. *See* Eversheds Letter, *supra* note 91, at 3.

[392] In the Amended BSTX Governance Proposal, the Exchange states that Overstock, which is a publicly held corporation, wholly owns Medici Ventures, Inc., which owns 80.07% of tZERO. *See* Amended BSTX Governance Proposal, *supra* note 17, 85 FR at 50851.

[393] *See* PKA Law Letter, *supra* note 175, at 2.

[394] *See* IEX Letter, *supra* note 77, at 5.

[395] *See* IEX Letter, *supra* note 77, at 6.

[396] 15 U.S.C. 78f(b)(5).

[397] 15 U.S.C. 78s(b)(2).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90726; File No. SR–NYSE–2020–89]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Amend Rule 7.35C

December 18, 2020.

On October 23, 2020, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to: (1) Provide the Exchange the authority to facilitate a Trading Halt Auction if a security has not reopened following a Level 1 or Level 2 trading halt due to extraordinary market volatility under Rule 7.12 (''MWCB Halt'') by 3:30 p.m.; (2) widen the Auction Collar for an Exchange-facilitated Trading Halt Auction following an MWCB Halt; (3) provide that certain DMM Interest would not be cancelled following an Exchange-facilitated Auction; and (4) change the Auction Reference Price for Exchange-facilitated Core Open Auctions. The proposed rule change was published for comment in the **Federal Register** on November 12 2020.[3]

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is December 27, 2020. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[5] designates February 10, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSE–2020–89).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28511 Filed 12–23–20; 8:45 am]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90363 (Nov. 5, 2020), 85 FR 71964 (Nov. 12, 2020).

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90730; File No. SR–NYSE–2020–87]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Rule 7.31

December 18, 2020.

I. Introduction

On October 20, 2020, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant

to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend NYSE Rule 7.31 to (1) cancel ALO Orders that lock displayed interest and (2) add two new types of Self Trade Prevention (''STP'') modifiers. The proposed rule change was published for comment in the **Federal Register** on November 6, 2020.[3] On December 15, 2020, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change in its entirety.[4] The Commission has received no comments on the proposed rule change. This order provides notice of the filing of Amendment No. 1 to the proposed rule change, and grants approval to the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Exchange's proposal, as modified by Amendment No. 1, seeks to amend NYSE Rule 7.31 to provide for two additional types of STP modifiers. Currently, NYSE offers two versions of STP: STP Cancel Newest (''STPN'') and STP Cancel Oldest (''STPO''), as described in NYSE Rules 7.31(i)(2)(A) and 7.31(i)(2)(B), respectively. NYSE proposes to expand its STP offerings to establish STP Decrement and Cancel (''STPD'') and STP Cancel Both (''STPC''), which would be set forth in proposed Rules 7.31(i)(2)(C) and 7.31(i)(2)(D), respectively. NYSE's proposed STPD and STPC offerings are based in part on the STPD and STPC offerings on NYSE's affiliates NYSE Arca, Inc. (''NYSE Arca''), NYSE American LLC (''NYSE American''), NYSE Chicago, Inc. (''NYSE Chicago''), and NYSE National, Inc. (''NYSE National'') (collectively, the ''Affiliated Exchanges''),[5] with differences to separately describe order processing for orders that are allocated in price-time priority and how STPD and STPC would function consistent with NYSE's parity allocation model.

For STPD, proposed NYSE Rule 7.31(i)(2)(C) would provide that an incoming order to buy (sell) with an STPD modifier would not trade with resting interest to sell (buy) marked with any of the STP modifiers from the same Client ID,[6] as outlined in proposed NYSE Rules 7.31(i)(2)(C)(i) and (ii).

Proposed NYSE Rule 7.31(i)(2)(C)(i) would apply to resting orders in a priority category that allocates orders on price-time priority. As proposed, if both orders with an STP modifier are equivalent in size, both orders would be canceled back to the originating member organization. If the orders are not equivalent in size, the equivalent size would be canceled back to the originating Client ID and the larger order would be decremented by the size of the smaller order, with the balance remaining on NYSE's Book. The Exchange states that this proposed functionality is based on the STPD functionality available on the Affiliated Exchanges.

Proposed NYSE Rule 7.31(i)(2)(C)(ii) would address how STPD would function for resting orders in a priority category that allocates orders on parity. As proposed, if a resting order would have been considered for an allocation, both the portion of the resting order that would receive an allocation and the portion of the incoming order marked with the STPD modifier that would be allocated to the resting order would be canceled back to the originating member organization. Resting orders with an STP modifier from the same Client ID that would not have been eligible for a parity allocation would remain on NYSE's Book. NYSE states that if a member organization designates an order with an STPD modifier, that member organization has instructed NYSE to cancel the equivalent portion of both the incoming order and resting order with an STP modifier from the same Client ID, resulting in the larger order being decremented by the size of the smaller order and remaining on NYSE's Book. According to the Exchange, in the case of a parity allocation, because resting orders are allocated based on their position on an allocation wheel,[7] it would be consistent with the incoming order's decrementing instruction to provide a parity allocation to an eligible resting order with an STP modifier from the same Client ID and cancel both the portion of the resting order corresponding to the allocation and the portion of the incoming order that would have been allocated to the resting order. The Exchange states that this proposed functionality is similar to how NYSE currently processes STPO modifiers if a resting order with an STP modifier from the same Client ID is in a priority category that allocates orders on parity, as described in NYSE Rule 7.31(i)(2)(B)(ii).

For STPC, proposed NYSE Rule 7.31(i)(2)(D) would provide that an incoming order to buy (sell) marked with the STPC modifier would not trade with resting interest to sell (buy) marked with any of the STP modifiers from the same Client ID, as outlined in proposed NYSE Rules 7.31(i)(2)(D)(i) and (ii).

Proposed NYSE Rule 7.31(i)(2)(D)(i) would apply to resting orders in a priority category that allocates orders on price-time priority. As proposed, the entire size of both orders with an STP modifier would be canceled back to the originating member organization. The Exchange states that the proposed functionality is based on the STPC functionality available on the Affiliated Exchanges.

Proposed NYSE Rule 7.31(i)(2)(D)(ii) would address how STPC would function for resting orders in a priority category that allocates orders on parity. As proposed, if a resting order with an STP modifier is in a priority category that allocates orders on parity and would have been considered for an allocation against an incoming order with an STPC modifier, none of the resting orders eligible for a parity allocation in that priority category would receive an allocation. The first resting order with an STP modifier eligible for a parity allocation would be canceled back, as would the incoming order. NYSE states that this proposed processing would be consistent with the member organization's instruction that both the incoming order and resting order with an STP modifier from the same Client ID be canceled if there were a potential for an execution between the two orders. The Exchange states that this proposed functionality is similar to how NYSE currently processes STPN modifiers if a resting order with an STP modifier from the same Client ID is in a priority category that allocates orders on parity, as described in NYSE Rule 7.31(i)(2)(A)(ii).

NYSE also proposes non-substantive changes to renumber current NYSE Rules 7.31(i)(2)(C) and 7.31(i)(2)(D) as NYSE Rules 7.31(i)(2)(E) and 7.31(i)(2)(F) to accommodate the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90309 (November 2, 2020), 85 FR 71127 (November 6, 2020).

[4] In Amendment No. 1 to the proposed rule change, the Exchange removed its proposal to cancel ALO Orders that lock displayed interest, and now only proposes to add two new types of STP modifiers to NYSE Rule 7.31. Amendment No. 1 is available on the Commission's website at *https://www.sec.gov/comments/sr-nyse-2020-87/srnyse202087-8146047-226657.pdf.*

[5] *See* NYSE Arca Rule 7.31–E(i)(2); NYSE American Rule 7.31E(i)(2); NYSE National Rule 7.31(i)(2); and NYSE Chicago Rule 7.31(i)(2).

[6] As specified in current NYSE Rule 7.31(i)(2)(D), for purposes of STP, references to Client ID mean a Client ID when using Pillar phase I protocols to communicate with NYSE or an MPID when using Pillar phase II protocols to communicate with NYSE.

[7] *See* NYSE Rule 7.37(b)(2).

addition of the proposed rules governing STPD and STPC. NYSE also proposes a conforming change to current NYSE Rules 7.31(d)(4)(F) and 7.31(i)(2)(C) to clarify that D Orders could only be designated with an STPN or STPO modifier (*i.e.,* that the new STPD and STPC modifiers would not be available for use with D Orders). NYSE also proposes to amend current NYSE Rule 7.31(i)(2)(D) to specify that STPD and STPC modifiers would only be available for use with Pillar phase II protocols.

The Exchange states that, because of the technology changes associated with this proposed rule change, it will announce the implementation date by Trader Update. Subject to approval of the proposed rule change, the Exchange anticipates that the proposed change will be implemented in January 2021.

III. Discussion and Commission Findings

After careful consideration of the proposed rule change, as modified by Amendment No. 1, the Commission finds that the Exchange's proposal is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges. In particular, the Commission finds that the Exchange's proposal is consistent with Section 6(b)(5) of the Act,[8] which requires that the rules of an exchange be designed, among other things, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers or dealers.

With respect to the proposed addition of STPD and STPC modifiers, NYSE asserts that the proposed change would remove impediments to and perfect the mechanism of a free and open market by allowing member organizations to better manage order flow and prevent executions with themselves. NYSE asserts that because orders routed by the same member organization via different connections may, in certain circumstances, be eligible to trade against each other, its proposal to establish additional STP modifiers would remove impediments to and perfect the mechanism of a free and open market, and serve to protect investors and the public interest, by enhancing member organizations' ability to prevent potentially undesirable trades and internalize order flow. NYSE also asserts that the proposed rule change is designed to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest because the proposed changes are based on the approved rules of its Affiliated Exchanges, with modifications to address functionality specific to the NYSE's parity allocation model, and aligning its STP modifiers with those offered by its Affiliated Exchanges would promote consistency for member organizations that are members of the Exchange and one or more other Affiliated Exchanges. NYSE further asserts that the proposed differences to address how the proposed STPD and STPC modifiers would function for resting orders that are in a priority category that allocates orders on parity would remove impediments to and perfect the mechanism of a free and open market because the proposed rules are designed to honor the STPD and STPC instructions consistent with the NYSE's parity model. These proposed rules are also similar to how NYSE currently processes STPN and STPO modifiers for resting orders that are in a priority category that allocates orders on parity.

The Commission believes that the proposed rule change, as amended, will make the Exchange's STP rules consistent with the existing rules and functionalities of other exchanges. Accordingly, the Commission believes that the proposal is reasonably designed to remove impediments to and perfect the mechanism of a free and open market and is not designed to permit unfair discrimination. Based on the foregoing, the Commission therefore finds that the proposed rule change is consistent with the Act.[9]

IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NYSE–2020–87 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSE–2020–87. The file numbers should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File No SR–NYSE–2020–87 and should be submitted on or before January 19, 2021.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the amended proposal in the **Federal Register**. In Amendment No. 1, the Exchange removed its proposal to cancel ALO Orders that lock displayed interest, and now only proposes to add two new types of STP modifiers. Amendment No. 1 does not change any substantive provisions of the latter part of the proposed rule change regarding STP modifiers that were noticed for public comment. As discussed above, the Exchange further states that this proposed rule change will make its rules consistent with the rules and

[8] 15 U.S.C. 78f(b)(5).

[9] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

functionalities of other exchanges. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[10] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (SR–NYSE–2020–87), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28522 Filed 12–23–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90729; File No. SR–NASDAQ–2020–060]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Treat as an Eligible Switch, for Purposes of IM–5900–7, an Acquisition Company That Switches From NYSE to Nasdaq After Announcing a Business Combination

December 18, 2020.

I. Introduction

On September 1, 2020, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to treat as an Eligible Switch, for purposes of IM–5900–7, an Acquisition Company that switches from the New York Stock Exchange (''NYSE'') to Nasdaq after announcing a business combination. On September 14, 2020, the Exchange filed Amendment No. 1 to the proposed rule change, which amended and replaced the proposed rule change in its entirety. The proposed rule change, as modified by Amendment No. 1, was published in the **Federal Register** on September 21, 2020.[3] The Commission received no comments on the proposal, as modified by Amendment No. 1. This order approves the proposed rule change, as modified by Amendment No. 1.

II. Description of the Proposal

Nasdaq proposes to modify IM–5900–7 to treat as an Eligible Switch under that rule any Acquisition Company[4] that both: (i) Switched its listing from NYSE to list on Nasdaq under IM–5101–2 after the company publicly announced that it entered into a binding agreement for a business combination; and (ii) subsequently satisfies the conditions in IM–5101–2(b) and lists on the Nasdaq Global or Global Select Markets, by meeting all listing requirements of one of these market tiers, in conjunction with that business combination.[5]

Currently, a company completing a business combination with a Nasdaq-listed Acquisition Company is eligible to receive services under IM–5900–7 when it lists, by meeting the listing requirements on the Nasdaq Global or Global Select Market, in conjunction with a business combination that satisfies the conditions in IM–5101–2(b).[6] According to Nasdaq, at this point, the Acquisition Company transitions to being an operating company and has a similar need as other companies for shareholder communication services, market analytic tools and market advisory tools. Nasdaq states that, for this purpose, the Acquisition Company is treated as an ''Eligible New Listing'' under the rule, similar to a company listing in connection with its IPO.[7]

Additionally, under IM–5900–7, Nasdaq treats a company that switches its listing from NYSE to the Nasdaq Global or Global Select Market as an ''Eligible Switch'' and, according to Nasdaq, offers such companies a package of services that can be more valuable than the package of services offered to Eligible New Listings.[8] Nasdaq states that, under the current rule, an Acquisition Company listed on NYSE that switches to Nasdaq as an Acquisition Company would not receive any services when it switches, even if it has already announced its business combination, but would receive services as an Eligible New Listing when it completes a business combination that satisfies the requirements of IM–5101–2(b). However, if the company waits until it completes a business combination and then switches to Nasdaq, the company would receive services as an Eligible Switch.[9] According to Nasdaq, removing the existing incentive for an Acquisition Company to delay switching its listing to Nasdaq until the time of its business combination will allow Nasdaq to process both the removal of the Acquisition Company and the simultaneous addition of the operating company, which will help ensure that the transaction is processed smoothly for the benefit of the company's investors.[10]

Pursuant to the proposed rule change, Nasdaq proposes to treat as an Eligible Switch any company that switches its listing from NYSE and lists on Nasdaq under IM–5101–2 after the company has publicly announced that it entered into a binding agreement for a business combination and that subsequently satisfies the conditions in IM–5101–2(b) and lists on the Global or Global Select Market in conjunction with that business combination.[11] Nasdaq states

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[10] 15 U.S.C. 78s(b)(2).

[11] *Id.*

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 89875 (September 15, 2020), 85 FR 59346 (''Notice'').

[4] IM–5101–2 imposes additional listing requirements on a company whose business plan is to complete an initial public offering (''IPO'') and engage in a merger or acquisition with one or more unidentified companies within a specific period of time (''Acquisition Companies'').

[5] *See* Notice, *supra* note 3, 85 FR at 59347. As Nasdaq states in its rule proposal, the combined company would again have to satisfy all initial listing requirements at the time of the business combination. *See* IM–5101–2(d) and (e); Notice, *supra* note 3, 85 FR at 59347. If the Company does not meet the requirements for initial listing or does not comply with one of the requirements set forth in IM–5101–2, Nasdaq will issue a Staff Delisting Determination under Nasdaq Rule 5810 to delist the company's securities.

[6] *See* IM–5900–7(e). Specifically, within 36 months of the effectiveness of its IPO registration statement, or such shorter period that the company specifies in its registration statement, the company must complete one or more business combinations having an aggregate fair market value of at least 80% of the value of the deposit account (excluding any deferred underwriters fees and taxes payable on the income earned on the deposit account) at the time of the agreement to enter into the initial combination. *See* IM–5101–2(b).

[7] *See* Notice, *supra* note 3, 85 FR at 59347.

[8] *See* Notice, *supra* note 3, 85 FR at 59347. In particular, an Eligible Switch with a market capitalization less than $750 million receives the same package of services for the same two year term as an Eligible New Listing. But an Eligible Switch with a market capitalization of $750 million or more receives services with a higher total retail value than a comparably sized Eligible New Listing and will receive those services for four years instead of two years. *See* Notice, *supra* note 3, 85 FR at 59347, n.8.

[9] *See* Notice, *supra* note 3, 85 FR at 59347 (stating that in this scenario the company would not be listing on Nasdaq as an Acquisition Company).

[10] *See* Notice, *supra* note 3, 85 FR at 59347. Nasdaq states that, otherwise, multiple markets would need to coordinate the removal of the company's securities from one market, a change in the name and symbol of the securities, and the addition of securities to another market, which all occurs in conjunction with the closing of the business combination (itself a significant corporate event). *See id.*

[11] *See* proposed IM 5900–7(a)(2). According to Nasdaq, in the event that the Acquisition Company terminates the business combination that was announced when it switched, it would not be eligible to receive services as an Eligible Switch

that an Acquisition Company could only switch its listing to Nasdaq if it satisfies all of Nasdaq's initial listing requirements. Nasdaq further states that the combined company would again have to satisfy all initial listing requirements at the time of the business combination.[12] According to Nasdaq, as under existing rules, the Acquisition Company itself would not receive services as an Eligible Switch under the proposed rule and the services would only be available to the company upon completing its business combination and listing on the Nasdaq Global or Global Select Markets pursuant to the conditions described in IM–5900–7(e).[13]

Nasdaq represents that no other company will be required to pay higher fees as a result of the proposed amendments and that providing these services will have no impact on the resources available for its regulatory programs.[14]

Finally, Nasdaq states that it proposes non-substantive technical amendments to IM–5900–7. Specifically, Nasdaq states that it proposes to eliminate most of the description of the history of the rule from the rule text because it is no longer applicable to any companies. However, Nasdaq further states that it proposes to relocate to a new paragraph (g) and make minor non-substantive changes to the discussion about the 2018 change to the services offered because some companies are still eligible to receive services under the rule in effect prior to the 2018 change. Nasdaq also proposes to renumber other paragraphs of the rule in order to improve the rule's readability.[15]

III. Discussion and Commission's Findings

The Commission has carefully reviewed the proposed rule change and finds that it is consistent with the requirements of Section 6 of the Act.[16] Specifically, the Commission believes the proposed rule change is consistent with the provisions of Sections 6(b)(4) and (5) of the Act,[17] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among Exchange members, issuers, and other persons using the Exchange's facilities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Moreover, the Commission believes that the proposed rule change is consistent with Section 6(b)(8) of the Act[18] in that it does not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

The Commission believes that it is consistent with the Act for the Exchange to treat as an Eligible Switch, for purposes of IM–5900–7, an Acquisition Company that (i) switched its listing from NYSE to list on Nasdaq under IM–5101–2 after the company publicly announced that it entered into a binding agreement for a business combination; and (ii) subsequently satisfies the conditions in IM–5101–2(b) and lists on the Nasdaq Global or Global Select Markets in conjunction with that business combination. According to the Exchange, an Acquisition Company may reconsider its listing market following the public announcement of a business combination that is intended to satisfy the conditions in IM–5101–2(b) in connection with its rebranding and the launch of the operating company as a public company. Moreover, according to the Exchange, the consideration about whether to switch markets is roughly the same for an Acquisition Company that has publicly announced a business combination as it is for other companies that are considered Eligible Switches. The Exchange believes that treating the company as an Eligible Switch would provide an incentive to the company to list on Nasdaq.[19] In addition, the Exchange believes that in most instances involving an Acquisition Company that has announced a business combination, the operating company plays a significant role in deciding where to list the combined company. The Exchange asserts, accordingly, it is not unfair to treat an Acquisition Company that has announced a business combination differently from one that has not yet made such an announcement.[20]

As noted in the Commission's previous order approving IM–5900–7, Section 6(b)(5) of the Act does not require that all issuers be treated the same; rather, the Act requires that the rules of an Exchange not unfairly discriminate between issuers.[21] The Commission believes that the Exchange has reasonably justified treating an Acquisition Company transferring its listing from NYSE under the circumstances described above as an Eligible Switch and that it reflects the competition between the exchanges, with the Exchange offering a more valuable package of services for transfers of listings from a competing exchange.[22] The Commission further notes that such companies will be receiving the same package of services as any other Eligible Switch and will not be receiving any additional benefits or services by virtue of the proposed rule change. In addition, the Commission notes that if the Acquisition Company terminates its announced business combination, it would not be eligible to receive services as an Eligible Switch, but the Acquisition Company may be eligible to receive services as an Eligible New Listing if it subsequently completes a different business combination.[23]

The Commission also believes that describing in the Exchange's rules the products and services available to listed companies and their associated values will ensure that individual listed companies, including Acquisition Companies, are not given specially negotiated packages of products or services to list, or remain listed, that would raise unfair discrimination issues under the Act.[24] The Commission has previously found that the package of complimentary services offered to Eligible New Listings and Eligible Switches is equitably allocated among issuers consistent with Section 6(b)(4) of the Act and that describing the values

under the proposed rule; however, if the Acquisition Company subsequently completes a different business combination it may be eligible to receive services as an Eligible New Listing as described in existing IM–5900–7(e). *See* Notice, *supra* note 3, 85 FR at 59347, n.9.

[12] *See* Notice, *supra* note 3, 85 FR at 59347.

[13] *See* Notice, *supra* note 3, 85 FR at 59347–48.

[14] *See* Notice, *supra* note 3, 85 FR at 59348.

[15] *See* Notice, *supra* note 3, 85 FR at 59348.

[16] 15 U.S.C. 78f. In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(4) and (5).

[18] 15 U.S.C. 78f(b)(8).

[19] *See* Notice, *supra* note 3, 85 FR at 59348.

[20] *See id.*

[21] 15 U.S.C. 78f(b)(5); *see also* Securities Exchange Act Release No. 65963 (December 15, 2011), 76 FR 79262, 79266 (December 21, 2011) (approving NASDAQ–2011–122) (''2011 Approval Order'') (''The Commission believes that NASDAQ has provided a sufficient basis for its different treatment of Eligible Switches and that this portion of NASDAQ's proposal meets the requirements of the Act in that it reflects competition between exchanges, with NASDAQ offering discounts for transfers of listings from a competing exchange.'').

[22] *See supra* note 8 and accompanying text.

[23] *See supra* note 11.

[24] *See* Securities Exchange Act Release No. 79366 (November 21, 2016), 81 FR 85663, 85665 (November 28, 2016) (approving Nasdaq–2016–106) (''2016 Approval Order'') (citing Securities Exchange Act Release No. 65127 (August 12, 2011), 76 FR 51449, 51452 (August 18, 2011) (approving NYSE–2011–20)). The Commission notes that the Exchange represents that no other company will be required to pay higher fees as a result of the proposal and that the proposal will have no impact on the resources available for its regulatory programs. *See supra* note 14 and accompanying text.

of the services adds greater transparency to the Exchange's rules and to the fees applicable to such companies.[25] Based on the foregoing, the Commission believes that the Exchange has provided a sufficient basis for treating as an Eligible Switch, for purposes of IM–5900–7, an Acquisition Company that switches from NYSE to Nasdaq after announcing a business combination and satisfies the conditions in IM–5101–2(b) and lists on the Nasdaq's Global or Global Select Markets by meeting all listing requirements and that this change does not unfairly discriminate among issuers and is therefore consistent with Section 6(b)(5) of the Act. For similar reasons, and as the value of services offered to an Eligible Switch is not changing, only whether certain Acquisition Companies are treated as an Eligible Switch instead of an Eligible Listing, the Commission believes that the proposal is consistent with Section 6(b)(4) of the Act.

Further, the Exchange asserts that its proposal removes an incentive for an Acquisition Company to wait until the consummation of a business combination to change listing exchanges if it would like to receive the more valuable package of services, which otherwise makes it more difficult to process the listing determinations smoothly.[26] As noted above, under the proposal the Acquisition Company will be treated as an Eligible Switch only in connection with the business combination that was announced prior to the transfer of its listing to Nasdaq.[27] Therefore, the proposal appears to be narrowly crafted and does not permit the company to be treated as an Eligible Switch indefinitely should the announced business combination be terminated. Based on the above, the Commission believes that the proposal should remove impediments to the operation of a free and open market and protect investors and the public interest, consistent with Section 6(b)(5) of the Act.

The Exchange has also stated that the proposal would provide an incentive for a company to list on Nasdaq given that companies often reconsider their listing market at the time of a public announcement to a business combination in connection with its rebranding and the launch of the operating company. As noted above, the Commission also believes that the Exchange is responding to competitive pressures in the market for listings in making this proposal. The Exchange states in its proposal that it faces competition in the market for listing services and the Commission understands that the Exchange competes, in part, by offering complimentary services to companies. Specifically, the Exchange is offering a more valuable listing package of complementary services to Acquisition Companies that transfer from NYSE at the time that they announce a business combination, and later satisfy the conditions in IM–5901–2(b) and all the initial listing requirements at the time of the business combination to list on the Nasdaq Global or Global Select Markets,[28] to attract new listings. Accordingly, the Commission believes that the proposed rule reflects the current competitive environment for exchange listings among national securities exchanges, and is appropriate and consistent with Section 6(b)(8) of the Act.[29]

Finally, the Commission finds that it is consistent with Section 6(b)(5) of the Act [30] for the Exchange to make various technical and conforming revisions to facilitate clarity of its Rules.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[31] that the proposed rule change, as modified by Amendment No. 1 (SR–NASDAQ–2020–060), be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28518 Filed 12–23–20; 8:45 am]

BILLING CODE 8011–01–P

[25] *See* 2016 Order, *supra* note 24, 81 FR at 85665; 2011 Approval Order, *supra* note 21, 76 FR at 79266.

[26] *See supra* note 10 and accompanying text.

[27] *See supra* note 11 and accompanying text.

[28] As Nasdaq states in its filing, ''[o]f course an Acquisition Company could only switch its listing to Nasdaq if it satisfies all of Nasdaq's initial listing requirements. In addition, the combined company would again have to satisfy all initial listing requirements at the time of the business combination.'' Notice, *supra* note 3, 85 FR at 59347.

[29] 15 U.S.C. 78f(b)(8).

[30] 15 U.S.C. 78f(b)(5).

[31] 15 U.S.C. 78s(b)(2).

[32] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. PA–56; File No. S7–21–20]

Privacy Act of 1974; System of Records

AGENCY: Securities and Exchange Commission.

ACTION: Rescindment of system of record notice.

SUMMARY: Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a) and Office of Management and Budget (OMB) Circular No. A–108, the Securities and Exchange Commission (Commission or SEC) proposes to rescind four existing systems of records. The Notice of Rescindment identifies the system of records, explains why the SORN is being rescinded, and provides an account of what will happen to the records previously maintained in the system.

DATES: The rescindments will become effective on February 8, 2021.

ADDRESSES:

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/submitcomments.htm*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–21–20 on the subject line.

Paper Comments

Send paper comments in triplicate to Vanessa A. Countryman, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to S7–21–20. This file number should be included on the subject line if email is used. To help process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/other.shtml*). Comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly.

FOR FURTHER INFORMATION CONTACT: Ronnette McDaniel, Privacy and Information Assurance Branch Chief, 202–551–7200 or *privacyhelp@sec.gov.*

SUPPLEMENTARY INFORMATION: Four systems were identified for rescindment from the SEC's Privacy Act systems of records inventory. The SORNs were identified for rescindment because they are duplicative, and covered by another SEC system of records. OMB requires that each agency provide assurance that systems of records do not duplicate any existing agency or government-wide systems of records. A description of

each rescindment justification, the applicable SORNs, and an account of what happened to the records is as follows:

1. *SEC–19:* Division of Corporation Finance and Support Office Working Files. The records in SEC–19 are duplicative of and share the same purpose as the records in SEC–68: SEC's Division of Corporation Finance Records, 83 FR 6892 (February 15, 2018).

2. *SEC–29:* Agency Correspondence Tracking System (ACTS). The records in SEC–29 are duplicative of and share the same purpose as the records in SEC–65: Investor Response Information System (IRIS), 76 FR 30213 (May 24, 2011).

3. *SEC–58:* System for Enforcement Case Tracking and Routing (SECTR). The records in SEC–58 are duplicative and share the same purpose as the records in SEC–70: SEC's Division of Trading and Market Records, 83 FR 6892 (February 15, 2018).

4. *SEC–61:* Municipal Advisor Records The records in SEC 61 are duplicative and share the same purpose as the records in SEC–62. Correspondence Files Pertaining to Municipal Advisors; Municipal Advisor Logs.

History:

System No.	**Federal Register** Number and publication date
SEC–19	Division of Corporation Finance and Support Office Working Files 40 FR 39253 (August 27, 1975).
SEC–29	Agency Correspondence Tracking System (ACTS) 40 FR 39253 (August 27, 1975) and 62 FR 47887 (September 11, 1997).
SEC–58	System for Enforcement Case Tracking and Routing (SECTR) 74 FR 36281 (July 22, 2009).
SEC–61	Municipal Advisor Records 75 FR 51854 (August 23, 2010).

By the Commission.

Dated: December 21, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–28600 Filed 12–23–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90719; File No. SR–NASDAQ–2020–087]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Exchange's Transaction Credits and Charges at Equity 7, Sections 114 and 118

December 18, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 7, 2020, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the Exchange's transaction credits [sic] at Equity 7, Sections 114 and 118, as described further below.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Presently, the Exchange provides its members with various credits for executing orders in securities priced at or above $1 that add liquidity to the Exchange and charges them various fees for executing orders, also in securities priced at or above $1 that remove liquidity from the Exchange, as set forth in Equity 7, Section 118(a) of the Exchange's Rules. Members may qualify for tiers of discounted fees and premium credits based, in part, upon the volume of their activities in securities priced at or above $1 on the Exchange as a percentage of total ''Consolidated Volume.''

Pursuant to Equity 7, Section 118(a), the term ''Consolidated Volume'' means the total consolidated volume reported to all consolidated transaction reporting plans by all exchanges and trade reporting facilities during a month in equity securities, excluding executed orders with a size of less than one round lot. For purposes of calculating Consolidated Volume and the extent of a member's trading activity the date of the annual reconstitution of the Russell Investments Indexes is excluded from both total Consolidated Volume and the member's trading activity.

Similarly, in Equity 7, Section 114, the Exchange offers several special pricing programs that are based, in part, upon members' activities in securities priced at or more than $1 relative to total Consolidated Volume. These programs provide credits to Qualified Market Makers, to members that establish the National Best Bid or Offer, and to members that grow their activity on the Exchange to a specified extent.

Generally, the ratio of consolidated volumes in securities priced at or above $1 (''dollar plus volume'') relative to securities priced below a dollar (''sub-dollar volume'') has been stable from month to month, such that ''Consolidated Volume'' has been a reasonable baseline for determining tiered and special pricing for members that execute dollar plus volume on the Exchange.

In December 2020, however, sub-dollar volume has increased dramatically and unusually relative to dollar plus volume due to activity concentrated in a handful of non-institutional firms, trading mostly one particular sub-dollar stock. Additionally, this volume spike may have been exacerbated by changes to other exchanges' pricing schemes,

which have incentivized sub-dollar trading.

Trading volume in just this one sub-dollar security comprised 9.68 percent of daily volume on December 1, 2020, and thus far in December 2020, sub-dollar volume comprises 15.75 percent of Consolidated Volume. By comparison, sub-dollar volume comprised only 8.69 percent of Consolidated Volume, on average, during the preceding 12 months.

This anomalous rise in sub-dollar volume stands to have a material adverse impact on members' qualifications for dollar plus pricing tiers and special pricing programs because such qualifications depend members upon achieving threshold percentages of volumes as a percentage of Consolidated Volume, and the extraordinary rise in sub-dollar volume stands to dilute Consolidated Volume in December 2020. As a result, members may find it more difficult, if not practically impossible, to qualify for or to continue to qualify for their existing dollar plus pricing tiers and incentives programs, even if their dollar plus volumes have not diminished relative to prior months. The Exchange notes that its members mostly have not been responsible for the spike in sub-dollar volume, such that they are likely to experience these adverse effects fully.

The Exchange believes that it would be unfair for its members that execute significant dollar plus volumes on the Exchange to fail to achieve or to lose their existing qualifications for tiered or special pricing for such volumes in December 2020 due to anomalous behavior which is entirely extraneous to them.

The Exchange is presently assessing whether the current spike in sub-dollar volumes is an isolated event or whether instead it is likely to recur. If the latter, the Exchange may wish to propose adjustments to its pricing formulas going forward to avoid extraordinary spikes in sub-dollar volumes from adversely affecting the pricing of dollar plus stock executions. In the interim, however, the Exchange believes that it would be fair and appropriate to take action to avoid adverse impacts for December 2020 pricing.

Accordingly, the Exchange proposes to amend its pricing schedule at Equity 7, Sections 114 and 118 to state that for purposes of determining which of the execution charges and credits listed therein a member qualifies for during the month of December 2020, the Exchange will calculate the member's volume and total Consolidated Volume twice. First, it will calculate the member's volume and Consolidated Volume as presently set forth in Equity 7, Section 118(a). Second, it will calculate the member's volume and Consolidated Volume by excluding volume and Consolidated Volume that consists of executed orders in securities priced less than $1. Thereafter, the Exchange proposes to evaluate which of these two member volume and Consolidated Volume calculations would qualify members for the most advantageous credits and charges for the month of December 2020 and then it will apply those credits and charges to its members. Thus, if but for the sub-dollar anomaly, a member would qualify for a higher credit or a lower fee tier in December, then the Exchange will apply that higher credit or lower fee tier to the member's trading activity during the month.

Impact of the Changes

As of December 4, 2020, the Exchange assesses that several members are at risk of failing to qualify for pricing tiers or for special inventive programs in the month of December due to sub-dollar activity. The proposal will ensure that no member suffers any such adverse impact. It will also ensure that members whose volumes in December would otherwise newly qualify them for better pricing tiers or special incentive programs will be able to achieve such qualifications.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[3] in general, and further the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[4] in particular, in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility, and is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The proposal is also consistent with Section 11A of the Act relating to the establishment of the national market system for securities.

The Exchange believes that the proposal is reasonable and equitable because in its absence, members may fail to qualify their existing pricing tiers and programs or fail to qualify for better pricing tiers or programs due to factors that are unrelated to the volumes they execute on the Exchange as well as the total consolidated volume of dollar plus securities executed on all trading venues. The Exchange does not wish to penalize members that execute significant volumes on the Exchange due to anomalous and extraneous trading activities of a small number of firms in sub-dollar securities. The proposed rule would seek to avoid such a penalty by determing whether calculating member volume and total Consolidated Volume for December to include or exclude sub-dollar volume would result in Exchange members qualifying for the most advantageous credits and charges, and then applying the calculations that would result in the pricing that is most advantageous to each member.

The Exchange notes that other exchanges have taken similar steps to avoid penalizing their members for unusual occurrences that would otherwise cause members to fail to qualify for volume-based tiered pricing.[5]

The Exchange believes that the proposed rule change is an equitable allocation and is not unfairly discriminatory because the Exchange intends for it to ensure that no member suffers adverse pricing impacts in December 2020 due to an anomalous spike in sub-dollar volumes. That is, the Exchange does not intend for the proposal to advantage any particular member; rather, it intends for the proposal to avoid disadvantaging any member.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. In terms of inter-market competition, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and credits to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee and credit changes in this

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(4) and (5).

[5] *See, e.g.,* Securities Exchange Act Release No. 34–90339 (November 4, 2020), 85 FR 71689 (November 10, 2020) (SR–PHLX–2020–50); Securities Exchange Act Release No. 34–85025 (Jan 1, 2019), 84 FR 2611 (February 7, 2019) (SR–ISE–2018–102).

market may impose any burden on competition is extremely limited.

In this instance, the proposal does not impose a burden on competition because the Exchange's execution services are completely voluntary and subject to extensive competition both from other exchanges and from off-exchange venues. If the changes proposed herein are unattractive to market participants, it is likely that the Exchange will lose market share as a result.

The Exchange does not believe that the proposal will burden intra-market competition. As noted above, the proposal will simply help to ensure that no member suffers a pricing disadvantage in December 2020 due to an anomalous spike in sub-dollar volumes which dilutes Consolidated Volume. It is not intended to provide a competitive advantage to any particular member.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[6]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NASDAQ–2020–087 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2020–087. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2020–087 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28513 Filed 12–23–20; 8:45 am]

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[6] 15 U.S.C. 78s(b)(3)(A)(ii).

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90722; File No. SR–NYSEAMER–2020–86]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Shorten the Time Period Before a Letter of Acceptance, Waiver, and Consent Under Rule 9216 and an Uncontested Offer of Settlement Under Rule 9270(f) Becomes Final

December 18, 2020

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that on December 17, 2020, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to shorten the time period before a letter of acceptance, waiver, and consent under Rule 9216 and an uncontested offer of settlement under Rule 9270(f) becomes final and the corresponding time period to request review of these settlements under Rule 9310 from 25 days to 10 days. The Exchange also proposes to define ''affiliate'' in Rules 9268 and 9310 by reference to the definition in the Act, thereby harmonizing its rules with those of its affiliates. The proposed rule change is available on the Exchange's website at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to shorten the time period before a letter of acceptance, waiver, and consent (''AWC'') under Rule 9216 and an uncontested offer of settlement under Rule 9270(f) becomes final and the corresponding time period to request review of these settlements under Rule 9310 from 25 days to 10 days. The Exchange also proposes to define ''affiliate'' in Rules 9268 and 9310 by reference to the definition in the Act, thereby harmonizing its rules with those of its affiliates.

In 2016, NYSE American adopted disciplinary rules that are, with certain exceptions, substantially the same as the FINRA Rule 8000 Series and Rule 9000 Series, and which set forth rules for conducting investigations and enforcement actions.[4] The NYSE American disciplinary rules were implemented on April 15, 2016.[5]

In adopting disciplinary rules modeled on FINRA's rules, the Exchange established processes for settling disciplinary matters both before and after issuance of a complaint.[6] As adopted, Rules 9216, 9270 and 9310 permit a Director and any member of the Committee for Review (''CFR'') to require a review by the Board of any AWC letter under Rule 9216 and any offer of settlement under Rule 9270 within 25 days after the AWC letter or offer of settlement was sent to each Director and each member of the CFR.

Proposed Rule Change

Time Period for Certain Settlements Under Rules 9216 and 9270(f)

Rule 9216 (Acceptance, Waiver, and Consent; Procedure for Imposition of Fines for Minor Violation(s) of Rules) establishes AWC procedures by which a member organization or covered person, prior to the issuance of a complaint, may execute a letter accepting a finding of violation, consenting to the imposition of sanctions, and agreeing to waive such member organization's or covered person's right to a hearing, appeal and certain other procedures. The rule also establishes procedures for executing a minor rule violation plan letter.

Under Rule 9216(a)(4), an AWC accepted by the Chief Regulatory Officer (''CRO'') must be sent to each Director and each member of the CFR and would be deemed final and constitute the complaint, answer, and decision in the matter 25 days after being sent to each Director and each member of the CFR, unless review by the Exchange Board of Directors is requested pursuant to Rule 9310(a)(1)(B).[7]

The Exchange proposes that an AWC accepted by the CRO would be deemed final and constitute the complaint, answer, and decision in a matter 10 days after being sent to each Director and each member of the CFR, unless review is requested pursuant to Rule 9310(a)(1)(B)(i). As described below, the time period to request review under Rule 9310(a)(1)(B)(i) would also be shortened to 10 days.

Rule 9270 (Settlement Procedure) provides a settlement procedure for a Respondent who has been notified of the initiation of a proceeding. Specifically, Rule 9270(f) provides that uncontested settlement offers accepted by the CRO, the Hearing Panel or, if applicable, Extended Hearing Panel must be issued and sent to each Director and each member of the CFR and becomes final 25 days after being sent to each Director and each member of the CFR, unless review by the Exchange Board of Directors is requested pursuant to Rule 9310(a)(1).

The Exchange proposes that uncontested settlement offers accepted by the CRO, the Hearing Panel or, if applicable, Extended Hearing Panel (together, a ''Panel'') under Rule 9270(f) would become final 10 days after being sent to each Director and each member of the CFR, unless review by the Exchange Board of Directors is requested pursuant to Rule 9310(a)(1). As noted, the time to request review of an uncontested settlement under Rule 9310(a)(1) would also be shortened to 10 days.

Finally, under Rule 9310(a)(1)(B)(i), any Director and any member of the CFR may require a review by the Board of any determination or penalty, or both, imposed in connection with an AWC letter under Rule 9216 or an offer of settlement determined to be uncontested before a hearing on the merits has begun under Rule 9270(f), except that none of those persons could request Board review of a determination or penalty concerning an affiliate of the Exchange.[8] A request for review under this provision is made by filing with the Secretary of the Exchange a written request stating the basis and reasons for such review, within 25 days after an AWC letter or an offer of settlement has been sent to each Director and each member of the CFR pursuant to Rule 9216(a)(4) or Rule 9270(f)(3).

To permit AWC letters and uncontested settlements to become final within 10 days as proposed, the Exchange would amend Rule 9310(a)(1)(B)(i) to provide that a request for review of these settlements as permitted by the rule must be made by filing the requisite written request with the Secretary of the Exchange within 10 days after the AWC letter or an offer of settlement is sent to each Director and each member of the CFR pursuant to Rule 9216(a)(4) or Rule 9270(f)(3).[9]

The Exchange believes maintaining a 25 day waiting period for negotiated settlements under Rule 9216 and uncontested settlements pursuant to 9270(f) unnecessarily delays final resolution of matters that have been resolved by the parties and accepted by the CRO or a Panel. Shortening the waiting period to 10 days, and requiring requests for Board of Directors review to be made within that same 10 day period, would significantly expedite the settlement process in situations where member organizations, covered persons and Respondents have entered into a consensual, negotiated settlement with Enforcement or made settlement offers that Enforcement does not oppose, while continuing to ensure the independence and integrity of the regulatory process by preserving the ability of Directors and CFR members to call those settlements for review.

[4] *See* Securities Exchange Act Release No. 77241 (February 26, 2016), 81 FR 11311 (March 3, 2016) (SR–NYSEMKT–2016–30) (''Notice'').

[5] *See* Information Memorandum 16–02 (March 14, 2016).

[6] *See* Notice, 81 FR at 11324–28.

[7] Requests for review of an AWC accepted by the CRO are governed by Rule 9310(a)(1)(B)(i). For the sake of clarity and transparency, the Exchange proposes the non-substantive change of including the omitted reference to subsection (B)(i) of Rule 9310(a)(1) in both in the current and proposed text of Rule 9216(a)(4).

[8] As discussed below, the Exchange proposes to amend Rule 9310 and Rule 9268 to incorporate the definition of ''affiliate'' from Rule 12b-2 under the Act, thereby harmonizing those rules with those of its affiliates.

[9] The time period for requesting review pursuant to Rule 9310(a)(1)(B)(ii) of any rejection by the CRO of any AWC letter under Rule 9216 or of an uncontested offer of settlement under Rule 9270(f), would remain unchanged as would the time period to request for review of any determination or penalty, or both, imposed by a Panel under the Rule 9310(a)(1)(A) other than an offer of settlement determined to be uncontested after a hearing on the merits have begun under Rule 9270(f). For the avoidance of doubt, the Exchange would add text to Rule 9310(a)(1)(A) providing that any request for review of an offer of settlement determined to be uncontested after a hearing on the merits has begun under Rule 9270(f) that has been accepted by a Panel shall be governed by Rule 9310((a)(1)(B)(i).

Further, the Exchange believes that the proposed 10 day period to call a settlement for review under Rule 9310(a)(1)(B)(i) is reasonable and sufficient. Like the current 25 day period, the time to call a settlement for review would begin when the AWC or uncontested settlement is sent to each Director and member of the CFR. Rules 9216 and 9270 specify that an AWC or uncontested settlement accepted by the CRO or a Panel can be sent to each Director and each CFR member via courier, express delivery or electronic means. As a practical matter, AWCs and settlements are sent to the Directors and CFR members by email, which ensures prompt and instantaneous communication. As a result, the Directors and members of the CFR will have the full 10 day period to determine whether to call these settlements for review. Moreover, the requirement in Rule 9310(a)(1)(B)(i) that a request for review be in writing and state the basis and reasons for such review can similarly be satisfied by a Director or CFR member sending an email to the Secretary of the Exchange requesting that a specific matter be reviewed within the proposed 10 day period. The Director or CFR member would need to take no additional steps nor include any additional information in order to call a matter for review under Rule 9310(a)(1)(B)(i). In light of these facts, and the relative infrequency of calls for review of AWCs and uncontested settlements,[10] the Exchange believes that 10 days are more than sufficient for a Director or member of the CFR to determine whether to call a settlement for review. Once accepted by the CRO or Panel, the proposed 10 day period for negotiated settlements to be called for review or become final would expedite disciplinary proceedings and provide finality to the disciplinary process sooner, to the benefit of the parties and the investing public.

Finally, the Exchange also believes that shortening these time periods would further promote efficiency in connection with cross-market settlements involving multiple self-regulatory organizations (''SROs''). Often such settlements are contingent upon the acceptance of a settlement by all of the SROs involved in the matter. In these situations, a settlement with the Exchange would not be final until the end of the time period specified in Rules 9216 and 9270 while a settlement with other SROs could be final once accepted.[11] Thus by reducing the amount of time these settlements are outstanding at the Exchange, the proposed change could speed up the settlement process for cross-market settlements involving multiple SROs, to the benefit of the parties and the investing public.

The Exchange intends to announce the operative date of the amended time periods in Rules 9216(a)(4), 9270(f)(3) and 9310(a)(1) at least 30 days in advance via regulatory notice.[12] To further facilitate an orderly transition from the current rules to the new rules, the Exchange proposes that matters already initiated under the current rules would be completed under such rules. Specifically, the Exchange proposes to apply the current 25 day period for AWCs prepared and submitted to a member organization or covered persons under Rule 9216(a)(1) prior to the operative date and to uncontested settlement offers in proceedings where a Party was served with a complaint by Enforcement pursuant to Rule 9131 prior to the operative date. Rules 9216(a)(4), 9270(f)(3) and 9310(a)(1)(B)(i) would be amended to reflect the transition process. When the transition is complete, the Exchange intends to submit a proposed rule change that would delete the unnecessary transition provisions of 9216(a)(4), 9270(f)(3) and 9310(a)(1)(B)(i).

Definition of ''Affiliate'' in Rules 9268 and 9310

The Exchange proposes to harmonize Rules 9268 and 9310 with the versions adopted by the Exchange's affiliates. To effectuate this harmonization, the Exchange proposes to delete the phrase ''an Exchange member or member organization that is'' before ''an affiliate'' and add the phrase ''as such term is defined in Rule 12b–2 under the Exchange Act'' after ''an affiliate'' in Rule 9268(e)(2) and Rule 9310(a)(1)(A) & (a)(1)(B)(i)–(ii).[13] The Exchange believes that utilizing the definition of affiliate set forth in in Rule 12b–2 under the Act would not diminish the current scope or application of either rule since the proposed definition of affiliate would continue to encompass members and member organizations. Finally, by harmonizing Rules 9268 and 9310 with the version of those rules adopted by the Exchange's affiliates, the proposal would add clarity and transparency to the Exchange's rules and further ensure that final determinations involving Exchange affiliates as defined in Rule 12b–2 under the Act cannot be appealed to its Board of Directors.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[14] in general, and furthers the objectives of Section 6(b)(5),[15] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[16] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

Specifically, the Exchange believes that shortening the waiting period for negotiated settlements and uncontested offers of settlement would serve to expedite the final resolution of both Exchange and cross-market matters that have been resolved by the parties and accepted by the CRO or Panel, thereby protecting investors and the public interest by addressing rule violations and achieving finality in disciplinary matters sooner. The proposed rule change to shorten the waiting period before an AWC letter and offer of settlement becomes final and the member of CFR or Board's time to call such settlements for review will

[10] For example, no AWC letter or uncontested settlement has been called for review in the past year.

[11] *See, e.g.,* FINRA Rule 9216(a)(4) (''If the [AWC] letter is accepted by the National Adjudicatory Council, the Review Subcommittee, or the Office of Disciplinary Affairs, it shall be deemed final and shall constitute the complaint, answer, and decision in the matter.''); FINRA Rule 9270(e)(3) (''If the offer of settlement and order of acceptance are accepted by the National Adjudicatory Council, the Review Subcommittee, or the Office of Disciplinary Affairs, they shall become final and the Director of the Office of Disciplinary Affairs shall issue the order and notify the Office of Hearing Officers. The Department of Enforcement shall provide a copy of an issued order of acceptance to each FINRA member with which a Respondent is associated.''). *See also e.g.,* Nasdaq Rule 9216(a)(4) & 9270(e)(3); Cboe BZX Exchange, Inc. Rule 8.8(a); Cboe EDGA Exchange, Inc. Rule 8.8(a).

[12] The effective date of the new time periods would be simultaneously communicated to the Directors and to the members of the CFR.

[13] *See* NYSE Rules 9268(e)(2) and 9310(a)(1)(A) & (a)(1)(B)(i)–(ii); NYSE Arca, Inc. Rules 10.9268(e)(2) and 10.9310(a)(1)(A) & (a)(1)(B)(i)–(ii); and NYSE National, Inc. Rules 10.9268.e.2. and 10.9310.a.1.A. & a.1.Bi.–ii. *See also* Securities Exchange Act Release No. 88613 (April 9, 2020), 85 FR 21035 (April 15, 2020) (SR–NYSE–2020–33).

[14] 15 U.S.C. 78f(b).

[15] 15 U.S.C. 78f(b)(5).

[16] *Id.*

therefore provide for a more efficient, streamlined disciplinary process.

The Exchange further believes that the proposed amendments are consistent with Section 6(b)(6) of the Act,[17] which provides that members and persons associated with members shall be appropriately disciplined for violation of the provisions of the rules of an exchange by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a member, or any other fitting sanction. As noted, the proposed changes will not affect the ability of Enforcement to enter into negotiated settlements or accepting uncontested settlement offers when appropriate, and will not alter the requirement that settlements be scrutinized by the CRO or Panel, who will continue to approve them, or the Directors and members of the CFR, whose right to call both types of voluntary settlements for review will not change.

For the same reasons, the Exchange believes that the proposed changes are designed to provide a fair procedure for the disciplining of members and persons associated with members, consistent with Sections 6(b)(7) and 6(d) of the Act.[18] Moreover, as noted, the Exchange believes that the proposed 10 day period to call a settlement for review under Rules 9310(a)(1)(B)(i) is reasonable and sufficient, and provides an appropriate balance between the procedural safeguards of the call for review process and the benefits of expediting the resolution of disciplinary matters and providing finality to the disciplinary process sooner. Reducing the period for review would also mean that AWCs and uncontested settlements would be published two weeks earlier, thereby allowing member organizations, covered persons and the investing public to be educated about the issues they addressed sooner. Finally, the Exchange believes that the proposed transition plan is designed to provide a fair procedure for the disciplining of member organizations and covered persons by providing for a clearly demarcated and orderly transition from the current 25 day period to the proposed 10 day period.

Further, the Exchange believes that the non-substantive changes to clarify the cross-reference to Rule 9310 in Rules 9216 and amending Rules 9268 and 9310 to reference the Act's definition of ''affiliate'' would remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest because the proposed non-substantive changes would add clarity, transparency and consistency to the Exchange's disciplinary rules. The Exchange believes that market participants would benefit from the increased clarity, thereby reducing potential confusion and ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rules. Similarly, the Exchange believes that the proposed amendments to Rules 9268 and 9270 would also make the Exchange's disciplinary rules more consistent with the rules of its affiliates, thereby ensuring that persons subject to the Exchange's jurisdiction, regulators, and the investing public can more easily navigate and understand the Exchange's rules.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is not intended to address competitive issues but is rather concerned with facilitating less burdensome regulatory compliance and processes and enhancing the quality of the regulatory process. The Exchange believes the proposed rule changes would reduce the burdens within the disciplinary process, as well as move matters through the process expeditiously by providing for more efficient finality of negotiated settlements and offers of settlement, to the benefit of all member organizations, covered persons and the investing public.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[19] and subparagraph (f)(6) of Rule 19b–4 thereunder.[20]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2020–86 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAMER–2020–86. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the

[17] 15 U.S.C. 78f(b)(6).

[18] 15 U.S.C. 78f(b)(7) and 78f(d).

[19] 15 U.S.C. 78s(b)(3)(A)(iii).

[20] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEAMER–2020–86, and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

J. Matthew DeLesDernier,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90732; File Nos. SR–NYSE–2020–73, SR–NYSEAMER–2020–66, SR–NYSENAT–2020–28, SR–NYSEArca–2020–82, SR–NYSECHX–2020–26]

Self-Regulatory Organizations; New York Stock Exchange LLC; NYSE American LLC; NYSE National, Inc.; NYSE Arca, Inc.; NYSE Chicago, Inc.; Notice of Filings of Amendment No. 1 and Order Granting Approval of Proposed Rule Changes, Each as Modified by Amendment No. 1, Amending the Exchanges' Co-Location Services To Establish Procedures for the Allocation of Cabinets to Co-Located Users if Cabinet Inventory Falls Below Certain Thresholds

December 18, 2020.

I. Introduction

On September 2, 2020, New York Stock Exchange LLC, NYSE American, LLC, NYSE National, Inc., NYSE Arca, Inc., and NYSE Chicago, Inc. (the ''Exchanges'') each filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish procedures for the allocation of cabinets to co-located Users if the Exchange cannot satisfy all User demand for cabinets.[3] Each proposed rule change was published for comment in the **Federal Register** on September 21, 2020[4] or September 22, 2020.[5] On November 3, 2020, the Commission extended the time period within which to approve, disapprove, or institute proceedings to determine whether to approve or disapprove the proposed rule changes.[6] The Commission received no comments on the proposed rule changes. On December 16, 2020, each Exchange filed Amendment No. 1 to its proposed rule change.[7] Amendment No. 1 replaces and supersedes each of the original filings in their entirety. This order provides notice of the filings of Amendment No. 1 to each of the proposed rule changes, and grants approval of the proposed rule changes, each as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Changes, as Modified by Amendment No. 1.

As more fully set forth in the Notices and their co-location fee schedules, the Exchanges offer co-location customers (''Users'')[8] options for purchasing cabinet space to house their servers and other equipment in co-location.[9] Cabinets are offered as dedicated cabinets or partial cabinets, and currently made available on a first-come, first-serve basis.[10] Users are assessed an initial fee depending on type of cabinet purchased, and a monthly fee based on the power, in kilowatts (kW), they purchase with the cabinet.[11] Users can also purchase

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See infra* note 8 for the definition of ''User.''

[4] *See* Securities Exchange Act Release Nos. 89879 (September 15, 2020), 85 FR 59361 (SR–NYSE–2020–73); 89880 (September 15, 2020), 85 FR 59365 (SR–NYSEAMER–2020–66) (each, a ''Notice'').

[5] *See* Securities Exchange Act Release Nos. 89884 (September 16, 2020), 85 FR 59576 (SR–NYSENAT–2020–28); 89883 (September 16, 2020), 85 FR 59568 (SR–NYSEArca-2020–82); 89886 (September 16, 2020) 85 FR 59582 (SR–NYSECHX–2020–26) (each, a ''Notice''). For ease of reference, page citations to the Notices refer to the Notice for SR–NYSE–2020–73, *supra* note 4, as published in the **Federal Register**.

[6] *See* Securities Exchange Act Release Nos. 90330 (November 3, 2020), 85 FR 71364 (November 9, 2020) (SR–NYSE–2020–73) and 90327 (November 3, 2020), 5 FR 71373 (November 9, 2020) (SR–NYSEAMER–2020–66), in which the Commission designated December 20, 2020 as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove these proposed rule changes; and Securities Exchange Act Release Nos. 90329 (November 3, 2020) 85 FR 71381 (November 9, 2020) (SR–NYSENAT–2020–28); 90326 (November 3, 2020) 85 FR 71365 (November 9, 2020) (SR–NYSEArca–2020–82); 90328 (November 3, 2020) 85 FR 71373 (November 9, 2020) 85 FR 71384 (November 9, 2020) (SR–NYSECHX–2020–26), in which the Commission designated December 21, 2020 as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove these proposed rule changes.

[7] Amendment No. 1 revises the proposals by: (i) Adding representations that the Exchanges are not presently in a situation where they cannot satisfy all User demand for cabinets; do not anticipate being so in the foreseeable future; and are currently working to expand the number of cabinets available in co-location; (ii) stating that the Cabinet Threshold level of 40 cabinets (chosen as a threshold not easily triggered) is offered as a reasonable buffer during which the Purchasing Limits would apply before the Cabinet Waitlist would become effective; (iii) clarifying that the determination of the whether the Cabinet Threshold is reached is not dependent on whether cabinets are configured to be subdivided into partial cabinets; (iv) specifying that if the Purchasing Limit of a maximum of four new dedicated cabinets applies, the maximum may be comprised of a mix of dedicated and partial cabinets, with two partial cabinets counting as one dedicated cabinet; (v) clarifying that if a User requests, in writing, a number of cabinets that, if provided, would cause the available cabinet inventory to be below 40 cabinets, the Purchasing Limits would only apply to the portion of the User's order below the Cabinet Threshold; and (vi) deleting the initially proposed 8 kW power limit for new dedicated cabinets when the cabinet Purchasing Limits are in effect. Amendment No 1 for each filing is available on the Commission's website at: *https://www.sec.gov/comments/sr-nyse-2020-73/srnyse202073-8154095-226755.pdf; https://www.sec.gov/comments/sr-nyseamer-2020-66/srnyseamer202066-8154097-226756.pdf; https://www.sec.gov/comments/sr-nysenat-2020-28/srnysenat202028-8154096-226737.pdf; https://www.sec.gov/comments/sr-nysearca-2020-82/srnysearca202082-8154094-226736.pdf; https://www.sec.gov/comments/sr-nysechx-2020-26/srnysechx202026-8154093-226754.pdf.*

[8] For purposes of the Exchanges' co-location services, a ''User'' means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). A User that incurs co-location fees for a particular co-location service pursuant to any one Exchange's co-location price list is not subject to co-location fees for the same co-location service charged by an affiliated SRO. *See* Notice, *supra* note 4 at n. 5.

[9] *See* Notice, *supra* note 4 at 59362. *See also, e.g.,* NYSE Price List, available at: *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf.*

[10] *See* Notice, *supra* note 5 at 59362.

[11] Partial cabinets are available in 8-rack units of space with power with options to purchase 1 kW (for $1,500 per month) or 2kW (for $2,700 per month) of power. A dedicated cabinet includes enough space for approximately four separate eight-rack units and includes the following options to purchase power: 4–8 kW (for $1,200 per month), 9–20 kW (for $1,050 per month), 21–40 kW (for $950 per month), and 41 or more kW (for $900 per month). *See* Securities Exchange Act Release Nos. 70978 (December 4, 2013), 78 FR 77739, 77740 (December 24, 2013) (SR–NYSE–2013–81); 71131 (December 18, 2013), 78 FR 77750 (December 24, 2013) (SR–NYSEMKT–2013–103); 71130 (December 18, 2013), 78 FR 77765 (December 24, 2013) (SR–NYSEArca–2013–143); 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07);87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12) (adding partial cabinets and related pricing). *See* Securities Exchange Act Release Nos. 62732 (August 16, 2010), 75 FR 51512, 51513 (August 20,

Continued

''PNU cabinets,'' which are cabinets in which power is not utilized. PNU cabinets are reserved cabinet space that may be converted to a dedicated cabinet when the User requests it.[12]

The Exchanges propose to amend their co-location rules to add new General Notes 7 and 8 to each fee schedule setting forth procedures for allocating cabinet space if, in the future, a situation arises where the Exchanges cannot fully satisfy User demand for the purchase of new cabinets.[13] The Exchanges represent that they are not presently in such a situation, do not anticipate being so in the foreseeable future, and are currently working to expand the number of cabinets available in co-location, but believe that it would be prudent to have cabinet allocation procedures in place to address demand for the purchase of new cabinets if needed.[14]

As further described below, if cabinet inventory falls to 40 cabinets or fewer (the ''Cabinet Threshold''), certain limits (''Purchasing Limits'') would apply to the purchase of new cabinets and remain in effect until unallocated cabinet inventory is more than 40 cabinets. Further, if the available cabinet inventory is zero, the Exchanges would create and maintain a waitlist (''Cabinet Waitlist'') until unallocated cabinet inventory is more than 10 cabinets.

If unallocated cabinet inventory is at or below 40 cabinets, whether or not such cabinets are configured to be subdivided into partial cabinets, the following Purchasing Limits would apply: [15] (i) A User with PNU cabinets would be required to either convert its PNU cabinets into dedicated cabinets or relinquish its PNU cabinets before being permitted to purchase new cabinets; [16] (ii) a User's purchase of new cabinets (dedicated and partial) would be limited to a maximum of four dedicated cabinets, which maximum may be comprised of a mix of dedicated and partial cabinets, with two partial cabinets counting as one dedicated cabinet; [17] (iii) If a User requests, in writing, a number of cabinets that, if provided, would cause the available cabinet inventory to be below 40 cabinets, the Purchasing Limits would only apply to the portion of the User's order below the Cabinet Threshold; [18] (iv) a User purchasing new cabinets would be required to wait 30 days from the date of its signed order form before purchasing new cabinets again; [19] and (v) new PNU cabinets would not be offered.[20] These Purchasing Limits would be discontinued when the unallocated cabinet inventory is more than 40 cabinets.[21]

If the available cabinet inventory is zero, or a User submits a written request for a number of cabinets that, if provided, would cause the available cabinet inventory to be zero, the Exchanges would create and maintain a Cabinet Waitlist, as follows: [22] (i) A User with PNU cabinets would be placed on the waitlist for the portion of its new cabinet request that exceeds its existing PNU cabinets (subject to the Purchasing Limits), and the User would not be placed on the waitlist if it could meet its request by converting its PNU cabinets to dedicated cabinets; [23] (ii) a User would be placed on the waitlist based on the date its signed order is received and may only have one order for new cabinets that is subject to the Purchasing Limits on the waitlist at a time; (iii) as cabinets become available, the Exchanges would offer them to the User at the top of the waitlist.[24]

In addition, a User would be removed from the Cabinet Waitlist when its order is completed and would remain at the top of the Cabinet Waitlist if its order is not completed.[25] A User would be removed from the Cabinet Waitlist (a) at the User's request or (b) if the User turns down an offer of a cabinet of the same size it requested in its order.[26] The User may turn down an Exchange's offer of a cabinet of a different size than the User requested in its order and remain at the top of the waitlist until its order is completed.[27] A User that is removed from the Cabinet Waitlist but subsequently submits a new written order for cabinets would be added to the bottom of the Cabinet Waitlist.[28] The Exchanges would cease use of the Cabinet Waitlist when unallocated cabinet inventory is more than 10 cabinets.[29]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule changes, each as modified by Amendment No. 1, are consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.[30] In particular, the Commission finds that the proposed rule changes, each is modified by Amendment No. 1, are consistent with Section 6(b)(5) of the Act,[31] which requires that the rules of a national securities exchange be designed, among

2010) (SR–NYSE–2010–56); 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56); 65237 (August 31, 2011), 76 FR 55432 (September 7, 2011) (SR–NYSE–2011–46); 62731 (August 16, 2010), 75 FR 51515 (August 20, 2010) (SR–NYSEAmex–2010–80); 62961 (September 21, 2010), 75 FR 59299 (September 27, 2010) (SR–NYSEAmex-2010–80); 65240 (August 31, 2011), 76 FR 55434 (September 7, 2011) (SR–NYSEAmex-2011–65); 63275 (November 8, 2010), 75 FR 70048 (November 16, 2010) (SR–NYSEArca–2010–100); 65236 (August 31, 2011), 76 FR 55437 (September 7, 2011) (SR–NYSEArca–2011–65); 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07);87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12) (adding dedicated cabinets and related pricing).

[12] PNU cabinets are available at a monthly charge of $360 per kW allocated to the PNU cabinet. *See* Securities Exchange Act Release Nos. 70913 (November 21, 2013), 78 FR 70987, 70988 (November 27, 2013) (SR–NYSE–2013–74); 70914 (November 21, 2013), 78 FR 71000 (November 27, 2013) (SR–NYSEMKT–2013–93); 70916 (November 21, 2013), 78 FR 70989 (November 27, 2013) (SR–NYSEArca–2013–124); 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07); 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12).

[13] *See* Notice, *supra* note 4 at 59362.

[14] *See* Amendment No. 1.

[15] *See* Notice, *supra* note 4 at 59362 and Amendment No. 1.

[16] *See* Notice, *supra* note 4, at 59363.

[17] *See id.* and Amendment No. 1 (specifying that the maximum may be comprised of a mix of dedicated and partial cabinets, with two partial cabinets counting as one dedicated cabinet.) In the original Notices, the proposed that when the Purchasing Limits were in effect, Users would be limited to purchasing 8 kW of power when purchasing a new dedicated cabinet. In Amendment No. 1, the Exchanges deleted this proposed limitation. Noting that the they makes dedicated cabinets available with standard power allocation of either 4 kW or 8 kW, and that partial cabinets are available in increments of eight-rack units of space, and each eight-rack unit may be allocated up to 2 kW, the Exchanges also noted that currently a User may request power upgrades to dedicated cabinets beyond 8 kW. *See* Securities Exchange Act Release Nos. 70978 (December 18, 2013), 78 FR 77739 (December 24, 2013) (SR–NYSE–2013–81); 71131 (December 18, 2013), 78 FR 77750 (December 24, 2013) (SR–NYSEMKT–2013–103); 71130 (December 18, 2013), 78 FR 77765 (December 24, 2014) (SR–NYSEArca–2013–143); 83351 (May 31, 2018), 83 FR 26314 (June 6, 2018) (SR–NYSENAT–2018–07); and 87408 (October 28, 2019), 84 FR 58778 (November 1, 2019) (SR–NYSECHX–2019–12).

[18] *See* Amendment No. 1. For example, if the Exchange had 50 available cabinets and a User requested to purchase 20 cabinets, the Purchasing Limits would not apply to the User's purchase of the first 10 cabinets. Once the available inventory reached 40 cabinets, the Purchasing Limits would be activated, limiting the User's purchase of additional cabinets to 4 cabinets. In all, the User would be permitted to purchase a total of 14 cabinets out of its original order of 20 cabinets. *Id.*

[19] *See* Notice, *supra* note 4, at 59363.

[20] *Id.*

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] In approving this proposed rule change, as modified by Amendment No. 1, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[31] 15 U.S.C. 78f(b)(5).

other things, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest, and not be designed to permit unfair discrimination between customers, issuers, brokers or dealers.

The Exchanges propose rational, objective procedures for allocating cabinet space in a situation in which all User demand cannot fully be satisfied, and particularly for responding to User demand for new cabinets when inventory falls and remains below specified thresholds. As noted above, the Exchanges represent that they are not presently in such a situation, do not anticipate being so in the foreseeable future, and are currently working to expand the number of cabinets available in co-location.

The proposed cabinet allocation procedures, establishing a Purchasing Limit on order size for new cabinet space when the Cabinet Threshold is reached and a Cabinet Waitlist when inventory falls to zero, are measures designed to respond to increasing demand for cabinets and facilitate an equitable distribution of new cabinet purchases if cabinet inventory becomes limited. The Commission notes the Exchanges' representation that the proposed Cabinet Threshold of 40 cabinets would not be easily triggered, yet would establish a reasonable buffer before the Cabinet Waitlist is effective. Because the Purchasing Limits provide a method for making limited cabinet space available to Users requesting new cabinets that is transparent, as well as reasonably designed to accommodate Users' needs while mitigating the potential for some Users to seek to obtain additional cabinet space resulting in limitations on other Users, the Commission believes the Purchasing Limits would promote just and equitable principles of trade and protect investors and the public interest and are not designed to permit unfair discrimination between customers, issuers, brokers or dealers.

Further, the Commission believes that the establishment of the Cabinet Waitlist based on the date of receipt of signed orders, limiting the size and number of orders a User may have on the waitlist at any one time, and removing a User from the waitlist if it turns down a cabinet that is the size that it requested, should prevent Users from utilizing the waitlist as a method to obtain a greater portion of the cabinets available, thereby facilitating a more equitable distribution of cabinets. Similarly, a 30-day delay before a User subject to the Purchasing Limits could purchase cabinets again, is reasonably designed to prevent a User from obtaining a greater portion of the cabinets available.

For the foregoing reasons, Commission finds that the proposals, each as modified by Amendment No. 1, are consistent with the Act.

IV. Solicitation of Comments on Amendment No. 1

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether Amendment No. 1 to the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Numbers SR–NYSE–2020–73, SR–NYSEAMER–2020–66, SR–NYSENAT–2020–28, SR–NYSEArca–2020–82, SR–NYSECHX–2020–26 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Numbers SR–NYSE–2020–73, SR–NYSEAMER–2020–66, SR–NYSENAT–2020–28, SR–NYSEArca–2020–82, SR–NYSECHX–2020–26. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Numbers SR–NYSE–2020–73, SR–NYSEAMER–2020–66, SR–NYSENAT–2020–28, SR–NYSEArca–2020–82, SR–NYSECHX–2020–26 and should be submitted on or before January 19, 2021.

V. Accelerated Approval of Proposed Rule Changes, Each as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule changes, each as modified by Amendment No. 1, prior to the 30th day after the date of publication of notice of Amendment No. 1 in the *Federal Register*. As noted above, Amendment No. 1. revises the proposals by: (i) Adding the Exchanges' representations that they are not presently in a situation where they cannot satisfy all User demand for cabinets, do not anticipate being so in the foreseeable future, and are currently working to expand the number of cabinets available in co-location; (ii) specifying that the Cabinet Threshold level of 40 cabinets (chosen as a threshold not easily triggered) is offered as a reasonable buffer during which the Purchasing Limits would apply before the Cabinet Waitlist would become effective; (iii) clarifying that the determination of the whether the Cabinet Threshold is reached is not dependent on whether cabinets are configured to be subdivided into partial cabinets, (iv) specifying that if the Purchasing Limit of a maximum of four new dedicated cabinets applies, the maximum may be comprised of a mix of dedicated and partial cabinets, with two partial cabinets counting as one dedicated cabinet; (v) clarifying that if a User requests, in writing, a number of cabinets that, if provided, would cause the available cabinet inventory to be below 40 cabinets, the Purchasing Limits would only apply to the portion of the User's order below the Cabinet Threshold; and (vi) deleting the initially proposed 8 kW power limit for new dedicated cabinets when the cabinet Purchasing Limits are in effect. The Commission believes that Amendment No. 1 provides additional clarity and detail to the rule text and additional analysis and examples of aspects of the proposal, thereby facilitating the Commission's ability to make the

findings set forth above to approve the proposal.

Accordingly, pursuant to Section 19(b)(2) of the Exchange Act,[32] the Commission finds good cause to approve the proposed rule changes, each as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[33] that the proposed rule changes (SR–NYSE–2020–73, SR–NYSEAMER–2020–66, SR–NYSENAT–2020–28, SR–NYSEArca–2020–82, SR–NYSECHX–2020–26), each as modified by Amendment No. 1 be, and hereby are, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28512 Filed 12–23–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90723; File No. SR–NYSE–2020–93]

Self-Regulatory Organizations; New York Stock Exchange LLC, Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change to Amend Rules 7.35 and 7.35A

December 18, 2020.

On November 3, 2020, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to (1) amend Rule 7.35 to make permanent that the Exchange would disseminate Auction Imbalance Information if a security is an IPO or Direct Listing and has not had its IPO Auction or Direct Listing Auction; and (2) amend Rule 7.35A regarding consultations in connection with an IPO or Direct Listing. The proposed rule change was published for comment in the **Federal Register** on November 17, 2020.[3] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act[4] provides that within 45 days of the publication of notice of the filing of a propose rule change, or within such longer period up to 90 days as the Commission may designate if it find such longer period to be appropriate and published its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the Notice for the proposed rule change is January 1, 2021. The Commission is extending this 45-day period.

The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, pursuant to Section 19(b)(2) of the Act,[5] the Commission designates February 15, 2021, as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to approve or disapprove, the proposed rule change (File No. SR–NYSE–2020–93).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28508 Filed 12–23–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90728; File No. SR–FINRA–2020–044]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Securities Transaction Credits Applicable to FINRA/Nasdaq TRF Participants

December 18, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on December 14, 2020, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 7610A to modify the securities transaction credits applicable to non-Retail Participants that use the FINRA/Nasdaq Trade Reporting Facility Carteret (the ''FINRA/Nasdaq TRF Carteret'') and the FINRA/Nasdaq Trade Reporting Facility Chicago (the ''FINRA/Nasdaq TRF Chicago'') (collectively, the ''FINRA/Nasdaq TRF'').

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The FINRA/Nasdaq TRF is a facility of FINRA that is operated by Nasdaq, Inc. (''Nasdaq''). In connection with the establishment of the FINRA/Nasdaq TRF, FINRA and Nasdaq entered into a limited liability company agreement (the ''LLC Agreement''). Under the LLC Agreement, FINRA, the ''SRO Member,'' has sole regulatory responsibility for the

[32] 15 U.S.C. 78s(b)(2).

[33] *See id.*

[34] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90387 (Nov. 10, 2020), 85 FR 73322 (Nov.17, 2020) (SR–NYSE–2020–93).

[4] 15 U.S.C. 78s(b)(2).

[5] 15 U.S.C. 78s(b)(2).

[6] 17 CFR 200.30–3(a)(31).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

FINRA/Nasdaq TRF. Nasdaq, the ''Business Member,'' is primarily responsible for the management of the FINRA/Nasdaq TRF's business affairs, including establishing pricing for use of the FINRA/Nasdaq TRF, to the extent those affairs are not inconsistent with the regulatory and oversight functions of FINRA. Additionally, the Business Member is obligated to pay the cost of regulation and is entitled to the profits and losses, if any, derived from the operation of the FINRA/Nasdaq TRF.

Pursuant to FINRA Rule 7610A, FINRA/Nasdaq TRF Participants that do not constitute Retail Participants [5] (such non-Retail Participants are referred to herein as ''Participants'') may qualify for revenue sharing payments, in the form of transaction credits, for trade reporting to the FINRA/Nasdaq TRF. Nasdaq administers this Rule in its capacity as the Business Member and operator of the FINRA/Nasdaq TRF on behalf of FINRA,[6] and Nasdaq collects all fees and issues all transaction credits on behalf of the FINRA/Nasdaq TRF.

Under Rule 7610A, FINRA members that report over-the-counter (''OTC'') transactions in NMS stocks to a FINRA/Nasdaq TRF for public dissemination or ''media'' purposes may receive quarterly transaction credits that equal a percentage of FINRA/Nasdaq TRF revenues that are attributable to the members' transactions.[7] The percentage of attributable revenue that a FINRA member may receive in the form of a transaction credit varies depending upon the member's market share on the FINRA/Nasdaq TRF.[8] The current schedule of transaction credits is as follows.

Percentage market share	Percent of attributable revenue shared
Tape A	
Greater than or equal to 2%	98
Less than 2% but greater than or equal to 1%	95
Less than 1% but greater than or equal to 0.50%	85
Less than 0.50% but greater than or equal to 0.10%	20
Less than 0.10%	0
Tape B	
Greater than or equal to 2%	98
Less than 2% but greater than or equal to 1%	90
Less than 1% but greater than or equal to 0.35%	85
Less than 0.35% but greater than or equal to 0.10%	10
Less than 0.10%	0
Tape C	
Greater than or equal to 2%	98
Less than 2% but greater than or equal to 1%	95
Less than 1% but greater than or equal to 0.50%	85
Less than 0.50% but greater than or equal to 0.10%	20
Less than 0.10%	0

The Rule 7600A Series expressly provides that the schedules of credits and fees apply to reporting activity that occurs on either or both of the FINRA/Nasdaq TRFs and a participant's eligibility for any volume-based credits or fee caps will be determined based upon its aggregate reporting volume between the two FINRA/Nasdaq TRFs.

Nasdaq, as the Business Member, has determined to modify the current schedule of transaction credits, and FINRA is proposing to amend Rule 7610A accordingly. Nasdaq believes that there is substantial competition in the market for OTC trade reporting between the FINRA/Nasdaq TRF and the FINRA/NYSE TRF, as evidenced by recent shifts in market share between these facilities. The proposed rule change responds to these competitive forces by providing a more generous percentage share of attributable revenue than under the current schedule to certain Participants that report trades in securities in Tape B to the FINRA/Nasdaq TRF.

Specifically, under the proposed rule change, Participants that achieve one percent or more, but less than two percent of market share on the FINRA/Nasdaq TRF in securities in Tape B would be entitled to receive credits equal to 95 percent of attributable revenue in Tape B, rather than the 90 percent of attributable revenue to which they are entitled under the existing Rule. This proposed change would result in Participants with one or more percent, but less than two percent of market share on the FINRA/Nasdaq TRF in securities in all Tapes receiving an identical percentage of attributable revenue. It would also result in the FINRA/Nasdaq TRF providing the same percentage of revenue sharing as does the FINRA/NYSE TRF for participants in this market segment.[9]

FINRA has filed the proposed rule change for immediate effectiveness. The operative date will be January 1, 2021.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[10] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.

The Proposal Is Reasonable

Nasdaq, as the Business Member, believes that the proposed rule change is reasonable as a means of rewarding Participants that engage in a significant volume of trade reporting activity on the FINRA/Nasdaq TRF. The availability of a higher credit may be an incentive for Participants to further increase the extent of their trade reporting activity on the FINRA/Nasdaq TRF. Moreover, the proposal will improve the competitiveness of the FINRA/Nasdaq TRF vis-à-vis the FINRA/NYSE TRF, which already shares 95% of attributable revenue for this same market segment.[11]

[5] ''Retail Participants,'' as that term is defined in Supplementary Material .01 to Rule 7620A, are not eligible to receive transaction credits from the FINRA/Nasdaq TRF.

[6] FINRA's oversight of this function performed by the Business Member is conducted through a recurring assessment and review of TRF operations by an outside independent audit firm.

[7] Under the Rule, a transaction is attributable to a FINRA member if a trade report submitted to the FINRA/Nasdaq TRF that the FINRA/Nasdaq TRF then submits to either of the securities information processors (''SIPs'') identifies the FINRA member as the Executing Party on the transaction.

[8] For purposes of this Rule, the term ''market share'' means a percentage calculated by dividing the total number of shares represented by trades reported by a FINRA member to the FINRA/Nasdaq TRF for media purposes during a given calendar quarter by the total number of shares represented by all trades reported to the Consolidated Tape Association or the Nasdaq Securities Information Processor, as applicable, during that quarter. Market Share is calculated separately for each tape. *See* Rule 7620A. If a FINRA member reports trades to both FINRA/Nasdaq TRFs during a given calendar quarter, then ''market share'' shall be calculated by dividing the total number of shares represented by trades reported by the member to both of the FINRA/Nasdaq TRFs during that calendar quarter by the total number of shares represented by all trades reported to the Consolidated Tape Association or the Nasdaq SIP, as applicable, during that quarter.

[9] Specifically, pursuant to FINRA Rule 7610B, FINRA/NYSE TRF participants with greater than or equal to 0.5% but less than 2.0% market share in securities in Tape B on the FINRA/NYSE TRF are entitled to 95% of attributable revenue in Tape B.

[10] 15 U.S.C. 78o–3(b)(5).

[11] Because the FINRA Nasdaq TRF and the FINRA/NYSE TRF are operated by different business members competing for market share, FINRA does not take a position on whether the pricing for one TRF is more favorable or competitive than the pricing for the other TRF.

The Proposal Is an Equitable Allocation of Fees

Nasdaq, as the Business Member, believes that the proposed rule change will allocate fees fairly among FINRA/Nasdaq TRF Participants. The proposal is an equitable allocation of reasonable fees because the FINRA/Nasdaq TRF has available to it only a limited amount of resources to expend for participation incentives, and it is fair and equitable to allocate those scarce resources to segments of the market where they are likely to have meaningful effects, both in terms of maintaining existing participation on the FINRA/Nasdaq TRF and in incentivizing new and increased participation. In this regard, Nasdaq notes that from July 2019 through June 2020 (the last four quarters for TRF transaction credit payments), eight Participants had market shares that qualified them for this revenue sharing tier, and collectively, their qualifying market share comprised approximately 24 percent of overall volume on the FINRA/Nasdaq TRF. Because the shared revenue percentage for this market segment is presently less than what the FINRA/NYSE TRF provides to a similar segment of its participants, Nasdaq believes that the proposed rule change will help the FINRA/Nasdaq TRF to maintain, if not increase, the extent of its trade reporting activity (both new and existing reporting) as well as the number of Participants that qualify for this revenue sharing tier.

The Proposal Is Not Unfairly Discriminatory

Nasdaq, as the Business Member, believes that the proposed rule change is not unfairly discriminatory. Although it targets only those Participants with at least one percent and less than two percent market share, and those Participants that report trades to the FINRA/Nasdaq TRF in securities in Tape B only, the proposed rule change is fair because this particular market segment is one where the FINRA/Nasdaq TRF shares a lower percentage of attributable revenues than does the FINRA/NYSE TRF. Thus, an increase is warranted for the FINRA/Nasdaq TRF to remain competitive in this market segment. Moreover, the proposed rule change is fair because it will result in the FINRA/Nasdaq TRF sharing the same percentage of attributable revenue across all three Tapes to Participants with market shares of one percent or more, but less than two percent.

Finally, participation in the FINRA/Nasdaq TRF is voluntary. Participants that determine that the transaction credits that the FINRA/Nasdaq TRF offers are unattractive or unfavorable can report their trades to another trade reporting facility offering more generous incentives.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Regulatory Need

Nasdaq, as the Business Member and operator of the FINRA/Nasdaq TRF, collects all fees and issues all transaction credits on behalf of the FINRA/Nasdaq TRF. As discussed above, Nasdaq has observed an increase in competition in the market for OTC trade reporting, and in response to competitive forces, determined to increase the percentage of the revenue that the FINRA/Nasdaq TRF shares with Participants for their trade reporting activity in securities in Tape B. Through the proposal, Nasdaq intends to render the FINRA/Nasdaq TRF more competitive for Participants in this market segment and to otherwise provide an incentive for Participants to increase the extent of trade reporting activity on the FINRA/Nasdaq TRF.

Economic Baseline

As discussed above, pursuant to FINRA Rule 7610A, Participants in the FINRA/Nasdaq TRF are entitled to receive quarterly transaction credits that equal a percentage of FINRA/Nasdaq TRF revenues attributable to their trade reporting activities on the FINRA/Nasdaq TRF to the extent that their market share on the FINRA/Nasdaq TRF is equal to or greater than 0.10 percent. Presently, Participants with a market share of one percent or more, but less than two percent, are entitled to receive 90 percent of attributable revenues for reports in securities in Tape B and 95 percent of attributable revenues for reports in securities in Tapes A and C.

Economic Impacts

The proposed rule change would increase to 95 percent the percentage of attributable revenue shared with Participants with trade reports in securities in Tape B, to the extent that such Participants have market shares of one percent or more, but less than two percent.

From July 2019 through June 2020 (the last four quarters for TRF transaction credit payments), eight Participants had market shares that qualified them for this revenue sharing tier, and collectively, their qualifying market share comprised approximately 24 percent of overall volume on the FINRA/Nasdaq TRF. The quarterly credits for these qualifying Participants ranged from $25,000 to $320,000. Assuming that, going forward, these same Participants maintain their existing levels of activity in reports in securities in Tape B, they stand to gain between $1,000 and $18,000 more in credits each quarter.

The potential net impact of the proposed rule change depends on whether Participants alter their reporting activity to become eligible for the revised revenue sharing tier. To the extent that the proposed rule change increases incentives to report trades in Tape B to the FINRA/Nasdaq TRF, Participants may choose to shift their reporting from the FINRA/NYSE TRF to the FINRA/Nasdaq TRF.

Finally, the proposed rule change occurs within the context of a competitive environment in which the various trade reporting facilities vie for market share. The FINRA/NYSE TRF is free to adjust its credit and fee programs in response to the changes proposed herein to render them more attractive relative to the FINRA/Nasdaq TRF. If any existing or prospective participant on the FINRA/Nasdaq TRF determines that the proposed amended credit is less attractive or is unfavorable relative to credits applicable to the FINRA/NYSE TRF, such Participants may choose to report to the FINRA/NYSE TRF in lieu of the FINRA/Nasdaq TRF, in which case the FINRA/Nasdaq TRFs would lose market share.

Alternatives Considered

No other alternatives were considered for the proposed rule change.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and paragraph (f)(2) of Rule 19b–4 thereunder.[13] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(2).

investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2020–044 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2020–044. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2020–044 and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[14]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28514 Filed 12–23–20; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–90731; File No. SR–LTSE–2020–22]

Self-Regulatory Organizations; Long-Term Stock Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Adopt Rules Related to Promotional Services and Listing Ceremonies for Listed Companies

December 18, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b-4 thereunder,[2] notice is hereby given that on December 10, 2020, Long-Term Stock Exchange, Inc. (''LTSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

LTSE proposes to adopt Rule 14.602 to provide for promotional services and listing ceremonies that will be offered by the Exchange in connection with a Company's approval for listing on the Exchange.

The text of the proposed rule change is available at the Exchange's website at *https://longtermstockexchange.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt Rule 14.602 to provide for promotional services and listing ceremonies that will be offered by the Exchange in connection with a Company's[3] approval for listing on the Exchange.

Proposed LTSE Rule 14.602 states that in connection with a Company's approval for listing, the Exchange offers promotional services (including press releases, articles, videos, and podcasts) and invites the Company to participate in listing ceremonies.[4] The promotional services would be tailored to meet the needs of the Company, and would allow the Company access to media services that would support the creation of press releases, articles, videos, and podcasts featuring the Company and its personnel. These promotional services also would include assistance with distributing such content on traditional and social media platforms, including websites operated by the Exchange.[5] A full suite of promotional services will be offered to each Company approved to list on the Exchange. Some Companies may choose to avail themselves of all promotional services, whereas others may choose only a subset of services or none.

Although the Exchange is only accepting dual-listings at the present time, it believes that the decision of a Company to list on the Exchange and adopt Long-Term Policies consistent with LTSE Rule 14.425 is a significant event for which a listing ceremony would be appropriate. Accordingly, the Exchange will establish a listing ceremony to commemorate a Company becoming listed on the Exchange. The

[14] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''Company'' means the issuer of a security listed or applying to list on the Exchange. *See* LTSE Rule 14.002(a)(5).

[4] If the Exchange expands the menu of promotional services offered, or elects to provide new products or services to listed Companies, the Exchange will incorporate such changes in a new proposed rule change.

[5] Such promotional services appear to be commonly provided by listing exchanges. *See, e.g., The NYSE Listed Company Network,* New York Stock Exchange LLC, *available at https://www.nyse.com/network* (last visited December 6, 2020) (featuring blog posts and videos about listed companies on NYSE).

Exchange does not have a trading floor or a market site and thus will work with each Company to design and plan a listing ceremony that reflects the Company's values and mission. The listing ceremony would be comparable to ''ringing a bell'' by gathering Company and Exchange personnel to celebrate that the Company has listed on the Exchange. The listing ceremony may be conducted in-person or remotely. Moreover, the absence of a LTSE trading floor or dedicated market site allows the Exchange to be flexible in providing listing ceremonies that can be more inclusive in terms of the number of Company personnel who may attend and the location of the ceremony.[6]

The listing ceremonies in the proposed rule change would be comparable to provisions in New York Stock Exchange LLC (''NYSE'') Listed Company Manual Section 106.03,[7] though tailored to address the fact that a Company listing on LTSE may be a public company and therefore is already trading on LTSE (as well as other national securities exchanges). Additionally, the Exchange proposes that its listing ceremonies be more inclusive, and does not plan to limit listing ceremonies to a particular physical location or solely to a Company's directors and officers. The Exchange believes that the Company should determine where such ceremonies should take place and who should participate in the ceremonies.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[8] in general, and furthers the objectives of Section 6(b)(4) of the Act,[9] in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees, and other charges among the Exchange's members and issuers and other persons using its facilities. The Exchange also believes that the proposed rule change is consistent with Section 6(b)(5) of the Act[10] in that it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that it is fair and reasonable to offer promotional services and listing ceremonies. The Exchange believes that the existing U.S. exchange listing market for operating companies is essentially a duopoly with the vast majority of operating companies listed on U.S. securities exchanges listing on NYSE or Nasdaq Stock Market LLC (''Nasdaq''). The Exchange expects to face competition from NYSE and Nasdaq as a new entrant into the exchange listing market, and believes that offering promotional services and listing ceremonies for Companies listing on the Exchange would allow the Exchange to more effectively attract Companies to list on the Exchange. The Exchange believes that to the extent the Exchange's listing program is successful, it will provide a competitive alternative, which will thereby benefit companies and investors, and remove impediments to and perfect the mechanism of a free and open market and a national market system, consistent with the protection of investors and the public interest.

The Exchange believes that its proposed offer of promotional services and listing ceremonies for listed Companies is fair and not unfairly discriminatory because the promotional services and listing ceremonies will be offered to all listed Companies on the same terms and conditions without differentiation. The scope of promotional services and listing ceremonies provided by the Exchange to each Company ultimately will depend on which services the Company selects insofar as these are optional services for the Company.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, and as discussed in the Statutory Basis section, LTSE believes that the proposed rule change will enhance competition by facilitating LTSE's listing program which will allow the Exchange to provide companies with another listing option, thereby promoting intermarket competition between exchanges in furtherance of the principles of Section 11A(a)(1) of the Act[11] in that it is designed to promote fair competition between exchange markets by offering a new listing market to compete with Nasdaq and NYSE. Moreover, as a dual listing venue, LTSE expects to face competition from existing exchanges because companies have a choice to list their securities solely on a primary listing venue. Consequently, the degree to which LTSE's promotional services and listing ceremonies for listed Companies could impose any burden on intermarket competition is extremely limited, and LTSE does not believe that such offerings would impose any burden on competing venues that is not necessary or appropriate in furtherance of the purposes of the Act.

LTSE also does not believe that the proposed rule change will result in any burden on intramarket competition since LTSE will offer the promotional services and listing ceremonies for all listed Companies on the same terms and conditions without differentiation. Consequently, LTSE does not believe that the proposal will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[6] As noted in the order approving LTSE as a national securities exchange, LTSE maintains a commercial relationship with LTSE Services to leverage the company's technological expertise to support the Exchange's software needs. *See* In the Matter of the Application of Long Term Stock Exchange, Inc.; for Registration as a National Securities Exchange; Findings, Opinion, and Order of the Commission, Exchange Act Release No. 85828 (May 10, 2019), 84 FR 21841, 21842 (May 15, 2019). LTSE Services also provides communications and marketing services to the Exchange. The Exchange anticipates that it will use LTSE Services, among other things, to draft marketing content for review by the Exchange and the Company, produce and edit videos and podcasts, and coordinate listing ceremonies, whether done as in-person or remote events.

[7] *See* NYSE Listed Company Manual Section 106.03 (''The Exchange invites the company's directors and officers to participate in listing ceremonies on the first day of trading. . . . The Exchange has a public relations area which will coordinate the publicity for the event including picture taking on the trading floor.'').

[8] 15 U.S.C. 78f.

[9] 15 U.S.C. 78f(b)(4).

[10] 15 U.S.C. 78f(b)(5).

[11] 15 U.S.C. 78k–1(a)(1).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–LTSE–2020–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–LTSE–2020–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–LTSE–2020–22, and should be submitted on or before January 19, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–28515 Filed 12–23–20; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Interest Rates

The Small Business Administration publishes an interest rate called the optional ''peg'' rate (13 CFR 120.214) on a quarterly basis. This rate is a weighted average cost of money to the government for maturities similar to the average SBA direct loan. This rate may be used as a base rate for guaranteed fluctuating interest rate SBA loans. This rate will be 1.13 percent for the January–March quarter of FY 2021.

Pursuant to 13 CFR 120.921(b), the maximum legal interest rate for any third party lender's commercial loan which funds any portion of the cost of a 504 project (see 13 CFR 120.801) shall be 6% over the New York Prime rate or, in the event that rate exceeds the maximum interest rate permitted by the constitution or laws of a given State, the maximum interest rate will be the rate permitted by the constitution or laws of the given State.

John Wade,

Chief, Secondary Market Division, Office of Financial Assistance.

[FR Doc. 2020–28533 Filed 12–23–20; 8:45 am]

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SURFACE TRANSPORTATION BOARD

[Docket No. AB 1302X]

City of Temple, Tex.—Abandonment Exemption—in Bell County, Tex.

[Docket No. AB 1309X]

Temple & Central Texas Railway, LLC—Discontinuance of Service Exemption—in Bell County, Tex.

The City of Temple, Tex. (the City), and Temple & Central Texas Railway, LLC (TCTR) (collectively, Applicants), jointly filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* for the City to abandon and TCTR to discontinue service over approximately 6.277 miles of rail line between Belton, Tex., milepost 0.0, and Smith, Tex., milepost 6.277, in Bell County, Tex. (the Line). The Line traverses U.S. Postal Service Zip Codes 76513 and 76502.

Applicants have certified that: (1) No local traffic has moved over the Line for at least two years; (2) there is no overhead traffic on the Line; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7 and 1105.8 (notice of environmental and historic report), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to these exemptions, any employee adversely affected by the abandonment and discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[1] the exemptions will be effective on January 27, 2021, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by January 7, 2021.[3] Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by January 19, 2021.

A copy of any petition filed with the Board should be sent to the City's representative, Peter W. Denton, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036, and to TCTR's representative, Bradley S. Gordon, Patriot Rail Company LLC, Patriot Port Holdings LLC, 10752 Deerwood Park Boulevard, Suite 300, Jacksonville, FL 32256.

If the verified notice contains false or misleading information, the exemptions are void ab initio.

Applicants have filed a combined environmental and historic report that

[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemptions' effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemptions' effective date.

[3] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by December 31, 2020. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or interim trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), the City shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by the City's filing of a notice of consummation by December 28, 2021, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Decided: December 21, 2020.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2020–28575 Filed 12–23–20; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1267 (Sub-No. 1X)]

Cassatt Management, LLC d/b/a Bay Coast Railroad—Discontinuance of Service Exemption—in Norfolk, Va.

Cassatt Management, LLC d/b/a Bay Coast Railroad (BCR), has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over a rail line comprised of segments (a) between milepost 102.1 and milepost 100.7 (Segment A) and (b) between milepost 100.7 and milepost 100.3 (Segment B), both in Norfolk, Va. (the Line).[1] The Line traverses U.S. Postal Service Zip Code 23504.

BCR has certified that: (1) No local traffic has moved over the Line in over two years; (2) there has been no overhead traffic over the Line in over two years; (3) no formal complaint filed by a user of rail service on the Line (or a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the discontinuance of service shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) [2] to subsidize continued rail service has been received, this exemption will be effective on January 27, 2021, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2) [3] must be filed by January 7, 2021.[4] Petitions for reconsideration must be filed by January 19, 2021.

A copy of any petition filed with Board should be sent to BCR's representative, Eric M. Hocky, Clark Hill, PLC, Two Commerce Square, 2001 Market St., Suite 2620, Philadelphia, PA 19103.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available at *www.stb.gov.*

Decided: December 21, 2020.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2020–28631 Filed 12–23–20; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1266 (Sub-No. 1X)]

Canonie Atlantic Co.—Abandonment Exemption—in Norfolk, Va.

On December 8, 2020, Canonie Atlantic Co. (CAC), a Class III rail carrier, filed with the Surface Transportation Board (Board) a petition under 49 U.S.C. 10502 for exemption from the prior approval requirements of 49 U.S.C. 10903 to abandon an approximately 1.4-mile rail line in Norfolk, Va., between milepost 100.7 at North Junction and milepost 102.1 at St. Julian (the Line). The Line traverses U.S. Postal Service Zip Code 23504.

CAC states it seeks to abandon the Line because it intends to sell the Line to the Virginia Department of Rail and Public Transportation (DRPT) for public use—specifically, commuter rail transportation. (Pet. 1.) CAC states that no freight traffic has moved over the Line in over two years and that the only recent use of the Line has been to support intercity passenger service by the National Railroad Passenger Corporation (Amtrak). (*Id.* at 1, 4.) [1]

In addition to an exemption from 49 U.S.C. 10903, CAC also seeks an exemption from the offer of financial assistance procedures of 49 U.S.C. 10904. In support, CAC argues that there is no overriding public need for freight rail service on the Line and that the right-of-way is needed for a valid public purpose, *i.e.,* DRPT's plans to utilize the Line to facilitate Amtrak passenger rail service. (Pet. 6.) This request will be addressed in the final decision.

CAC states that, based on the information in its possession, the Line does not contain federally granted rights-of-way. Any documentation in

[1] The verified notice states that Segment A is owned by the Canonie Atlantic Co. (CAC) and Segment B is owned by Norfolk Southern Railway Company. CAC concurrently is seeking Board authority to abandon Segment A. *See Canonie Atl. Co.—Aban. Exemption—in Norfolk, Va.,* Docket No. AB 1266 (Sub-No. 1X). Here, the verified notice states that CAC is acting on behalf of BCR in filing the discontinuance request. *See also Cassatt Management LLC—Discontinuance of Service Exemption—Hallwood to Cape Charles, Va.,* Docket No. AB 1267X.

[2] Persons interested in submitting an OFA to subsidize continued rail service must first file a formal expression of intent to file an offer, indicating the intent to file an OFA for subsidy and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[3] The filing fee for OFAs can be found at 49 CFR 1002.2(f)(25).

[4] Because this is a discontinuance proceeding and not an abandonment, interim trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require environmental review.

[1] In a related docket, a verified notice of exemption has been filed for BCR to discontinue its operations over the Line, as well as over an adjacent line owned by Norfolk Southern Railway Company between milepost 100.7 and milepost 100.3. *See Cassatt Mgmt., LLC—Discontinuance of Serv. Exemption—in Norfolk, Va.,* Docket No. AB 1267 (Sub-No. 1X).

CAC's possession will be made available to those requesting it.

The interest of railroad employees will be protected by the conditions set forth in *Oregon Short Line Railroad—Abandonment Portion Goshen Branch between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979).

By issuing this notice, the Board is instituting an exemption proceeding pursuant to 49 U.S.C. 10502(b). A final decision will be issued by March 26, 2021.

Any offer of financial assistance (OFA) under 49 CFR 1152.27(b)(2) will be due no later than 120 days after the filing of the petition for exemption, or 10 days after service of a decision granting the petition for exemption, whichever occurs sooner. Persons interested in submitting an OFA must first file a formal expression of intent to file an offer by January 7, 2021, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(1)(i).

Following abandonment, the Line may be suitable for other public use, including interim trail use. Any request for a public use condition under 49 CFR 1152.28 or for interim trail use/rail banking under 49 CFR 1152.29 will be due no later than January 19, 2021.[2]

All pleadings, referring to Docket No. AB 1266 (Sub-No. 1X), should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, a copy of each pleading must be served on CAC's representative, Eric M. Hocky, Clark Hill, PLC, Two Commerce Square, 2001 Market St., Suite 2620, Philadelphia, PA 19103. Replies to the petition are due on or before January 19, 2021.

Persons seeking further information concerning abandonment procedures may contact the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245–0238 or refer to the full abandonment regulations at 49 CFR part 1152. Questions concerning environmental issues may be directed to the Board's Office of Environmental Analysis (OEA) at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

An environmental assessment (EA) (or environmental impact statement (EIS), if necessary) prepared by OEA will be served upon all parties of record and upon any other agencies or persons who comment during its preparation. Other interested persons may contact OEA to obtain a copy of the EA (or EIS). EAs in abandonment proceedings normally will be made available within 60 days of the filing of the petition. The deadline for submission of comments on the EA generally will be within 30 days of its service.

Board decisions and notices are available at *www.stb.gov.*

Decided: December 21, 2020.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Tammy Lowery,

Clearance Clerk.

[FR Doc. 2020–28629 Filed 12–23–20; 8:45 am]

BILLING CODE 4915–01–P

[2] CAC states that, because it plans to sell the Line to DRPT, it is unwilling to negotiate for interim trail use. (Pet. 8.) Nevertheless, filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0997]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Noise Certification Standards for Subsonic Jet Airplanes and Subsonic Transport Category Large Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on October 21, 2020. The collection involves the noise certification regulations for subsonic aircraft. Without this data collection, the FAA would be unable to make the required noise certification compliance finding.

DATES: Written comments should be submitted by January 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sandy Liu by email at: *sandy.liu@faa.gov;* phone: 202–267–4748.

SUPPLEMENTARY INFORMATION: *Public Comments Invited:* You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0659.

Title: Noise Certification Standards for Subsonic Jet Airplanes and Subsonic Transport Category Large Airplanes.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on October 21, 2020 (85 FR 67089). The aircraft noise information collected are the results of noise certification tests that demonstrate compliance with 14 CFR part 36. The original information collection was implemented to show compliance in accordance with the Aircraft Noise Abatement Act of 1968; that statute is now part of the overall codification of the FAA's regulatory authority over aircraft noise in 49 U.S.C. 44715. For this renewal, the FAA proposes to maintain this PRA collection at 14 total noise certification projects per year. Each applicant's collected information is incorporated into a noise compliance report that is provided to and approved by the FAA. The noise compliance report is used by the FAA in making a finding that the airplane is in noise compliance with the regulations. These compliance reports are required only once when an applicant wants to certificate an aircraft type. Without this data collection, the FAA would be unable to make the required noise certification compliance finding.

Respondents: Aircraft manufacturer/applicant seeking type certification;

Frequency: Estimated 14 total applicants per year;

Estimated Average Burden per Response: Estimated 200 hours per applicant for the compliance report; and

Estimated Total Annual Burden: $25,000 per applicant or cumulative total $350,000 per year for 14 applicants.

Issued in Washington, DC on December 18, 2020.

Sandy Liu,

Engineer, Office of Environment and Energy, Noise Division (AEE–100).

[FR Doc. 2020–28485 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2020–0563]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Noise Certification Documents for International Operations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 5, 2020. The collection aids to make the aircraft noise certification information easily accessible to the flight crew and presentable upon request to the appropriate foreign officials for international airline operation of U.S. carriers. The information to be collected upholds the U.S. obligations under the Convention on International Civil Aviation and for which FAA policy comply with International Civil Aviation Organization (ICAO) Standards and Recommended Practices to the maximum extent practicable.

DATES: Written comments should be submitted by January 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Sandy Liu by email at: *sandy.liu@faa.gov;* phone: 202–276–4748.

SUPPLEMENTARY INFORMATION: *Public Comments Invited:* You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

OMB Control Number: 2120–0737.

Title: Aircraft Noise Certification Documents for International Operations.

Form Numbers: None. Reference: ICAO Annex 16, Vol.1—Aircraft Noise, Eighth edition (July 2017) Attachment G for format.

Type of Review: Renewal of an information collection.

Background: The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on June 5, 2020 (85 FR 34711). On March 2, 2010, the FAA published the final rule Notice No. 91–312, Aircraft Noise Certification Documents for International Operations (75 FR 9327). It requires operators that fly outside the United States, using aircraft subject to ICAO, Annex 16, Volume 1, to carry aircraft noise certification information on board the aircraft. This collection is needed to ensure consistent international compliance with the ICAO, Annex 16, Volume 1, Amendment 8 that requires certain noise information be carried on board the aircraft. This information must be easily accessible to the flight crew and presentable upon request to the appropriate foreign National Aviation Authority (NAA) officials. The collection is mandatory based on U.S. regulations and international standards.

Respondents: Operators of U.S. registered civil aircraft flying outside the United States.

Frequency: 70 airplanes.

Estimated Average Burden per Response: 25 minutes (0.42 hours).

Estimated Total Annual Burden: $25 per airplane × 70 airplanes affected = $1,750.

Issued in Washington, DC, on December 18, 2020.

Sandy Liu,

Engineer, Noise Division, Office of Environment and Energy, Noise Division (AEE–100).

[FR Doc. 2020–28486 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2020–0020]

Surface Transportation Project Delivery Program; Arizona Department of Transportation Draft FHWA Audit Report

AGENCY: Federal Highway Administration (FHWA), U.S. Department of Transportation (DOT).

ACTION: Notice; Request for comment.

SUMMARY: The Moving Ahead for Progress in the 21st Century Act (MAP–21) established the Surface Transportation Project Delivery Program that allows a State to assume FHWA's environmental responsibilities for environmental review, consultation, and compliance under the National Environmental Policy Act (NEPA) for Federal highway projects. When a State assumes these Federal responsibilities, the State becomes solely responsible and liable for carrying out the responsibilities it has assumed, in lieu of FHWA. This program mandates annual audits during each of the first 4 years of State participation to ensure compliance with program requirements. This is the first audit of the Arizona Department of Transportation's (ADOT) performance of its responsibilities under the Surface Transportation Project Delivery Program (NEPA Assignment Program). This notice announces and solicits comments on the first audit report for ADOT.

DATES: Comments must be received on or before January 27, 2021.

ADDRESSES: Mail or hand deliver comments to Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, Washington, DC 20590. You may also submit comments electronically at *www.regulations.gov.* All comments should include the docket number that appears in the heading of this document. All comments received will be available for examination and copying at the above address from 9 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped postcard or you may print the acknowledgment page that appears after submitting comments electronically. Anyone can search the electronic form of all comments in any one of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on

behalf of an association, business, or labor union). The DOT posts these comments, without edits, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Mr. Neel Vanikar, Office of Project Development and Environmental Review, (202) 366–2068, *neel.vanikar@dot.gov,* Federal Highway Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, or Mr. Jay Payne, Office of the Chief Counsel, (202) 366–4241, *james.o.payne@dot.gov,* Federal Highway Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590. Office hours are from 8:00 a.m. to 4:30 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this notice may be downloaded from the specific docket page at *www.regulations.gov.*

Background

The Surface Transportation Project Delivery Program, codified at 23 U.S.C. 327, commonly known as the NEPA Assignment Program, allows a State to assume FHWA's environmental responsibilities for review, consultation, and compliance for Federal highway projects. When a State assumes these Federal responsibilities, the State becomes solely liable for carrying out the responsibilities it has assumed, in lieu of FHWA. The ADOT published its application for NEPA assumption on June 29, 2018, and solicited public comment. After considering public comments, ADOT submitted its application to FHWA on November 16, 2018. The application served as the basis for developing a memorandum of understanding (MOU) that identifies the responsibilities and obligations that ADOT would assume. The FHWA published a notice of the draft MOU in the **Federal Register** on February 11, 2019, at 84 FR 3275, with a 30-day comment period to solicit the views of the public and Federal Agencies. After the close of the comment period, FHWA and ADOT considered comments and proceeded to execute the MOU. Effective April 16, 2019, ADOT assumed FHWA's responsibilities under NEPA, and the responsibilities for NEPA-related Federal environmental laws described in the MOU.

Section 327(g) of Title 23, U.S.C., requires the Secretary to conduct annual audits to ensure compliance with the memorandum of understanding during each of the first four years of State participation and, after the fourth year, monitor compliance. The FHWA must make the results of each audit available for public comment. This notice announces the availability of the first audit report for ADOT and solicits comments on the same.

Authority: Section 1313 of Public Law 112–141; Section 6005 of Public Law 109–59; 23 U.S.C. 327; 23 CFR 773.

Nicole R. Nason,

Administrator, Federal Highway Administration.

Surface Transportation Project Delivery Program

Draft FHWA Audit #1 of the Arizona Department of Transportation

Executive Summary

This is Audit #1 of the Arizona Department of Transportation's (ADOT) assumption of National Environmental Policy Act (NEPA) responsibilities under the Surface Transportation Project Delivery Program. Under the authority of 23 U.S.C. 327, ADOT and the Federal Highway Administration (FHWA) executed a memorandum of understanding (MOU) on April 16, 2019, to memorialize ADOT's NEPA responsibilities and liabilities for Federal-aid highway projects and other related environmental reviews for highway projects in Arizona. This 23 U.S.C. 327 MOU covers environmental review responsibilities for projects that require the preparation of environmental assessments (EA), environmental impact statements (EIS), and non-designated individual categorical exclusions (CE). A separate MOU between FHWA and ADOT, pursuant to 23 U.S.C. 326, authorizes environmental review responsibilities for other CE. This audit does not cover the CE responsibilities and projects assigned to ADOT under the 23 U.S.C. 326 MOU.

The FHWA conducted an audit of ADOT's performance according to the terms of the MOU March 9–12, 2020. Prior to the audit, the FHWA audit team held internal meetings to prepare for an onsite visit to the Arizona Division and ADOT offices. Prior to the onsite visit, the audit team reviewed ADOT's environmental manuals and procedures, NEPA project files, ADOT's response to FHWA's pre-audit information request (PAIR), and ADOT's NEPA Assignment Self-Assessment Report. During the March 2020 audit, the audit team conducted interviews with staff from ADOT Environmental Planning (EP) and ADOT's external partners, and prepared preliminary audit results. The audit team presented these preliminary results to ADOT EP leadership on March 12, 2020.

Overall, the audit team found that ADOT has carried out the responsibilities it has assumed consistent with the intent of the MOU and ADOT's application. The ADOT continues to develop, revise, and implement procedures and processes required to deliver its NEPA Assignment Program. This report describes several observations and successful practices. Through this report, FHWA is notifying ADOT of two non-compliance observations that require ADOT to take corrective action. By addressing the observations in this report, ADOT will continue to assure successful program assignment.

Background

The purpose of the audits performed under the authority of 23 U.S.C. 327 is to assess a State's compliance with the provisions of the MOU as well as all applicable Federal statutes, regulations, policies, and guidance. The FHWA's review and oversight obligation entails the need to collect information to evaluate the success of the NEPA Assignment Program; to evaluate a State's progress toward achieving its performance measures as specified in the MOU; and to collect information for the administration of the NEPA Assignment Program. This report summarizes the results of the first audit in Arizona and ADOT's progress towards meeting the program review objectives identified in the MOU. Following this audit, FHWA will conduct three additional annual NEPA Assignment Program audits in Arizona.

Scope and Methodology

The overall scope of this audit review is defined both in statute (23 U.S.C. 327) and the MOU (Part 11). The definition of an audit is one where an independent unbiased body makes an official and careful examination and verification of accounts and records, especially of financial accounts. Auditors who have special training with regard to accounts or financial records may follow a prescribed process or methodology in conducting an audit of those processes or methods. The FHWA considers its review to meet the definition of an audit because it is an unbiased, independent, official, and careful examination and verification of records and information about ADOT's assumption of environmental responsibilities.

The audit team consisted of NEPA subject matter experts (SME) from FHWA Headquarters and Resource Center, as well as staff from FHWA's Arizona Division. This audit is an unbiased official action taken by FHWA, which included an audit team of diverse composition, and followed an established process for developing the review report and publishing it in the **Federal Register**.

The audit team reviewed six NEPA Assignment Program elements: Program management; documentation and records management; quality assurance/quality control (QA/QC); performance measures; legal sufficiency; and training. The audit team considered three additional focus areas for this review: Project-level conformity procedures; Section 4(f) procedures; and public involvement procedures.

The audit team conducted a careful examination of ADOT policies, guidance, and manuals pertaining to NEPA responsibilities,

as well as a representative sample of ADOT's project files. Other documents, such as ADOT's PAIR responses and ADOT's Self-Assessment Report, also informed this review. In addition, the audit team interviewed staff from ADOT EP and ADOT's external partners, both in person and via teleconference.

The timeframe defined for this first audit includes highway project environmental approvals completed between April 16, 2019, and December 31, 2019. During this timeframe, ADOT completed NEPA approvals and documented NEPA decision points for 12 projects. Due to the small sample size, the audit team reviewed all 12 projects. This consisted of four Individual CEs, one EA with a Finding of No Significant Impact (FONSI), two draft EAs, one EA initiated with scoping completed, one draft EIS, and three EA re-evaluations.

The PAIR submitted to ADOT contained 23 questions covering all 6 NEPA Assignment Program elements. The audit team developed specific follow-up questions for the onsite interviews with ADOT staff based on ADOT responses to the PAIR.

The audit team conducted a total of 17 interviews. Interview participants included staff from ADOT EP, Arizona Attorney General's Office (AGO), Environmental Protection Agency (EPA) Region 9, Arizona Game and Fish Department (AZGFD), Maricopa Association of Governments (MAG), and the city of Phoenix.

The audit team compared ADOT manuals and procedures to the information obtained during interviews and project file reviews to determine if ADOT's performance of its MOU responsibilities is in accordance with ADOT procedures and Federal requirements. The audit team documented individual observations and successful practices during the interviews and reviews and combined these under the six NEPA Assignment Program elements. The audit results are described below by program element.

Overall Audit Opinion

The audit team found ADOT has carried out the responsibilities it has assumed consistent with the intent of the MOU and ADOT's application. The FHWA is notifying ADOT of two non-compliance observations that require ADOT to take corrective action. By addressing the observations cited in this report, ADOT will continue to assure a successful program.

Successful Practices and Observations

Successful practices are practices that the team believes are positive, and encourages ADOT to consider continuing or expanding those programs in the future. The audit team identified numerous successful practices in this report.

Observations are items the audit team would like to draw ADOT's attention to, which may improve processes, procedures, and/or outcomes. The team identified three observations in this report.

Non-compliance observations are instances where the audit team finds the State is not in compliance or is deficient with regard to a Federal regulation, statute, guidance, policy, State procedure, or the MOU. Non-compliance may also include instances where the State has failed to secure or maintain adequate personnel and/or financial resources to carry out the responsibilities they have assumed. The FHWA expects the State to develop and implement corrective actions to address all non-compliance observations. The audit team identified two non-compliance observations in this report.

The audit team shared initial results during the site visit closeout and shared the draft audit report with ADOT to provide them the opportunity to clarify any observation, as needed, and/or begin implementing corrective actions to improve the program. The FHWA will consider actions taken by ADOT to address these observations as part of the scope of the second audit.

Successful Practices and Observations

Program Management

Successful Practices

The ADOT EP has developed several detailed guidance manuals for implementing NEPA Assignment and evaluating environmental resources. These manuals are readily available online at ADOT's environmental website. The ADOT continuously updates their manuals and has a process for tracking updates by including a list of changes as an appendix in each version. Several staff members stated they regularly consult the guidance manuals and are informed of updates.

The ADOT EP has developed internal procedures for resolving and escalating conflicts. The ADOT Project Development Procedures Manual describes these escalation procedures. The ADOT has found this to be an effective tool to assist in evaluating controversial issues, identifying appropriate levels of communication, and determining the best approach for dispute resolution.

During interviews with staff, the audit team learned that ADOT EP makes a considerable effort at internal communication and coordination through meetings, emails, and informal interaction. The staff holds weekly and monthly meetings for environmental planners and technical groups to discuss project issues, address program-level questions, and update staff on guidance. Interviewed staff said they were well-informed about procedures and comfortable discussing complex situations with team leads and technical experts. In addition, ADOT EP attends partnering/preconstruction meetings with other ADOT sections to convey environmental commitments and to stay informed of project changes.

During interviews, EPA, AZGFD, and the city of Phoenix commented on ADOT EP's collaboration and communication efforts with them. The EPA was appreciative of ADOT EP holding bi-monthly coordination meetings to discuss the status of projects and commented on their much-improved relationship with ADOT. The AZGFD acknowledged and appreciated the opportunities to provide input through the outreach efforts of ADOT biologists on projects with wildlife concerns. The city of Phoenix noted ADOT's improved communication with local governments and efforts to increase flexibility in the environmental review process. The audit team recognizes ADOT EP's outreach efforts with these external partners. One area identified by the audit team in need of improved collaboration is project-level conformity determinations, where legal responsibility remains assigned to FHWA.

Observations

Non-Compliance Observation #1: Incomplete Project Files Submission

For this audit, pursuant to MOU Sections 8.2.2 and 8.2.3, FHWA requested all project files pertaining to the NEPA approvals and documented NEPA decision points completed during the audit review period. The request specified the approved NEPA document and all supporting documentation related to the decision milestones, such as consultation letters, technical memos, and resource evaluations (email to ADOT November 26, 2019). The FHWA provided additional clarification to ADOT regarding the types of NEPA approvals and NEPA decision documents that ADOT should submit (email to ADOT December 18, 2019).

The audit team found several inconsistences between ADOT's procedures for maintaining project files (as identified in the ADOT CE Checklist Manual, ADOT EA/EIS Manual, ADOT QA/QC Plan, and ADOT Project Development Procedures Manual) and the project file documentation provided to FHWA. The ADOT's procedures specify utilizing a standard folder structure for all projects and saving all project documentation and supporting information in the project files. However, the project files submitted by ADOT for this audit were incomplete and did not include all supporting documentation. The project files that ADOT submitted consisted primarily of final decision documents and, in most cases, did not include correspondence, internal communication, technical memos/reports, or other types of information to support NEPA decisions or demonstrate how ADOT evaluated resources.

The audit team learned during interviews that ADOT EP management created a duplicate project file for each project which consisted of a subset of their project files. Due to the incomplete project files, it is unclear how ADOT is maintaining electronic project files and administrative records, and how ADOT is complying with its procedures and the terms of the 23 U.S.C. 327 MOU as they apply to records retention. The audit team determined that ADOT EP management made the decision to not submit all requested project files for review by FHWA as required by the MOU (Section 8.2.3). In the last 23 U.S.C. 326 MOU monitoring review, FHWA observed this same practice and informed ADOT that such a practice was in non-compliance with the MOU. Just as that practice was in non-compliance with the 23 U.S.C. 326 MOU, this practice is also in non-compliance with the 23 U.S.C. 327 MOU.

Observation #1: Use of the Federal Infrastructure Permitting Dashboard

The ADOT is responsible for inputting project information for assigned projects into the Federal Infrastructure Permitting

Dashboard, per MOU Section 8.5.1. During the audit, the audit team reviewed the Permitting Dashboard and found that it did not include information for any of the applicable projects assigned to ADOT. The audit team confirmed during interviews that ADOT has not updated the dashboard. The audit team acknowledges that ADOT is working with FHWA to obtain access to the dashboard and address this issue.

Documentation and Records Management

The audit team reviewed 12 projects as part of this audit. This consisted of four Individual CEs, one EA with a FONSI, two draft EAs, one EA initiated with scoping completed, one draft EIS, and three EA re-evaluations.

Successful Practices

The ADOT EP has developed several standard templates (*e.g.,* checklists, forms, etc.) to document various actions and decision-points throughout the NEPA process. These are an effective tool for ADOT to consistently evaluate environmental resources and document decisions. Staff indicated that these templates have aided in streamlining the review process and provided consistency across projects.

Observations

Non-Compliance Observation #2: Project-Level Conformity Compliance Issues

The statutory provisions of the NEPA Assignment Program, along with Section 3.2.1 of the MOU, prohibit ADOT from assuming the responsibility for making conformity determinations for projects processed under the 23 U.S.C. 327 MOU. However, pursuant to the Federal transportation conformity regulations at 40 CFR 93.105(c) and Section 7.2.1 of the MOU, ADOT and FHWA Arizona Division can agree on procedures that allow ADOT to engage in activities to assist in this process and establish when and how consultation with FHWA must occur.

The audit team reviewed ADOT's protocols for seeking FHWA's project-level conformity determinations, conducted a focused review of project-level conformity procedures on six projects, and interviewed ADOT, MAG, and EPA staff. The audit team found that ADOT had not given FHWA a chance to review and agree on the protocols and, as a result, the protocols do not provide for the appropriate consultation, coordination, and communication with FHWA and other agencies, such as EPA and MAG, to ensure the projects meet the project-level conformity requirements where required.

The audit team found documentation for two projects showing that ADOT staff did not coordinate with FHWA on the application of conformity requirements and, by doing so, ADOT took actions that were not assigned to them. This failure to coordinate prevented FHWA from meeting its conformity determination responsibilities. The ADOT incorrectly concluded that the conformity requirements did not apply to one of the two projects because they assumed that the project would not trigger any FHWA approvals. The ADOT proceeded to complete NEPA without FHWA's conformity determination. This deficient approval prevents FHWA from authorizing the project until the conformity requirements are met. In another project, ADOT incorrectly determined that a widening project was exempt from project conformity under 40 CFR 93.126.

The audit team found multiple projects that did not demonstrate ADOT's compliance with interagency consultation requirements, per 40 CFR 93.105. The ADOT appears to have conducted some degree of interagency consultation but information on such consultation was not included in the project files. Therefore, it is unclear whether the interagency consultation agencies had an opportunity to participate in consultation or if ADOT provided them an opportunity to review and comment on the materials as required by 40 CFR 93.105 and MOU Section 7.2.1. During interviews, EPA expressed concerns regarding how ADOT conducts project-level interagency consultation. Both EPA and MAG also felt that the interagency consultation is not fully transparent since ADOT does not: (1) Share comments with all interagency consultation agencies throughout the process; (2) provide responses to agency comments; and (3) consistently follow up with agencies to ensure their comments are adequately addressed. In cases where a project-level conformity determination is required, the interagency consultation process must meet the conformity rule requirements found in 40 CFR 93.105.

During interviews, ADOT staff did not demonstrate a full of understanding project-level conformity requirements. The audit team identified that ADOT staff were not aware that: (1) Certain FHWA approvals (in addition to Federal funding) may necessitate a project-level conformity determination; (2) certain situations may require a redetermination of project-level conformity under 40 CFR 93.104(d); (3) the importance of specific traffic data requirements for the reviews; and (4) the public involvement requirements associated with project-level conformity.

The lack of agreed-upon interagency consultation procedures with clear roles, responsibilities, and coordination protocols, particularly between ADOT and FHWA, creates a significant risk of project schedule delays and, ultimately, project non-compliance. The ADOT should revise their procedures to be consistent with 40 CFR 93.105 and obtain agreement from FHWA to make sure the correct workflows are established, the responsibilities of FHWA are not curtailed, and that interagency consultation is transparent. Until agreed-upon protocols between FHWA and ADOT are in place, ADOT should consult with FHWA on all projects in non-attainment and maintenance areas to determine if conformity determination will be required for the project and the appropriate interagency consultation needed.

Observation #2: Inconsistencies and Deficiencies Based on the Review of Project File Documentation

The audit team preliminarily identified several inconsistencies between ADOT's procedures for documenting project decisions (as identified in the ADOT CE Checklist Manual, ADOT EA/EIS Manual, ADOT QA/QC Plan, and ADOT Project Development Procedures Manual) and the incomplete project file documentation provided. Section 4.2.4 of the MOU specifies that ADOT must implement documentation procedures to support appropriate environmental analysis and decisionmaking under NEPA and associated laws and regulations. The FHWA informed ADOT EP leadership during the audit week that project files were incomplete and, in response, ADOT submitted additional project files and supporting documentation. The ADOT was provided a second opportunity after the audit week to clarify inconsistences identified by the audit team and answer follow-up questions regarding the project documentation.

After completing the project file review (including the supplemental information provided by ADOT), the audit team identified the following procedural deficiencies relating to the MOU and FHWA's regulations, policies, and guidance:

- One project did not include the disclosure statement on the Draft Environmental Impact Statement cover page regarding the intent to combine the final EIS and record of decision as identified in the January 14, 2013, interim guidance memorandum on MAP–21 Section 1319 Accelerated Decision making in Environmental Reviews.
- One corridor widening project did not demonstrate independent utility and logical termini as required in 23 CFR 771.111(f)(1) and 23 CFR 771.111(f)(2).
- One project did not demonstrate that funding for the project is programmed beyond Fiscal Year 2019 and did not demonstrate that the project is identified on a current Statewide Transportation Improvement Program per 23 CFR 771.113(a)(3).

In addition, the audit team found several inconsistencies between ADOT's documentation of Section 4(f) determinations (as identified in ADOT's Section 4(f) procedures and FHWA Section 4(f) regulation and guidance) and the project file documentation. Due to the inadequate information provided, it is unclear how ADOT is implementing Section 4(f) and how ADOT is complying with its Section 4(f) procedures. The audit team identified the following inconsistencies in project files relating to Section 4(f) evaluations and determinations:

- One project included a Section 106 no adverse effect finding and Section 4(f) no use determinations for six historic properties; however, ADOT did not provide any information demonstrating how they evaluated these resources under Section 4(f), or if they consulted the officials with jurisdiction over the resources.
- Two projects included a Section 106 finding of either adverse effect or no adverse effect, indicating the presence of potential Section 4(f) resources; however, ADOT did not provide any information demonstrating how they evaluated these resources under Section 4(f), or if they had consulted the officials with jurisdiction over the resources.
- One project included a Section 4(f) joint development determination but it is unclear

what information ADOT used to support this determination (such as a master plan map or other planning information), or if they consulted the official with jurisdiction over the resource regarding potential impacts to the Section 4(f) resource.

- One project included a temporary occupancy determination and the description of the impact to the resource is inconsistent with the definition provided in 23 CFR 774.13(d)(3).
- One project stated that a Section 4(f) resource within the project area is jointly owned by two entities, but it is unclear if ADOT consulted with both officials with jurisdiction regarding the *de minimis* use since only one official with jurisdiction concurred with the *de minimis* use.

The audit team acknowledges that ADOT is aware that implementation of Section 4(f) is an area in need of improvement and recognizes their efforts to update its procedures, including ADOT recently developing standard evaluation forms.

Quality Assurance/Quality Control (QA/QC)

The audit team verified that ADOT has procedures in place for QA/QC which are described in the ADOT QA/QC Manual and ADOT Project Development Procedures Manual. The ADOT has developed QC checklists and forms to assist in implementing project-level QC procedures. During the project file reviews, the audit team noted some variation in how ADOT implements project-level QC procedures, and inconsistencies in how ADOT documents QC reviews. It was unclear how ADOT conducts thorough project-level QC reviews (completeness vs. accuracy), how ADOT corrects errors it identifies during QC reviews, and how the environmental planners coordinate with technical experts during QC reviews. Staff indicated during interviews that informal QC reviews are often conducted before QC checklists are completed, though it is unclear how this process is tracked to ensure comments are addressed. Due to these inconsistencies, the audit team was unable to fully assess the implementation of project-level QC procedures. The FHWA will continue to evaluate this program objective in subsequent audits.

Performance Measures

Observations

Observation #3: Incomplete Development and Implementation of Performance Measures

The audit team reviewed ADOT's development and implementation of performance measures to evaluate their program as required in the MOU (Part 10.2.1). The ADOT's QA/QC Plan and self-assessment report identified several performance measures but both indicated that ADOT was still refining these measures and had not fully implemented them. The ADOT's PAIR response stated that ADOT has focused on tracking projects for schedule issues and has not begun gathering data for other performance measures. The self-assessment report did not include reporting data for any of the performance measures. The audit team confirmed during staff interviews that ADOT does not have data for its performance measures and is looking to further refine its performance measures. Due to the lack of performance measure data, the audit team determined that ADOT has not fully established and initiated data collection as it relates to performance metrics per the MOU.

Legal Sufficiency

Through information provided by ADOT and an interview by the FHWA Office of Chief Counsel with an Assistant Attorney General (AAG) assigned to ADOT's NEPA Assignment Program, the auditors determined ADOT had not conducted formal legal sufficiency reviews of assigned environmental documents during the audit period. Currently, ADOT retains the services of two AAGs for NEPA Assignment reviews and related matters. The assigned AAGs have received formal and informal training in environmental law matters. The ADOT also has the ability to retain outside counsel to review projects or conduct litigation should the need arise.

Successful Practice

Through the interview, the audit team learned ADOT seeks to involve lawyers early in the environmental review phase, with AAGs participating in project coordination team meetings and reviews of early drafts of environmental documents. In addition, ADOT and the AGO have a process in place by which ADOT can request written legal opinions and advice from an AAG on environmental review legal matters. For formal reviews, the process would include a formal transmittal memo from an ADOT environmental manager, a review package (hard copy or electronic), and a completed ADOT EA/EIS Quality Control Checklist.

Training

The audit team reviewed ADOT's 2020 Training Plan and ADOT's PAIR responses pertaining to its training program. The ADOT's training program includes in-house, Web-based, and instructor-led courses training opportunities for staff. Since assuming NEPA responsibilities, ADOT has held several formal training courses and plans to continue these efforts during the upcoming year. The ADOT provides new hires with structured onboarding training which includes coaching, mentoring, and collaborative on-the-job training to facilitate professional development. The ADOT EP Training Officer tracks staff training needs and completion of courses and updates this document quarterly. Staff remarked during interviews on the availability of training offered to them and opportunities to travel out of State for specialty technical courses.

Successful Practices

The audit team commends ADOT for developing a detailed training plan and committing resources to provide training opportunities for staff. The ADOT EP encourages staff to pursue individual training interests and has undertaken efforts to ensure staff maintains professional certifications. The ADOT EP has developed a Web-based training course for staff as an introduction to NEPA Assignment. To further support the training program, ADOT EP utilizes a dedicated training coordinator within the environmental section.

Finalizing This Report

The FHWA provided a draft of the audit report to ADOT for a 14-day review and comment period. The ADOT provided comments which the audit team considered in finalizing this draft audit report. The audit team acknowledges that ADOT has begun to address some of the observations identified in this report and recognizes ADOT's efforts toward improving their program. The FHWA is publishing this notice in the **Federal Register** for a 30-day comment period in accordance with 23 U.S.C. 327(g). No later than 60 days after the close of the comment period, FHWA will address all comments submitted to finalize this draft audit report pursuant to 23 U.S.C. 327(g)(2)(B). Subsequently, FHWA will publish the final audit report in the **Federal Register**. The FHWA will consider the results of this audit in preparing the scope of the next annual audit. The next audit report will include a summary that describes the status of ADOT's corrective and other actions taken in response to this audit's conclusions.

[FR Doc. 2020–28503 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2020–0027–N–36]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, this notice announces that FRA is forwarding the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On September 29, 2020, FRA published a notice providing a 60-day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or before January 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed ICR should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find the particular ICR by selecting ''Currently under 30-day Review—Open

for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Hodan Wells, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, Federal Railroad Administration, telephone: (202) 493–0440, email: *Hodan.wells@dot.gov.*

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On September 29, 2020, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICR for which it is now seeking OMB approval. *See* 85 FR 61085. FRA received no comments in response to this notice.

Before OMB decides whether to approve the proposed collection of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Training, Qualification, and Oversight for Safety-Related Railroad Employees.

OMB Control Number: 2130–0597.

Abstract: In 2014, FRA published a final rule establishing minimum training standards for all safety-related railroad employees, as required by the Rail Safety Improvement Act of 2008. The final rule requires each railroad or contractor that employs one or more safety-related employees to develop and submit a training program to FRA for approval and to designate the minimum training qualifications for each occupational category of employee. Additionally, the rule requires most employers to conduct periodic oversight of their own employees and annual written reviews of their training programs to close performance gaps.

FRA will use the information collected to ensure each employer—railroad or contractor—conducting operations subject to 49 CFR part 243 develops, adopts, submits, and complies with a training program for each category and subcategory of safety-related railroad employee. Each program must have training components identified so that FRA will understand how the program works when it reviews the program for approval. Further, FRA will review the required training programs to ensure they include: Initial, ongoing, and on-the-job criteria; testing and skills evaluation measures designed to foster continual compliance with Federal standards; and the identification of critical safety defects and plans for immediate remedial actions to correct them.

In response to petitions for reconsideration, FRA extended the effective date for developing the required training program under § 243.101 for each Class I railroad, and each intercity or commuter passenger railroad conducting operations with 400,000 or more total annual employee work hours to January 1, 2020, and for all remaining employers subject to this part to May 1, 2021.

Type of Request: Extension with change (revised estimates) of a currently approved collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 1,155 railroads/contractors/training organizations/learning institutions.

Frequency of Submission: On occasion.

Total Estimated Annual Responses: 165,054.

Total Estimated Annual Burden: 91,069 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $7,020,889.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that a respondent is not required to respond to, conduct, or sponsor a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Deputy Chief Counsel.

[FR Doc. 2020–28471 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2020–0097]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

Under part 235 of title 49 Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that on December 14, 2020, the National Railroad Passenger Corporation (Amtrak) petitioned the Federal Railroad Administration (FRA) seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2020–0097.

Applicant: National Railroad Passenger Corporation, Nicholas J. Croce III, PE, Deputy Chief Engineer, C&S, 2995 Market Street, Philadelphia, PA 19104

Specifically, Amtrak requests permission to convert approximately 13 miles of its cab signal and fixed automatic block signal system to a signal system having cab signals without fixed automatic block signals, operated under NORAC Rule 562, on Amtrak's New York Division, Main Line New York to Philadelphia, Northeast Corridor, between County Interlocking located at milepost (MP) 32.8 in New Brunswick, New Jersey, and Union Interlocking located at MP 19.7 in Rahway, New Jersey. Amtrak is the owner and operator of this line, but Conrail and New Jersey Transit Rail Operations (NJTRO) both operate on portions of this line as tenants with trackage rights. Both Conrail and NJTRO have concurred with the application.

Amtrak's proposed changes are to remove 34 fixed automatic block signals between County Interlocking and Union Interlocking; convert each of the former signal locations to block points on Tracks 1, 2, 3, and 4; and install Clear to the Next Interlocking ''C'' lights, per NORAC Rule 280a, on interlocking signals at County Interlocking (eastward) and Edison, Lincoln, and Union Interlockings (westward).

Amtrak states removing the signals will eliminate maintenance and

operation of unnecessary hardware and reduce delays to trains caused by failures of the signals.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov.*

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation (DOT), 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Ave., SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by February 11, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of regulations.gov.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2020–28557 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2020–0027–N–31]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA) and its implementing regulations, this notice announces that FRA is forwarding the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On September 11, 2020, FRA published a notice providing a 60-day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or before January 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed ICR should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find the particular ICR by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Hodan Wells, Information Collection Clearance Officer, Office of Railroad Safety, Regulatory Analysis Division, Federal Railroad Administration, telephone: (202) 493–0440, email: *Hodan.wells@dot.gov.*

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On September 11, 2020, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICR for which it is now seeking OMB approval. *See* 85 FR 56286. FRA received no comments in response to this notice.

Before OMB decides whether to approve the proposed collection of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Railroad Operating Rules.

OMB Control Number: 2130–0035.

Abstract: The collection of information associated with Title 49 Code of Federal Regulations (CFR) parts 217 and 218, *Railroad Operating Rules and Practices,* requires railroads to file with FRA copies of their operating rules, timetables, timetable special instructions, and subsequent amendments. The regulations also require railroads to retain copies of these documents at their systems headquarters and make these documents available to FRA upon request.

Through these requirements, FRA learns of operating rules and practices for trains and instructions railroads provide their employees on operating practices.

Type of Request: Extension with change (revised estimates) of a currently approved collection.

Affected Public: Businesses.

Form(s): N/A.

Respondent Universe: 765 railroads.

Frequency of Submission: On occasion.

Reporting Burden:[1]

CFR section[2]	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total cost equivalent[3]
217.7(a)—Operating rules; filing and recordkeeping—Filing of code of operating rules, timetables, and timetable special instructions by Class Is, Class IIs, Amtrak, and commuter railroads with FRA.	2 new railroads	2 documents	1 hour	2	$154
—(b) Amendments to code of operating rules, timetables, and timetable special instructions by Class Is, Class IIs, Amtrak, and commuter railroads with FRA.	53 railroads	312 revised documents.	20 minutes	104	8,008
—(c) Class III and other railroads—Copy of code of operating rules, timetables, and timetable special instructions at system headquarters.	2 new railroads	2 documents	1 hour	2	154
—(c) Class III and other railroads—Amendments to code of operating rules, timetables, and timetable special instructions at system headquarters.	798 railroads	1,596 copies	15 minutes	399	30,723
217.9(b)(2)—Program of operational tests and inspections; recordkeeping—Written records documenting qualification of each railroad testing officer.	765 railroads	4,732 records	2 minutes	158	12,166
—(c) Written program of operational tests and inspections.	2 new railroads	2 programs	10 hours	20	2,300
—(d)(1) Records of operational tests/inspections.	765 railroads	9,120,000 test records and updates.	5 minutes	760,000	58,520,000
—(d)(2) Railroad copy of current program operational tests/inspections—Amendments.	53 railroads	159 program revisions.	70 minutes	186	14,322
—(e)(1)(i) Written quarterly review of operational tests/inspections by RRs other than passenger RRs.	7 Class I railroads + Amtrak.	32 reviews	2 hours	64	4,928
—(e)(1)(ii) 6-month review of operational tests/inspections/naming of officer.	7 Class I railroads	14 reviews	2 hours	28	2,156
—(e)(2) 6-month review by passenger railroads designated officers of operational testing and inspection data.	35 Amtrak + passenger railroads.	70 reviews	2 hours	140	10,780
—(e)(3) Records of periodic reviews	50 railroads	116 records	1 minute	2	154
—(f)–(g) Annual summary of operational tests and inspections.	50 railroads	50 summary records	1 hour	50	3,850
—(h)(1)(i) RR amended program of operational tests/inspections.	765 railroads	6 revised programs	30 minutes	3	231
—(h)(1)(ii) FRA disapproval of RR program of operational tests/inspections and RR written response in support of program.	765 railroads	6 supporting documents.	1 hour	6	462
217.11(a)—RR periodic instruction of employees on operating rules—New railroads.	2 new railroads	2 written programs	8 hours	16	1,232
217.11(b)—RR copy of program amendments for periodic instruction of employees.	765 railroads	110 modified written programs.	30 minutes	55	4,235
218.95(a)(5)–(b)—Instruction, training, examination—Employee completed test records.	765 railroads	85,600 employee records.	1 minute	1,427	109,879

[1] FRA provides a revised PRA table that includes updated burdens associated with §§ 217.11, 218.95, and 218.97. The estimates have been updated after an internal review.

[2] **Note:** The current inventory estimates a total burden of 4,791,614 hours while the requesting inventory estimates a total burden of 763,236 hours. There is no change in the method of the collection. However, FRA determined some of the estimates were double counted and/or outdated, while other estimates were not PRA requirements, thus leading to the increased figures in the current inventory, which were decreased accordingly in this notice. Also, totals may not add due to rounding.

[3] The dollar equivalent cost is derived from the Surface Transportation Board's Full Year Wage A&B data series using the appropriate employee group hourly wage rate that includes a 75-percent overhead charge. The hourly wage rate used is $77 per hour ($44.27 * 1.75 = $77).

CFR section [2]	Respondent universe	Total annual responses	Average time per response	Total annual burden hours	Total cost equivalent [3]
—(c)(1)(i) Amended RR program of instruction, testing, examination.	765 railroads	5 amended programs	30 minutes	3	231
218.97(b)(4)—RR copy of good faith challenge procedures.	765 railroads	4,732 copies to new employees.	6 minutes	473	36,421
218.97(c)(1) and (4)—RR employee good faith challenge of RR directive.	10 workers	10 good faith challenges.	15 minutes	3	231
—(c)(5) RR resolution of employee good faith challenge.	2 new railroads	5 responses	15 minutes	1	77
—(d)(1) RR officer immediate review of unresolved good faith challenge.	2 new railroads	3 reviews	30 minutes	2	154
—(d)(2) RR officer explanation to employee that Federal law may protect against employer retaliation for refusal to carry out work if employee refusal is a lawful, good faith act.	2 new railroads	3 answers	15 minutes	1	77
—(d)(3) Employee written/electronic protest of employer final decision.	2 new railroads	3 written protests	15 minutes	1	77
—(d)(3) Employee copy of protest	2 new railroads	3 copies	1 minute	0.1	8
—(d)(4) Employer further review of good faith challenge after employee written request.	2 new railroads	2 further reviews	15 minutes	0.5	39
—(d)(4) RR verification decision to employee in writing.	2 new railroads	2 decisions	15 minutes	0.5	39
—(e) Recordkeeping and record retention—Employer's copy of written procedures at division headquarters.	765 railroads	765 copies	5 minutes	64	4,928
218.99(a)—Shoving or pushing movement—RR operating rule complying with section's requirements.	2 new railroads	2 rule modifications	1 hour	2	154
218.101(a)–(c)—Leaving equipment in the clear—Operating rule that complies with this section.	2 new railroads	2 rule modifications	30 minutes	1	77
218.103(a)(1)—Hand-Operated Switches—Operating Rule that Complies with this section.	2 new railroads	2 rule modifications	30 minutes	1	77
Total	765 railroads	9,348,371 responses	N/A	763,236	58,770,040

Total Estimated Annual Responses: 9,348,371.

Total Estimated Annual Burden: 763,236 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $58,770,040.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that a respondent is not required to respond to, conduct, or sponsor a collection of information that does not display a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Deputy Chief Counsel.

[FR Doc. 2020–28472 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2020–0095]

Notice of Application for Approval of Discontinuance or Modification of a Railroad Signal System

Under part 235 of title 49 Code of Federal Regulations (CFR) and 49 U.S.C. 20502(a), this document provides the public notice that on December 4, 2020, Norfolk Southern Corporation (NS) petitioned the Federal Railroad Administration (FRA) seeking approval to discontinue or modify a signal system. FRA assigned the petition Docket Number FRA–2020–0095.

Applicant: Norfolk Southern Corporation, T.A. Phillips, Senior Director—C&S Engineering, 1200 Peachtree Street NE, Atlanta, GA 30309.

Specifically, NS requests permission to discontinue a traffic control system (TCS) from milepost (MP) V 327 (PD Junction) to V 381.8 (Maben) on the Princeton-Deepwater line of the Pocahontas Division. This area includes control points (CPs) at Ambrose, Beggs, Princeton, Rock, Weyanoke, Clark Gap, Algoquin, Herndon, Alpoca, CP No. 1 Crossover, Elmore, Gulf Junction, Virwest, Maben, and nine automatic signals. An operative approach signal will be placed at MP V 329.4 in approach to the CP PD Junction. All slide fences within the application limits will also be retired. The main track between MP V 327 and MP V 381.8 will be converted to NS Rule 171 operation. The signaled sidings within the application limits will be made non-controlled, other than main track.

NS states that operations in this area no longer require a TCS.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov*.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested parties desire an opportunity for oral comment and a public hearing, they should notify FRA,

in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- *website: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* Docket Operations Facility, U.S. Department of Transportation (DOT), 1200 New Jersey Ave. SE, W12–140, Washington, DC 20590.
- *Hand Delivery:* 1200 New Jersey Ave. SE, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by February 11, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacyNotice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2020–28556 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2020–0030; Notice 1]

Collins Bus Corporation, Receipt of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Receipt of petition.

SUMMARY: Collins Bus Corporation (Collins) has determined that certain model year (MY) 2012–2020 Ford and Chevrolet school buses do not fully comply with Federal Motor Vehicle Safety Standard (FMVSS) No. 217, *Bus Emergency Exits and Window Retention and Release.* Collins filed a noncompliance report dated April 15, 2020. Collins subsequently petitioned NHTSA on April 30, 2020, for a decision that the subject noncompliance is inconsequential as it relates to motor vehicle safety. This notice announces receipt of Collins's petition.

DATES: Send comments on or before January 27, 2021.

ADDRESSES: Interested persons are invited to submit written data, views, and arguments on this petition. Comments must refer to the docket and notice number cited in the title of this notice and submitted by any of the following methods:

- *Mail:* Send comments by mail addressed to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver comments by hand to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590. The Docket Section is open on weekdays from 10 a.m. to 5 p.m. except for Federal holidays.
- *Electronically:* Submit comments electronically by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov/.* Follow the online instructions for submitting comments.
- Comments may also be faxed to (202) 493–2251.

Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that comments you have submitted by mail were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided.

All comments and supporting materials received before the close of business on the closing date indicated above will be filed in the docket and will be considered. All comments and supporting materials received after the closing date will also be filed and will be considered to the fullest extent possible.

When the petition is granted or denied, notice of the decision will also be published in the **Federal Register** pursuant to the authority indicated at the end of this notice.

All comments, background documentation, and supporting materials submitted to the docket may be viewed by anyone at the address and times given above. The documents may also be viewed on the internet at *https://www.regulations.gov* by following the online instructions for accessing the docket. The docket ID number for this petition is shown in the heading of this notice.

DOT's complete Privacy Act Statement is available for review in a **Federal Register** notice published on April 11, 2000 (65 FR 19477–78).

SUPPLEMENTARY INFORMATION:

I. Overview: Collins has determined that certain MY 2012–2020 Ford and Chevrolet school buses do not fully comply with the requirements of paragraph S5.5.3(b) of FMVSS No. 217, *Bus Emergency Exits and Window Retention and Release* (49 CFR 571.217). Collins filed a noncompliance report dated April 15, 2020, pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports.* Collins subsequently petitioned NHTSA on April 30, 2020, for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential as it relates to motor vehicle safety, pursuant to 49 U.S.C. 30118(d) and 30120(h) and 49 CFR part 556, *Exemption for Inconsequential Defect or Noncompliance.*

This notice of receipt of Collins's petition is published under 49 U.S.C. 30118 and 30120 and does not represent any Agency decision or other exercise of judgment concerning the merits of the petition.

II. Buses Involved: Approximately 11,079 MY 2012-2012;2020 Ford and Chevrolet school buses manufactured between February 2, 2012, and April 3, 2020, are potentially involved:

- Ford TH 400
- Ford Sh416, models SL, SH, DH, DE, TH, and TL
- Chevrolet DE516
- Chevrolet DH516
- Chevrolet DH500
- Ford TL 400
- Ford T24
- Chevrolet DH400

III. Noncompliance: Collins explains that the noncompliance is that the letter

height for the operating instructions describing the motions necessary to unlatch and open the emergency exits in the subject school buses does not fully comply with the requirements set forth in paragraph S5.5.3(b) of FMVSS No. 217. Specifically, the operating instructions describing the motions necessary to unlatch and open the emergency window exits are only eight (8) millimeters in height rather than the required one (1) centimeter.

IV. Rule Requirements: Paragraph S5.5.3(b) of FMVSS No. 217 includes the requirements relevant to this petition. Paragraph S5.5.3(b) requires that concise operating instructions describing the motions necessary to unlatch and open the emergency exit shall be located within 15 centimeters of the release mechanism on the inside surface of the bus. These instructions shall be in letters at least 1 centimeter high and of a color that contrasts with its background.

V. Summary of Collins's Petition: The following views and arguments presented in this section, ''V. Summary of Collins's Petition,'' are the views and arguments provided by Collins. They have not been evaluated by the Agency and do not reflect the views of the Agency. Collins describes the subject noncompliance and contends that the noncompliance is inconsequential as it relates to motor vehicle safety.

In support of its petition, Collins offers the following reasoning:

1. The Noncompliance is Inconsequential to Motor Vehicle Safety: Collins states that the 2-millimeter deficiency in the letter height is inconsequential to motor vehicle safety. The actual height of the emergency window exit operating instructions letters—eight (8) millimeters—is 80 percent of the height required by FMVSS No. 217 (ten (10) millimeters). NHTSA has previously granted inconsequential noncompliance petitions for labeling defects across various motor vehicle safety standards, including for more significant lettering height deficiencies:

- *Notice Granting Petition by Kia Motors:* Letters as little as 53.1 percent of the minimum height requirement. *See* 69 FR 41333 (July 8, 2004) (Docket No. NHTSA–2004–17439).
- *Notice Granting Petition by General Motors:* Lettering height 76.3 percent of the minimum height requirement. *See* 81 FR 92963 (Docket No. NHTSA–2016–0093).
- *Notice Granting Petition by Hyundai:* Letters as little as 78.1 percent of the minimum height requirement. *See* 69 FR 41568 (Docket No. NHTSA–2004–17439).
- *Notice Granting Petition by Mercedes-Benz:* Letters ''about 78 percent of the minimum height required for such letters.'' *See* 67 FR 72026 (Docket No. NHTSA–2002–12544).

2. Further, the instruction label includes the words ''Emergency Exit'' in letters with a height of 11 millimeters, which not only meets but substantially exceeds the 1-centimeter requirement. *See* 67 FR 72026 (noting that some of the letters did meet the minimum height requirements in finding that insufficient height of other letters did not have an adverse effect on vehicle safety).

3. Collins claims that the height discrepancy *does not affect the readability* of the instructions. *See* 67 FR 72026 (finding that letters which were roughly 78 percent of the required size (which required size was nearly one-third of the relevant one-centimeter letter height requirement at issue here) would not ''degrade the legibility'' of the words); 81 FR 92964 (finding ''the lettering height for the park brake applied indicator 'Park' at 2.44 mm versus the FMVSS No. 135 requirement of 3.2 mm poses little if any risk to motor vehicle safety'').

4. Further, Collins says the discrepancy *does not compromise the conspicuity* of the instructions. The instructions are not only in a color that sharply contrasts with their background (red) as required by FMVSS No. 217, the letters are additionally in bold and block capital letters, which is not required by the standard but which preserves the 8-millimeter height across the width of the words and increases the visibility of the instructions. *See* 81 FR 92964 (finding the use of all capitalized letters, where not required, provided ''a more pronounced indicator''). And as noted above, some of the words in the label (*i.e.,* ''Emergency Exit'') not only meet but exceed the minimum height requirement, thereby increasing the visibility of the instructions.

5. Collins states that NHTSA has previously granted petitions for inconsequential noncompliance under FMVSS No. 217 for conditions that present a more direct safety risk than the potential safety risk (if any) created here. *See* New Flyer of America, Inc.; Grant of Application for Decision of Inconsequential Noncompliance, 63 FR 32694 (granting petition for inconsequential noncompliance where buses were manufactured with only one emergency exit instead of two); IC Corporation, Grant of Petition for Decision of Inconsequential Noncompliance, 70 FR 24464 (granting petition for inconsequential noncompliance where school buses were manufactured with two emergency doors under the same post and roof bow panel space).

6. Finally, Collins states that the emergency window exit instructions on the affected vehicles meet all other labeling requirements of FMVSS No. 217 and do not affect the actual operation of the emergency window exit, and Collins has not received any complaints regarding the size or visibility of the instructions and is not aware of any injuries associated with the size or visibility of the instructions. Collins has corrected the noncompliance in all buses remaining within its possession.

Collins concludes by again contending that the subject noncompliance is inconsequential as it relates to motor vehicle safety, and that its petition to be exempted from providing notification of the noncompliance, as required by 49 U.S.C. 30118, and a remedy for the noncompliance, as required by 49 U.S.C. 30120, should be granted.

Collins's complete petition and all supporting documents are available by logging onto the Federal Docket Management System (FDMS) website at *https://www.regulations.gov* and by following the online search instructions to locate the docket number as listed in the title of this notice.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, any decision on this petition only applies to the subject buses that Collins no longer controlled at the time it determined that the noncompliance existed. However, any decision on this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant buses under their control after Collins notified them that the subject noncompliance existed.

(Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8)

Otto G. Matheke III,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2020–28542 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

[Docket No. PHMSA–2019–0141]

Pipeline Safety; Information Collection Activities

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the information collection request abstracted below is being forwarded to the Office of Management and Budget (OMB) for review and comment. PHMSA will request a revision to PHMSA F 7000–1 Accident Report—Hazardous Liquid Pipeline Systems identified by OMB control number 2137–0047. A **Federal Register** notice soliciting comments on this information collection was published on March 9, 2020, (85 FR 13700). PHMSA received comments which are summarized below.

DATES: Comments must be submitted on or before January 27, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* You can find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this notice contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this notice, it is important that you clearly designate the submitted comments as CBI. Pursuant to 49 CFR 190.343, you may ask PHMSA to give confidential treatment to information you give to the agency by taking the following steps: (1) Mark each page of the original document submission containing CBI as ''Confidential''; (2) send PHMSA, along with the original document, a second copy of the original document with the CBI deleted; and (3) explain why the information you are submitting is CBI. Unless you are notified otherwise, PHMSA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this notice. Submissions containing CBI should be sent to Angela Hill, DOT, PHMSA, 1200 New Jersey Avenue SE, PHP–30, Washington, DC 20590–0001. Any commentary PHMSA receives that is not specifically designated as CBI will be placed in the public docket for this matter.

FOR FURTHER INFORMATION CONTACT: For information regarding this notice contact Angela Hill, Transportation Specialist, by telephone at 202–366–1246, or by email at *Angela.Hill@dot.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 1320.8(d), title 5, Code of Federal Regulations, requires PHMSA to provide interested members of the public and affected entities an opportunity to comment on information collection and recordkeeping requests. This notice identifies proposed changes to an information collection that PHMSA will submit to OMB for approval. To streamline and improve the data collection processes, PHMSA is revising the form and instructions for PHMSA F 7000–1 Accident Report—Hazardous Liquid Pipeline Systems for hazardous liquid and carbon dioxide pipeline operators.

In response to the March 9, 2020, **Federal Register** notice and request for comment (85 FR 13700), PHMSA received comments from the Institute for Policy Integrity at New York University School of Law (Policy Integrity), from the American Petroleum Institute (API), and the Association of Oil Pipe Lines (AOPL). Comments recommending changes, organized by topic area, are summarized and addressed below:

1. *Change Form Name:* PHMSA received no comments pertaining to this change.

2. *Time Zone and Daylight Savings:* PHMSA received no comments pertaining to this change.

3. *Operational Status:* API/AOPL requested clarification of the phrase ''operational status'' and requested that PHMSA undertake a new rulemaking to correct an apparent discrepancy between PHMSA's August 16, 2016, Advisory Bulletin titled, ''Clarification of Terms Relating to Pipeline Operational Status'' (81 FR 54512) and recently published frequently asked questions concerning PHMSA's October 1, 2019, Final Rule titled, ''Safety of Hazardous Liquid Pipelines'' (84 FR 52260). As to ''operational status'', PHMSA has included a description of each choice for operational status in the instructions for PHMSA F 7000–1 to provide clarification. PHMSA routinely updates its data collection forms to align with the regulations. If there are any changes to the definitions related to operational status of pipelines in the future, PHMSA will revise the reports as necessary.

4. *Part A Reorganization and Detailed Questions About Accident Response:* API/AOPL generally supported reorganizing Part A of the form, but recommended PHMSA clarify the term ''identified,'' which is used in Part E. API/AOPL opined that responses to questions regarding the ''identification'' of a pipeline failure are not uniform due to a lack of guidance and definition of the term. API/AOPL requested that PHMSA align the term with ''confirmed discovery,'' as defined in the Code of Federal Regulations, which ''means when it can be reasonably determined, based on information available to the operator at the time a reportable event has occurred, even if only based on a preliminary evaluation.'' PHMSA notes that proposed question A13, ''Local time operator identified failure'', has been part of the report for many years and has not resulted in confusion. Further, the instructions provide guidance for properly determining the date and time identified in several scenarios. PHMSA will add date and time of ''confirmed discovery'' as a new question A20 since ''confirmed discovery'' occurs either concurrent with identifying the failure or later.

5. *Multiple NRC Reports:* API/AOPL proposed that PHMSA requires one master National Response Center (NRC) report that is linked to multiple NRC reports, arising from a single accident. Alternatively, API/AOPL proposed that PHMSA collect all the NRC report numbers for one accident in Part A6, allowing multiple numbers to be entered in one box, rather than create an additional question. API/AOPL also proposed that PHMSA provide instructions or guidance informing operators that this question includes the initial report and all subsequent reports. PHMSA has provided instructions making it clear that the initial NRC report is entered as a response to question A21b and all subsequent NRC reports are entered in response to question A21c. The response to question A21c is submitted via a text field so multiple NRC reports can be entered. PHMSA needs the initial NRC report number in a separate data field so it can

be stored as a number and used in analysis.

6. *Flow Control and Valve Closures:* API/AOPL commented that the ''current form provides adequate details on valve closures and shut-in response to an accident.'' They opined that each accident is unique and response actions to address them may vary widely based on the pipeline system, the individual line affected, pipeline ROW versus facility release, etc. API/AOPL commented that the additional request for information regarding valve closures and shut-in responses on the form will likely result in several operators choosing ''other'' as a selection, which they say PHMSA is trying to avoid. Further, API/AOPL disagreed that adding more questions will allow stakeholders to understand the actions taken by the operator to control the flow of products while responding to an accident. They commented that additional questions may unintentionally cause confusion regarding which valve information to report. Finally, API/AOPL comment that PHMSA should distinguish between manual and remote-operated valves. PHMSA is proposing to collect data about the operator's initial upstream and downstream actions to control the flow of product to the failure site. There are only two options—valve closure or a text field explaining the method of operation control implemented. There is no option for ''other.'' The form and instructions clearly indicate to report the initial method of flow control. When a valve closure is the initial method, the operator also identifies the type of valve. PHMSA recognizes that valve closure is not always the appropriate method of flow control, which is why ''operational control'' was added. Finally, the terms ''manual,'' ''automatic,'' and ''remotely controlled'' have been in the report for several years without raising any concerns or presenting issues in practice. These are commonly used terms familiar to the operators. PHMSA also offers a pipeline glossary including types of valves.

7. *Area of Accident:* API/AOPL commented that clarity is needed regarding the term ''underground.'' They commented that PHMSA's proposal may not accurately capture operators' current processes. For instance, there may be locations on a pipeline that were originally buried but have become exposed over time, such as stream and ditch crossings, of which the operator is aware and manages as aboveground piping. API/AOPL commented that PHMSA should clarify the difference between underground and aboveground piping as it relates to an unforeseen loss of cover. They noted that the definition of underground should refer to the overall condition of the pipeline segment and not only the location where the accident occurred. PHMSA notes that the instructions provide definitions for both underground and aboveground pipe. The additional options under each provide more detail about the situations that should be reported for underground and aboveground pipe. PHMSA is collecting the data for the failure location, not for the overall pipeline segment. PHMSA also notes that this scenario, ''pipelines that were originally buried but have become exposed over time—such as stream and ditch crossings—of which the operator is aware and manages as aboveground piping,'' would be reported as aboveground and then specifying ''in or spanning an open ditch.'' Further, PHMSA notes that the form allows the selection of ''other'' after selecting either aboveground or underground to accommodate reporting in all possible scenarios.

8. *Date of Water Crossing Evaluation:* API/AOPL commented that more clarification is needed regarding the term ''evaluation.'' PHMSA concurs that the term ''engineering/risk evaluation'' is not well defined and is removing it from the form.

9. *Outer Continental Shelf Regions:* API/AOPL commented they are unclear as to what exactly will be required when reporting outer continental shelf (OCS) regions, as this information appears to currently be captured in Part B14 of the form. PHMSA currently captures OCS Area and Block Number as text fields. In the revision, PHMSA is also requiring one of the following to be reported: OCS Alaska, OCS Pacific, OCS Gulf of Mexico, or OCS Atlantic. In cases where OCS Area or Block Number are not recognized, PHMSA requires that the general area of the OCS accident be reported at a minimum.

10. *Item Involved and Age of Failed Item:* API/AOPL suggested PHMSA retain the selection of ''unknown'' for items of which age cannot be ascertained. Regarding ''other'' as a selection for ''item involved,'' API/AOPL suggested PHMSA change the option to ''unknown'' or ''data not available.'' PHMSA notes that the report has, and continues to, allow ''unknown'' as an option for both ''date of manufacture'' and ''date of installation.'' PHMSA sees no meaningful difference among ''other,'' ''unknown,'' and ''data not available.'' PHMSA plans to retain ''other'' as the final option for ''item involved.''

11. *Details About Consequences, Other injuries not requiring in-patient hospitalization:* API/AOPL recommended that PHMSA provide the definition of injuries treated on-site or clarify whether operators should defer to the Occupational Safety and Health Administration's (OSHA) definition. Also, API/AOPL asked if the new categories of injuries will be classified as ''Impacting People or the Environment'' (IPE). PHMSA is requesting information in D10 for ''Estimated number of persons with injuries requiring treatment by EMTs at the site of accident.'' This terminology is readily understood in the context of a pipeline failure. Operators should not use any OSHA definition as they apply to work-related injuries only. PHMSA does not plan to consider the two new categories of injuries when determining IPE.

12. *Details About Consequences, Volume of product consumed by fire:* The Institute for Policy Integrity at New York University School of Law supported collecting ''volume of product consumed by fire'' to assess the social costs of accidents. API/AOPL argued that operators are unable to accurately determine or differentiate between the volume of product burned and the volume that evaporated. API/AOPL recommended that PHMSA not duplicate oversight with the Environmental Protection Agency (EPA) and defer to the EPA's jurisdiction under the Clean Air Act. PHMSA is requiring operators to estimate the volume of product consumed by fire. By gathering this data through accident reports, PHMSA enhances its regulatory cost and benefit estimates and improves its assessment of regulatory alternatives as required by the Executive Order 12866. PHMSA is not duplicating oversight of EPA's jurisdiction, rather PHMSA is complying with OMB's Circular A–4, which advises agencies to ''monetize quantitative effects whenever possible'' as required by Executive Order 12866.

13. *Details About Consequences, Number of building affected by the accident:* API/AOPL requested that PHMSA use the same classification/definition of building as prescribed in 49 CFR 192.903. PHMSA notes that this code section does not include building classifications. PHMSA proposes two categories of buildings—commercial and residential.

14. *Establishing Maximum Pressure:* API/AOPL asked that PHMSA rephrase the term ''maximum pressure'' to ''maximum operating pressure (MOP)'' in accordance with 49 CFR 195.406. Also, API/AOPL requested the PHMSA

revise the form to ask whether the MOP was exceeded. Finally, API/AOPL opined that PHMSA should not seek MOP validity in the accident report and believes the information would be more appropriate in the National Pipeline Mapping System (NPMS) or the hazardous liquid and carbon dioxide annual report (Form F 7000.1–1). PHMSA has used MOP consistently throughout the accident report form and instructions. PHMSA's data collection software will determine if MOP was exceeded and the degree of exceedance. PHMSA considers the ''limiting factor establishing MOP'' as a critical piece of data about the failure location.

15. *Length of Segment Isolated:* API/AOPL asked for clarification regarding the term ''isolated.'' PHMSA's instructions clarify that this is only answered when the method of flow control is valve closure both upstream and downstream of the failure location. PHMSA will also add this clarification to the form.

16. *External Corrosion and Stray Current:* API/AOPL do not object to additional details regarding stray current, however, they note this information is generally not available within the 30-day requirement for accident reports. PHMSA notes that operators can submit an original accident report without the information in 2a and 2b and submit a supplemental report once the information becomes available.

17. *Natural Force Damage Additional Sub-Cause:* The API/AOPL do not believe that adding tree root damage to the form will significantly reduce the number of accidents reported as ''Other Accident Cause.'' PHMSA agrees that tree root damage to hazardous liquid pipelines may not significantly reduce the number of accidents reported as ''Other Accident Cause.'' PHMSA seeks to collect consistent cause codes for all pipeline systems for ease of data analysis and realizes that some of the detailed cause codes may be more relevant to a specific pipeline system type.

18. *Excavation Details For All Excavation Damages:* API/AOPL commented they are unclear as to what additional information will be collected for first- and second-party excavators. In the March 9, 2020 Notice, PHMSA incorrectly stated that data is collected only when the excavator is a third-party. In fact, the current accident report already collects data about all excavation damages. PHMSA now proposes to only collect data about the excavations in a structure matching the current Common Ground Alliance (CGA) Damage Information Reporting Tool (DIRT). PHMSA also proposes to add questions about exemptions from State damage prevention laws.

19. *State Damage Prevention Law Exemption:* API/AOPL recommended that PHMSA keep the excavation questions consistent with the information collected on the DIRT form. PHMSA's question on State Damage Prevention Law Exemption is not part of the CGA–DIRT and is applicable only to accidents where a third-party is identified as the cause of the accident. Data about exemptions is important to PHMSA and its State partners to assess instances where excavators have been exempted from notifying operators prior to excavating.

20. *Material Failure Cause Changes:* API/AOPL objected to adding a question that collects post-construction pressure test values since original pressure test information is often missing or unavailable. Further, without more information, API/AOPL do not see the value in providing this data. PHMSA concurs and will remove the question.

21. *Additional Integrity Inspection Data:* API/AOPL asked that PHMSA rephrase Part J ''Integrity Inspection'' to ''Successful Integrity Inspection'' or ''Completed Integrity Inspection.'' They noted this would ensure that operators only provide data on ILI tool runs that provided a consistent and complete data set. API/AOPL also asked PHMSA to add a list of direct assessment methods available to operators.

PHMSA has renamed Part J from ''Integrity Inspections'' to ''Completed Integrity Inspections,'' as suggested. PHMSA understands a ''completed integrity inspection'' to be when the tool has been successfully run and not when the remediation is completed.

The form currently includes two options for the type of direct assessment—''External Corrosion Direct Assessment'' and ''Other.'' The selection for ''Other'' would include any ''other technology'' as determined by 195.452(j)(5)(iv) or 195.452(c)(1)(i)(D).

22. *Contributing Factors:* API/AOPL recommended that PHMSA modify Part K by adding an option for ''no contributing factors'' and emphasized that contributing factors are often not known until the completion of internal company analysis. PHMSA notes that making no selection in Part K is equivalent to ''no contributing factors'' and has not added the additional option recommended by API/AOPL. PHMSA will modify the form and instructions to emphasize that contributing factors are often not known until the completion of a root cause analysis. Supplemental reports are permitted as operators make determinations regarding contributing factors.

The following information is provided for this information collection: (1) Title of the information collection; (2) OMB control number; (3) Current expiration date; (4) Type of request; (5) Abstract of the information collection activity; (6) Description of affected public; (7) Estimate of total annual reporting and recordkeeping burden; and (8) Frequency of collection. PHMSA will request a three-year term of approval for this information collection activity. PHMSA requests comments on the following information:

1. *Title:* Transportation of Hazardous Liquids by Pipeline: Recordkeeping and Accident Reporting.

OMB Control Number: 2137–0047.

Current Expiration Date: 1/31/2023.

Type of Request: Revision.

Abstract: This information collection covers recordkeeping and accident reporting by hazardous liquid pipeline operators who are subject to 49 CFR part 195. Section 195.50 specifies the definition of an ''accident'' and the reporting criteria for submitting a Hazardous Liquid Accident Report (form PHMSA F7000–1) is detailed in § 195.54. PHMSA is proposing to revise the form and instructions for PHMSA F7000–1 for editorial and clarification purposes and to collect additional data. Currently, PHMSA estimates that 406 Hazardous Liquid Accident Report forms are submitted each year with operators spending, on average, 10 hours to complete each report. Due to the proposed changes, PHMSA expects the burden for completing each report to increase by 2 hours. This will result in an overall burden increase of 812 hours for this information collection.

Affected Public: Hazardous liquid pipeline operators.

Annual Reporting and Recordkeeping Burden:

Annual Responses: 1,644.

Annual Burden Hours: 53,504.

Comments to Office of Management and Budget are invited on:

(a) The need for the proposed information, including whether the information will have practical utility in helping the agency to achieve its pipeline safety goals;

(b) The accuracy of the agency's estimate of the burden of the proposed collection;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(d) Ways to minimize the burden on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued in Washington, DC, on December 16, 2020, under authority delegated in 49 CFR 1.97.

Alan K. Mayberry,

Associate Administrator for Pipeline Safety.

[FR Doc. 2020–28481 Filed 12–23–20; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more individuals that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List). OFAC has determined that one or more applicable legal criteria were satisfied to place the individuals on the SDN List. All property and interests in property subject to U.S. jurisdiction of these individuals are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT:

OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; or Assistant Director for Regulatory Affairs, tel.: 202–622–4855.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On December 21, 2020, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following individuals are blocked under the relevant sanctions authorities listed below.

Individuals:

1. AGUILAR GARCIA, Marvin Ramiro, Altos de Motastepe Casa No 430, Managua, Nicaragua; DOB 10 Jan 1957; POB Chontales, Nicaragua; nationality Nicaragua; Gender Male; Passport A0008313 (Nicaragua) issued 03 Jun 2009 expires 02 Jun 2014 (individual) [NICARAGUA].

Designated pursuant to section 1(a)(iii) of Executive Order 13851 of November 27, 2018, ''Blocking Property of Certain Persons Contributing to the Situation in Nicaragua,'' 83 FR 61505, (''E.O. 13851''), for being an official of the Government of Nicaragua or having served as an official of the Government of Nicaragua at any time on or after January 10, 2007.

2. GUTIERREZ MERCADO, Walmaro Antonio, KM. 43.5 South Road Panamerican, South Panamerican Highway, Diriamba, Carazo, Nicaragua; DOB 05 May 1968; POB Managua, Nicaragua; nationality Nicaragua; Gender Male; Passport A0007922 (Nicaragua) issued 25 Sep 2007 expires 24 Sep 2012 (individual) [NICARAGUA].

Designated pursuant to section 1(a)(iii) of E.O. 13851 for being an official of the Government of Nicaragua or having served as an official of the Government of Nicaragua at any time on or after January 10, 2007.

3. DOMINGUEZ ALVAREZ, Fidel De Jesus, Altos E San Isidro A15, Managua, Nicaragua; DOB 21 Mar 1963; POB Rivas, Nicaragua; nationality Nicaragua; Gender Male (individual) [NICARAGUA].

Designated pursuant to section 1(a)(iii) of E.O. 13851 for being an official of the Government of Nicaragua or having served as an official of the Government of Nicaragua at any time on or after January 10, 2007.

Dated: December 21, 2020.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2020–28582 Filed 12–23–20; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

[Case IDs: CU–19766, CU–19767, CU–19699]

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the identifying information of three entities that were added to OFAC's list of Specially Designated Nationals and Blocked Persons (SDN List).

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT:

OFAC: Andrea Gacki, Director, tel.: 202–622–2490; Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*www.treasury.gov/ofac*).

Notice of OFAC Action(s)

On December 17, 2020, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following entities are blocked under the relevant sanctions authority listed below.

Entities

1. KAVE COFFEE S.A. (a.k.a. KAVE COFFEE S A), Panama; Calle A No. 310 entre 3ra y 5ta, Municipio Playa, Havana, Cuba; RUC # 22044–123–197519 (Panama) [CUBA].

Identified pursuant to the Cuban Assets Control Regulations, 31 CFR part 515 (CACR), as meeting the definition of a Cuban national, a person whose property and interests in property are blocked pursuant to CACR.

2. FINANCIERA CIMEX S.A (a.k.a. FINCIMEX), Calle 8, Entre 3ra Y 5ta Ave, 319 Playa, Havana, Cuba; Panama; RUC # 12555–91–124494 (Panama) [CUBA].

Identified pursuant to the CACR as meeting the definition of a Cuban national, a person whose property and interests in property are blocked pursuant to CACR.

3. GRUPO DE ADMINISTRACION EMPRESARIAL S.A. (a.k.a. GAESA; a.k.a. ''GRUPO GAE''), Edificio de la Marina, Avenida Del Puerto Y Brapia, Havana, Cuba; Organization Established Date 28 Feb 1999; Organization Type: Activities of holding companies [CUBA].

Identified pursuant to the CACR as meeting the definition of a Cuban national, a person whose property and interests in property are blocked pursuant to CACR.

Dated: December 17, 2020.

Andrea Gacki,

Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2020–28584 Filed 12–23–20; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Multiple Internal Revenue Service Information Collection Requests

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury will submit the following information collection requests to the

Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. The public is invited to submit comments on these requests.

DATES: Comments should be received on or before January 27, 2021 to be assured of consideration.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of the submissions may be obtained from Molly Stasko by emailing *PRA@treasury.gov,* calling (202) 622–8922, or viewing the entire information collection request at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION:

Internal Revenue Service (IRS)

1. Title: United States Gift (and Generation-Skipping Transfer) Tax Return.

OMB Control Number: 1545–0020.

Type of Review: Extension of a currently approved collection.

Description: Form 709 is used by individuals to report transfers subject to the gift and generation-skipping transfer taxes and to compute these taxes. The IRS uses the information to collect and enforce these taxes, to verify that the taxes are properly computed, and to compute the tax base for the estate tax.

Form: IRS Form 709.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 255,500.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 255,500.

Estimated Time per Response: 6 hour, 12 minutes.

Estimated Total Annual Burden Hours: 1,584,100 hours.

2. Title: Quarterly Federal Excise Tax Return.

OMB Control Number: 1545–0023.

Type of Review: Extension of a currently approved collection.

Description: Excise taxes are taxes paid when purchases are made on a specific good, such as gasoline. 26 U.S.C. 4081 imposes tax for miscellaneous excise taxes, manufacturers excise taxes, automotive and related items, petroleum products and motor and aviation fuel. Form 720, Quarterly Federal Excise Tax Return, is used to report liability by IRS number and to pay the excise taxes listed on the form.

Form: IRS Form 720.

Affected Public: Individuals or Households; Businesses or other for-profit organizations; Not-for-profit institutions; and Federal, State, Local, and Tribal governments.

Estimated Number of Respondents: 180,000.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 180,000.

Estimated Time per Response: 12 hours, 4 minutes.

Estimated Total Annual Burden Hours: 2,173,641 hours.

3. Title: Application for Approval of Prototype Simplified Employee Pension (SEP) or Savings Incentive Match Plan for Employees of Small Employers (SIMPLE IRA Plan).

OMB Control Number: 1545–0199.

Type of Review: Extension of a currently approved collection.

Description: This form is used by banks, credit unions, insurance companies, and trade or professional associations to apply for approval of a simplified employee pension plan or a Savings Incentive Match Plan to be used by more than one employer. The data collected is used to determine if the prototype plan submitted is an approved plan.

Form: IRS Form 5306–A.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 6.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 6.

Estimated Time per Response: 19 hours, 22 minutes.

Estimated Total Annual Burden Hours: 117 hours.

4. Title: Return of Excise Taxes Related to Employee Benefit Plans.

OMB Control Number: 1545–0575.

Type of Review: Extension of a currently approved collection.

Description: Internal Revenue Code sections 4971, 4972, 4973(a)(3), 4975, 4976, 4977, 4978, 4978A, 4978B, 4979, 4979A and 4980 impose various excise taxes in connection with employee benefit plans. Form 5330 is used to compute and collect these taxes.

Form: IRS Form 5330.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 8,403.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 8,403.

Estimated Time per Response: 64.28 hours.

Estimated Total Annual Burden Hours: 540,145 hours.

5. Title: General Business Credit.

OMB Control Number: 1545–0895.

Type of Review: Extension of a currently approved collection.

Description: Internal Revenue Code section 38 permits taxpayers to reduce their income tax liability by the amount of their general business credit, which is an aggregation of their investment credit, work opportunity credit, welfare-to-work credit, alcohol fuel credit, research credit, low-income housing credit, disabled access credit, enhanced oil recovery credit, etc. Form 3800 is used to figure the correct credit.

Form: IRS Form 3800.

Affected Public: Businesses or other for-profit organizations; Individuals or Households.

Estimated Number of Respondents: 250,000.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 250,000.

Estimated Time per Response: 33.38 hours.

Estimated Total Annual Burden Hours: 8,345,500 hours.

6. Title: Enhanced Oil Recovery Project.

OMB Control Number: 1545–1292.

Type of Review: Revision of a currently approved collection.

Description: For purpose of section 43 of the Code, this document provides final regulations relating to the enhanced oil recovery credit for certain costs that are paid or incurred in connection with a qualified enhanced oil recovery project. Changes to the applicable law were made by the Omnibus Budget Reconciliation Act of 1990. These final regulations provide the public with guidance in determining the costs that are subject to the credit, the circumstances under which the credit is available, and the procedures whereby a project is certified as a qualified enhanced oil recovery project.

Regulation Project Number: TD 8448.

Affected Public: Businesses or other for-profit organizations; individuals; Not-for-profit institutions; and Federal, State, Local, or Tribal governments.

Estimated Number of Respondents: 40.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 40.

Estimated Time per Response: 73 hours.

Estimated Total Annual Burden Hours: 1,460 hours.

7. Title: Health Plan Administrator (HPA) Return of Funds.

OMB Control Number: 1545–1891.

Type of Review: Extension of a currently approved collection.

Description: Form 13560 is completed by Health Plan Administrators (HPAs) and accompanies a return of funds in order to ensure proper handling. This form serves as supporting documentation for any funds returned by an HPA and clarifies where the payment should be applied and why it is being sent.

Form Number: IRS Form 13560.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 200.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 200.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 50 hours.

8. Title: Employer's Annual Employment Tax Return.

OMB Control Number: 1545–2007.

Type of Review: Extension of a currently approved collection.

Description: The information on Form 944 will be collected to ensure the smallest nonagricultural and non-household employers are paying the correct amount of social security tax, Medicare tax, and withheld federal income tax. Information on line 13 will be used to determine if employers made any required deposits of these taxes. Form 944(SP) is the Spanish version of the Form 944. 944–X and Form 944–X(SP) is used to correct errors made on Form 944.

Form Number: IRS Form 944, IRS Form 944(SP), IRS Form 944–X and IRS Form 944–X(SP).

Affected Public: Businesses or other for-profit organizations; Individuals or households; Not-for-profit institutions; and State, Local, or Tribal governments.

Estimated Number of Respondents: 137,000.

Frequency of Response: Annually.

Estimated Total Number of Annual Responses: 137,000.

Estimated Time per Response: 15 hours, 33 minutes.

Estimated Total Annual Burden Hours: 2,168,681 hours.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: December 18, 2020.

Molly Stasko,

Treasury PRA Clearance Officer.

[FR Doc. 2020–28537 Filed 12–23–20; 8:45 am]

BILLING CODE 4830–01–P



FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 410, 414, et al.
Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 410, 414, 415, 423, 424, and 425

[CMS–1734–F, CMS–1734–IFC, CMS–1744–F, CMS–5531–F and CMS–3401–IFC]

RIN 0938–AU10, 0938–AU31, 0938–AU32, and 0938–AU33

Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID–19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID–19

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

ACTION: Final rule and interim final rule.

SUMMARY: This major final rule addresses: Changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; Medicare Shared Savings Program requirements; Medicaid Promoting Interoperability Program requirements for Eligible Professionals; updates to the Quality Payment Program; Medicare coverage of opioid use disorder services furnished by opioid treatment programs; Medicare enrollment of Opioid Treatment Programs; payment for office/outpatient evaluation and management services; Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA–PD plan and Medicare Diabetes Prevention Program (MDPP) expanded model Emergency Policy. This final rule also finalizes certain provisions of the interim final rules with comment period that CMS issued on March 31, 2020, May 8, 2020, and September 2, 2020 in response to the Public Health Emergency (PHE) for the Coronavirus Disease 2019 (COVID–19). This rule also establishes coding and payment for virtual check-in services and for personal protective equipment (PPE) on an interim final basis.

DATES: *Effective Date:* The regulations in the final rule are effective on January 1, 2021.

Applicability date: The policies in this final rule are applicable on January 1, 2021, except as follows:

(1) The revisions to 42 CFR 400.200 and 425.611(b)(1)(ii) are applicable retroactively to the start of the PHE for COVID–19 on January 27, 2020. (See discussions in sections II.J. and III.G.5.d.(2) of this final rule, respectively.)

(2) The revisions to 42 CFR 425.400(c)(2) are applicable retroactively for the performance year starting on January 1, 2020. (See discussion in section III.G.5.e.(3) of this final rule.)

Comment date: Comments will be accepted/considered ONLY on the ''Interim Final Rule with Comment Period for Coding and Payment of Virtual Check-in Services'' contained in section II.D. of the preamble of this document and ''Interim Final Rule with Comment Period for Coding and Payment for Personal Protective Equipment (PPE)'' contained in section II.H. of the preamble of this document. To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on February 1, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1734–IFC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1734–IFC,P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1734–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

FOR FURTHER INFORMATION CONTACT: Jamie Hermansen, (410) 786–2064, for any issues not identified below.

Michael Soracoe, (410) 786–6312, for issues related to practice expense, work RVUs, conversion factor, PFS specialty-specific impacts, and the interim final rule with comment period for coding and payment for PPE.

Larry Chan, (410) 786–6864, for issues related to potentially misvalued services under the PFS.

Emily Yoder, (410) 786–1804, Donta Henson, (410) 786–1947, and Patrick Sartini, (410) 786–9252, for issues related to telehealth, other services involving communications technology, and interim final rule with comment period for coding and payment of virtual check-in services.

Liane Grayson, (410) 786–6583, for issues related to care management services and remote physiologic monitoring services.

Emily Yoder, (410) 786–1804, Christiane LaBonte, (410) 786–7237, Ann Marshall, (410) 786–3059, and Patrick Sartini, (410) 786–9252, for issues related to payment for office/outpatient evaluation and management visits.

Christiane LaBonte, (410) 786–7237, and Cindy Bergin, (401) 786–1176, for issues related to teaching physician services.

Roberta Epps, (410) 786–4503, and Regina Walker-Wren, (410) 786–9160, for issues related to supervision of diagnostic tests.

Ann Marshall, (410) 786–3059, for issues related to incident to pharmacist services.

Gift Tee, (410) 786–9316, for issues related to therapy services.

Sarah Leipnik, (410) 786–3933, for issues related to medical record documentation.

Lindsey Baldwin, (410) 786–1694 and Terry Simananda, (410) 786–8144, for issues related to Medicare coverage of opioid use disorder treatment services furnished by opioid treatment programs.

Laura Ashbaugh, (410) 786–1113, for issues related to Clinical Laboratory Fee

Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions

Joseph Schultz, (410) 786–2656, for issues related to opioid treatment program provider enrollment regulation updates for institutional claim submissions.

Lisa Parker, (410) 786–4949, for issues related to RHCs and FQHCs, primary care management services, and the FQHC market basket.

Rachel Katonak, (410) 786–8564, or JoAnna Baldwin (410) 786–7205, for issues related to comprehensive screenings for seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act).

David Koppel, (303) 844–2883, or Elizabeth LeBreton (202) 615–3816 for issues related to the Medicaid Promoting Interoperability Program.

Fiona Larbi, (410) 786–7224, or Sabrina Ahmed, (410) 786–7499, for issues related to the Medicare Shared Savings Program (Shared Savings Program) Quality performance standard, quality reporting requirements and finalization of Shared Savings Program provisions from the March 31st COVID–19 IFC.

Janae James, (410) 786–0801, or Elizabeth November, (410) 786–4518, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment, repayment mechanism requirements, and finalization of Shared Savings Program provisions from the May 8th COVID–19 IFC.

Cheryl Gilbreath, (410) 786–5919, for issues related to home infusion therapy benefit.

Heather Hostetler, (410) 786–4515 for issues related to removal of selected national coverage determinations.

Joella Roland, (410) 786–7638, for issues related to requirement for electronic prescribing for controlled substances for a covered Part D drug under a prescription drug plan or an MA–PD plan.

Edmund Kasaitis, (410) 786–0477, for issues related to Part B drug payment and Food Drug & Cosmetic Act section 505(b)(2) drug products.

Elizabeth Holland, (410) 786–1309, for issues related to updates to certified electronic health record technology due to the 21st Century Cures Act.

Julia Venanzi, (410) 786–1471, for issues related to the Hospital Inpatient Quality Reporting (IQR) Program.

Cynthia Hake, (410) 786–3404, for issues related to HCPCS Level II codes.

Amanda Rhee, (410) 786–3888, for the Medicare Diabetes Prevention Program (MDPP) expanded model emergency policy.

Molly MacHarris, (410) 786–4461, for inquiries related to Merit-based Incentive Payment System (MIPS).

Brittany LaCouture, (410), 786–0481, for inquiries related to Alternative Payment Models (APMs).

Patricia Taft, (410) 786–4561, for issues related to the Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Addenda Available Only Through the internet on the CMS website: The PFS Addenda along with other supporting documents and tables referenced in this final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2021 PFS final rule, refer to item CMS–1734–F. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this final rule and posted on the CMS website identified above should contact Jamie Hermansen at (410) 786–2064.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this final rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2019 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major final rule revises payment polices under the Medicare PFS and makes other policy changes, including to the implementation of certain provisions of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018) and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (the SUPPORT Act) (Pub. L. 115–271, October 24, 2018), related to Medicare Part B payment. In addition, this final rule includes provisions related to other payment policy changes that are addressed in sections III. and IV. of this final rule.

We are issuing an interim final rule with comment period (IFC) to establish coding and payment for virtual check-in services to support the continuing need for coding and payment to reflect the provision of lengthier audio-only services outside of the PHE for COVID–19, if not as substitutes for in-person services, then as a tool to determine whether an in-person visit is needed, particularly as beneficiaries may still be cautious about exposure risks associated with in-person services. We are also issuing an interim final rule with comment period to establish coding and payment for PPE as a bundled service and certain supply pricing increases in recognition of the increased market-based costs for certain types of PPE.

1. Summary of the Major Provisions

The statute requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: Work; practice expense (PE); and malpractice (MP) expense. In addition, the statute requires that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major final rule, we are establishing RVUs for CY 2021 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This final rule also includes

discussions and provisions regarding several other Medicare Part B payment policies.

Specifically, this final rule addresses:

- Practice Expense RVUs (section II.B.)
- Potentially Misvalued Services Under the PFS (section II.C.)
- Telehealth and Other Services Involving Communications Technology, and the Interim Final Rule with Comment Period for Coding and Payment for Virtual Check-in Services (section II.D.)
- Care Management Services and Remote Physiologic Monitoring Services (section II.E.)
- Refinements to Values for Certain Services to Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability during the PHE for COVID–19 (section II.F.)
- Scopes of Practice and Related Issues (section II.G.)
- Valuation of Specific Codes, and the Interim Final rule with Comment Period for Coding and Payment for Personal Protective Equipment (PPE) (section II.H.)
- Modifications related to Medicare Coverage for Opioid Use Disorder (OUD) Services Furnished by Opioid Treatment Programs (OTPs) (section II.I.)
- Technical Correction to the Definition of Public Health Emergency (section II.J.)
- Clinical Laboratory Fee Schedule (section III.A.)
- Opioid Treatment Program Provider Enrollment Regulation Updates for Institutional Claim Submissions (section III.B.)
- Payment for Primary Care Management Services in RHCs and FQHCs (section III.C.)
- Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Rebasing and Revising of the FQHC Market Basket (section III.D.)
- Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention that Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (section III.E.)
- Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs) (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Notification of Infusion Therapy Options Available Prior to Furnishing Home Infusion Therapy Services (section III.H.)
- Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020 (section III.I.)
- Removal of Selected National Coverage Determinations (section III.J.)
- Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D drug under a prescription drug plan or an MA–PD plan (section III.K.)
- Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act (section III.L.)
- Updates to Certified Electronic Health Record Technology Requirements in the Promoting Interoperability Program, Quality Payment Program, and Hospital Inpatient Quality Reporting Program due to the 21st Century Cures Act (section III.M.)
- Establishing New Code Categories (section III.N.)
- Medicare Diabetes Prevention Program (MDPP) expanded model emergency policy (section III.O.)
- Updates to the Quality Payment Program (section IV.)
- Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes (section V.)
- Waiver of Delay in Effective Date for this Final Rule (section VI.)
- Collection of Information Requirements (section VII.)
- Regulatory Impact Analysis (section VIII.)

2. Provisions Related to the PHE for COVID–19

The United States is currently responding to an outbreak of respiratory disease caused by a novel (new) coronavirus. This virus has been named ''severe acute respiratory syndrome coronavirus 2'' (''SARS-CoV–2''), and the disease it causes has been named ''coronavirus disease 2019'' (''COVID–19''). On January 31, 2020, the Secretary determined that a PHE existed nationwide as a result of the consequences of the COVID–19 pandemic (hereafter referred to as the PHE for COVID–19). On March 13, 2020, President Trump declared the COVID–19 pandemic a national emergency. Effective, October 23, 2020, the Secretary renewed the January 31, 2020 determination that a PHE exists and has existed since January 27, 2020. (Note: This declaration was previously renewed on April 21, 2020 and July 25, 2020.)

As the healthcare community continues to establish and implement recommended infection prevention and control practices, regulatory agencies operating under appropriate waiver authority during the PHE for COVID–19 are also working to revise and implement regulations that support these healthcare community infection prevention and treatment practices. We addressed some of these regulations in three previous interim final rules with comment period (IFCs):

- The ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' IFC appeared in the April 6, 2020 **Federal Register** (85 FR 19230) with an effective date of March 31, 2020 (hereafter referred to as the ''March 31st COVID–19 IFC'');
- The ''Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' IFC appeared in the May 8, 2020 **Federal Register** (85 FR 27550) with an effective date of May 8, 2020 (hereafter referred to as the ''May 8th COVID–19 IFC''); and
- The ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' IFC appeared in the September 2, 2020 **Federal Register** (85 FR 54820) with an effective date of September 2, 2020 (hereinafter referred to as the ''September 2nd COVID–19 IFC).

In this final rule, we are finalizing certain provisions of the March 31st, May 8th, and September 2nd COVID–19 IFCs.

We indicated in the CY 2021 PFS proposed rule (85 FR 50140 and 50147) our intent that for certain provisions of the March 31st, May 8th, and September 2nd COVID–19 IFCs, we would respond to comments received in this final rule. In this final rule, we are responding to public comments and finalizing certain provisions of the March 31st, May 8th, and September 2nd COVID–19 IFCs.

3. Summary of Costs and Benefits

We have determined that this final rule is economically significant. For a detailed discussion of the economic impacts, *see* section VIII. of this final rule.

4. Waiver of the 60-Day Delay in Effective Date for the Final Rule

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190

locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS CoV 2'' and the disease it causes has been named ''Coronavirus disease 2019'' (abbreviated ''COVID–19'').

Due to the significant devotion of resources to the COVID–19 response, as discussed in section VI. of the preamble of this final rule, we are hereby waiving the 60-day delay in the effective date for this final rule as proposed, and replacing it with a 30-day delay in the effective date for this final rule.

II. Summary of the Proposed Provisions, Analysis of and Response to Public Comments, and the Provisions of the Final Rule for the PFS

A. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Social Security Act (the Act), ''Payment for Physicians' Services.'' The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this final rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

1. Development of the RVUs

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended by section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding MP expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA '97) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA '97 provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in the November 2, 1998 final rule (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: The Clinical Practice Expert Panel (CPEP) data; and the AMA's Socioeconomic Monitoring System (SMS) data. These data sources are described in greater detail in the CY 2012 PFS final rule with comment period (76 FR 73033).

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some resource costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those specific facility resource costs is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept

these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA '97 amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' MP insurance premium data from all the states, the District of Columbia, and Puerto Rico.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed 5-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the 5-year reviews, beginning for CY 2009, CMS and the RUC identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, that require the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VIII. of this final rule, the Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component. Please refer to the CY 2020 PFS final rule for a discussion of the last GPCI update (84 FR 62615 through 62623).

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS' Office of the Actuary (OACT). The formula for calculating the Medicare PFS payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work × GPCI work) + (RVU PE × GPCI PE) + (RVU MP × GPCI MP)] × CF

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia CF, in a manner to ensure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate CF for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding MP expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked, in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty

that was obtained from the AMA's SMS. The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2021 PFS Final Rule PE/HR'' on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

As noted above, we have established PE/HR values for various specialties without SMS or PPIS survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. On this note, stakeholders have raised concerns regarding the appropriate specialty crosswalk used for home PT/INR monitoring services. These services are currently classified under the independent diagnostic testing facilities (IDTF) specialty for PE/HR purposes, due to a lack of survey data for these services, and stakeholders have suggested to CMS that this specialty does not reflect the indirect costs associated with furnishing these services. Stakeholders have raised concerns that the practice pattern of PT/INR monitoring services are markedly different from that of the dominant parent specialty as most of the services are furnished remotely and require long-term relationship with beneficiaries similar to chronic therapy. Stakeholders also stated that this is a unique request due to the lack of home PT/INR monitoring supplier involvement in the last PPIS, and that payments for these services are derived from previously used supplemental survey data from the Association for Quality Imaging (AQI), blended with supplementary survey data from the American College of Radiology (ACR)—neither of which reflect indirect cost inputs for home PT/INR monitoring.

Therefore, we are solicited comment from the public regarding the most accurate specialty crosswalk to use for indirect PE when it comes to home PT/INR monitoring services. We sought information on any additional costs associated with these services that are not reflected in our currently assigned PE/HR for independent diagnostic testing facilities, as well as which specialties would best capture these costs through the use of a crosswalk.

We received public comments on our comment solicitation regarding the most accurate specialty crosswalk to use for indirect PE for home PT/INR monitoring services. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they had numerous concerns about the labor, supplies, equipment, and utilization associated with home PT/INR monitoring services. Commenters questioned why the typical clinical staff type for these services is an RN when 95 percent of Medicare claims for HCPCS code G0248 indicate that the service is instead furnished by the IDTF provider specialty. Commenters also questioned the clinical staff labor associated with HCPCS code G0249, as the commenters stated that they did not believe that an electrodiagnostic technologist is the appropriate clinical staff type since these technologists furnish cardiac event monitoring (CEM)-related services, not PT/INR monitoring services. Commenters stated that they believed a patient education booklet is likely a duplicative supply item for HCPCS code G0248, as the patient is expected to have already received booklet(s) related to anticoagulation at previous physician visits, and a free booklet is also supplied with INR meters. Commenters also questioned the discrepancy between the description and billing rules for this code, which state that four tests are performed, and the supply details for this code, which include supplies for six tests. Commenters stated that CMS should decrease the minutes assigned to the home INR monitor (EQ031) equipment and questioned whether this frequency of physician review meets Medicare medical necessity criteria for all patients receiving such services. One commenter submitted a shipping invoice for the INR test strip (SJ055) supply.

Response: We appreciate the additional information provided by the commenters regarding the direct PE inputs and claims data utilization for home PT/INR monitoring services. However, our comment solicitation

sought information regarding the most accurate specialty crosswalk to use for indirect PE as well as which specialties would best capture these costs through the use of a crosswalk. We did not propose to make revisions to the direct PE inputs or conduct a review of the Medicare claims data. Although we appreciate the information provided by the commenters, we are not finalizing any changes to the direct PE inputs for home PT/INR monitoring services. With regard to the shipping invoice for the INR test strip supply, we welcome the submission of invoices or other pricing information as part of our ongoing market-based supply and equipment pricing update. However, this invoice listed the transportation costs of shipping the test strips and not the price of the test strips themselves, and as a result we were unable to make use of it.

Comment: Many commenters stated that there were inherent differences between home PT/INR monitoring services and independent diagnostic testing facilities. Several commenters stated that given the significant changes to technology and associated decrease in costs since the IDTF PE/HR value was first developed, they believed that many of the indirect PE inputs originally recognized for IDTFs in 2007 no longer apply in 2020 and home PT/INR monitoring services should no longer be crosswalked to them. Several commenters stated that typical IDTF services include the use of large, capital-intensive equipment while home PT/INR monitoring services typically involve the use of equipment by a patient in his/her home, frequently intended for use for the remainder of the patient's life—more like a therapeutic device than a diagnostic one. Several commenters emphasized that PT/INR monitoring services are very different from typical imaging and scanning services provided by IDTFs, and because there are so few suppliers of home PT/INR monitoring services, the distribution of direct and indirect costs and the indirect practice cost index (IPCI) applied to IDTFs do not accurately reflect indirect resources expended by the specialty suppliers of home PT/INR monitoring.

Several commenters provided feedback regarding the most accurate specialty crosswalk to use for indirect PE when it comes to home PT/INR monitoring services. Several commenters submitted data indicating that the direct to indirect cost percentages used to furnish home PT/INR monitoring are in the range of 31:69 rather than the approximately 50:50 currently considered in determining the PE RVUs for these services as IDTFs. These commenters recommended a crosswalk to the Pathology or All Physicians specialty type based on the submitted data. One commenter stated that they were not equipped to say which specific indirect factors may be optimal for crosswalk due to a lack of information on direct and indirect cost data from the suppliers but did wish to highlight the importance of ensuring sure that home PT/INR monitoring rates are adequate to assure access. Several commenters stated that the payment rates for these services have fallen dramatically over the past several years and they were very concerned about the impact of these cuts on patient access to these critically important services.

Response: We appreciate the detailed feedback from the commenters regarding home PT/INR monitoring services and especially the submission of data associated with the direct to indirect cost percentages. We also share the concerns of the commenters regarding maintaining access to care for these services. After consideration of the comments, we are finalizing a crosswalk to the General Practice specialty to use for indirect PE when it comes to home PT/INR monitoring services (HCPCS codes G0248, G0249, and G0250). The data submitted by the commenters indicated that the direct to indirect cost percentages to furnish home PT/INR monitoring are in the range of 31:69, similar to the ratio associated with the General Practice specialty. We also share the concerns of the commenters who were uncertain which specific indirect factors may be optimal for crosswalking due to a lack of information, and we believe that the broad nature of the General Practice specialty will serve as a more accurate proxy for home PT/INR monitoring services as opposed to trying to select a more specific specialty designation.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

We allocate the indirect costs at the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect

cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(3) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: Facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the nonfacility PE RVUs.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file contains a table that illustrates the calculation of PE RVUs as described in this final rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to a RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 59283) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert stakeholders. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other stakeholders on changes to this list on an annual basis. Services for which the specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 59283) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

We received public comments on the proposed list of expected specialty assignments for CY 2021. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that the 2021 expected specialty assignment for the low volume services code list included a number of services that were reassigned from cardiac surgery to thoracic surgery in CY 2020. The commenter identified these services and stated that they had concerns that CMS had erroneously assigned them as thoracic surgery procedures instead of cardiac surgery procedures. The commenter requested that CMS to correct the list and permanently assign the identified codes to the requested thoracic surgery specialty assignment.

Response: We finalized a proposal in CY 2020 to update the expected specialty list to accurately reflect a previously finalized crosswalk to thoracic surgery for the services in question. As we stated at the time, we did not finalize a proposal to assign the codes in question to the cardiac surgery specialty. Instead, we finalized a proposal to update the incorrect

documentation in our expected specialty list to accurately reflect a previously finalized crosswalk to thoracic surgery for these services. The previously finalized assignment of the cardiac specialty to these services has been in place since the CY 2012 rule cycle, and we believe that the expected specialty list should be updated to reflect the correct specialty assignment. We did not propose to make further changes to the anticipated specialty assignment of these codes for CY 2021 and we are not finalizing any changes. We direct readers to the discussion of this topic in the CY 2020 PFS final rule (84 FR 62574 through 62578) and we reiterate again that we do not anticipate this finalized proposal having a discernible effect on the valuation of the affected codes due to the similarity between the cardiac surgery and thoracic surgery specialties.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (*Note:* For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS budget neutrality. (See ''Specialties excluded from ratesetting calculation'' later in this final rule.)

Step 19: Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year one reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

(e) Setup File Information

- *Specialties excluded from ratesetting calculation:* For the purposes of calculating the PE and MP RVUs, we exclude certain specialties, such as certain NPPs paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1: Specialties Excluded from Ratesetting Calculation

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (e.g., drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	SNF
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

- Crosswalk *certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- Physical *therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual TC and 26 modifiers:* Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2: Application of Payment Modifiers to Utilization Files

Modifier	Description	Volume Adjustment	Time Adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion
AS	Assistant at Surgery – Physician Assistant	14% (85% * 16%)	Intraoperative portion
50 or LT and RT	Bilateral Surgery	150%	150% of work time
51	Multiple Procedure	50%	Intraoperative portion
52	Reduced Services	50%	50%
53	Discontinued Procedure	50%	50%
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims	Preoperative + Intraoperative portion
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims	Postoperative portion
62	Co-surgeons	62.5%	50%
66	Team Surgeons	33%	33%

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- Work *RVUs:* The setup file contains the work RVUs from this final rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1-(1/((1 + interest rate) ∧ life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage=1); generally 150,000 minutes.
usage = variable, *see* discussion below in this final rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, *see* discussion below in this final rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

We received public comments on equipment utilization rate assumptions. The following is a summary of the comments we received and our responses.

Comment: Several commenters requested that CMS review the utilization assumptions for equipment due to decreased practice capacity during the public health emergency (PHE) for COVID–19. Commenters stated that equipment was used less frequently than normal and that this should be reflected in the equipment utilization rate. Commenters stated that any modifications to the equipment utilization during the public health emergency also should not be subject to budget neutrality.

Response: We disagree with the commenters that utilization assumptions for equipment should be revisited as part of the public health emergency. While we agree that many services had a reduced volume of Medicare beneficiaries at times during the 2020 calendar year, we note that equipment costs under the PFS are amortized across the full useful life of the equipment which in the vast majority of cases is 5–10 years. We believe that it would distort relativity to apply a temporary decrease in utilization caused by the public health emergency to the pricing structure of the equipment's full useful life duration. We also note that we do not have statutory authority to exempt any modifications to the equipment utilization assumptions from budget neutrality calculations.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS proposed rule, we noted that stakeholders including the RUC, specialty societies, and other commenters suggested a useful life of less than 1 year for several of the new equipment items for CY 2021, and as low as 3 months in one case. We have rarely, if ever, received requests for equipment useful life of less than one

year in duration and note that these very short useful life durations are significantly lower than anything in our current equipment database, and if finalized would represent major outliers when compared to the rest of the equipment. Table 3 details the distribution of useful life durations of the equipment currently in our database:

TABLE 3: Equipment Life Durations

Useful Life Duration	Number of Equipment Codes	Percentage of Total
15 years or greater	37	5%
10-14 years	159	20%
6-9 years	210	27%
5 years	313	40%
3-4 years	54	7%
1-2 years	4	1%

As Table 3 demonstrates, the vast majority of equipment items have a useful life duration of 5 to 10 years, and only 4 out of the 777 equipment codes have a useful life duration of less than 3 years. We also noted that due to the formula used to calculate the equipment cost per minute, decreasing the useful life of any equipment item from 5 years to 3 months has the same effect as increasing the price of the equipment 20 times over. In other words, decreasing the useful life from 5 years to 0.25 years has the same multiplicative effect as increasing the price of the equipment from $5,000 to 100,000 due to the formula listed above. Since we currently do not have any equipment items in our database with a useful life of less than one year, we proposed a clarification on how to address these cases.

We disagreed that assigning a useful life at these very short durations would be typical for new equipment, especially in light of the data provided by the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' reference. The equipment life durations listed in Table 3 were finalized over the last 15 years through the use of this reference material. We noted concerns that assigning very low useful life durations to equipment items would fail to maintain relativity with other equipment on the PFS, effectively assigning a much higher price than other equipment items with more typical useful life durations. We noted that we believe that equipment items with very low useful life durations represent outlier cases that are not handled appropriately by the current equipment methodology and which we clarified through this rulemaking. We also noted that the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. Our current equipment formula is not designed to address cases in which equipment is replaced multiple times per year, and we believe that applying a multi-year depreciation in these situations would not be reflective of market pricing. We noted that we did not believe that items which are replaced on a monthly basis can be accurately priced using a formula which assumes they will be in use for years at a time, and that the use of such a formula would distort relativity with the overwhelming majority of equipment items which are in use for 5–10 years.

Therefore, we proposed to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. We noted that we believe that this is the most accurate way to incorporate these short equipment life durations within the framework of our current methodology. In the rare cases where items are replaced every few months, we noted that we believe that it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For example, we proposed to establish the EECP compression equipment package (SD341) and the EECP electrical equipment package (SD342) as disposable supplies instead of equipment items as described in the Valuation of Specific Codes (section II.H. of this final rule) portion of the preamble. We noted that we expect these situations to occur only rarely, and we will evaluate them on an individual case-by-case basis. Our criteria will be based on whether or not the item in question could be more accurately classified as a disposable supply while maintaining overall relativity within our PE methodology. We welcomed additional comments from stakeholders regarding the subject of useful life durations for new equipment items with unique useful life durations as described above and any additional suggestions on alternative ways to incorporate these items into our methodology or potential wider changes to the equipment cost per minute formula more broadly.

We received public comments on our proposals associated with equipment life duration. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that although they had asked CMS to use 0.75 years as the useful life duration for the radionuclide rod source set (ER044) equipment, the commenter recognized that one year was in accordance with the CMS policy to treat equipment useful life durations of less than one year as having a duration of one year.

Response: We appreciate the feedback from the commenter and the acknowledgment of our proposed policy.

After consideration of the public comments, we are finalizing our proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe that it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations.

- *Maintenance:* This factor for maintenance was finalized in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also

noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding sources of data containing equipment maintenance rates, commenters were unable to identify an auditable, robust data source that could be used by CMS on a wide scale. We noted that we did not believe that voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (*see* 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The Interest rates are listed in Table 4.

TABLE 4: SBA Maximum Interest Rates

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We did not propose any changes to the equipment interest rates for CY 2021.

3. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2021 direct PE input public use files, which are available on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated simultaneously for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we continue to believe that in these cases the 3 total minutes of clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. For additional details, we direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 and 59464).

Following the publication of the CY 2020 PFS proposed rule, a commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of the applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed that it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect that these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. For additional details, we direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584).

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time and among the medical specialties developing the recommendations. These variations have made it difficult for both the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC has mandated the use of a new PE worksheet for purposes of their recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations will help us to simplify and standardize the hundreds of different clinical labor tasks currently listed in our direct PE database. As we did in previous calendar years, to facilitate rulemaking for CY 2021, we are continuing to display two versions of the Labor Task Detail public use file: One version with the old listing of clinical labor tasks, and one with the same tasks crosswalked to the new listing of clinical labor activity codes. These lists are available on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

b. Equipment Recommendations for Scope Systems

During our routine reviews of direct PE input recommendations, we have regularly found unexplained inconsistencies involving the use of scopes and the video systems associated with them. Some of the scopes include video systems bundled into the equipment item, some of them include scope accessories as part of their price, and some of them are standalone scopes with no other equipment included. It is not always clear which equipment items related to scopes fall into which of these categories. We have also frequently found anomalies in the equipment recommendations, with equipment items that consist of a scope and video system bundle recommended, along with a separate scope video system. Based on our review, the variations do not appear to be consistent with the different code descriptions.

To promote appropriate relativity among the services and facilitate the transparency of our review process, during the review of the recommended direct PE inputs for the CY 2017 PFS proposed rule, we developed a structure that separates the scope, the associated video system, and any scope accessories that might be typical as distinct equipment items for each code. Under this approach, we proposed standalone prices for each scope, and separate prices for the video systems and accessories that are used with scopes.

(1) Scope Equipment

Beginning in the CY 2017 PFS proposed rule (81 FR 46176 through 46177), we proposed standardizing refinements to the way scopes have been defined in the direct PE input database. We believe that there are four general types of scopes: Non-video scopes; flexible scopes; semi-rigid scopes, and rigid scopes. Flexible scopes, semi-rigid scopes, and rigid scopes would typically be paired with one of the scope video systems, while the non-video scopes would not. The flexible scopes can be further divided into diagnostic (or non-channeled) and therapeutic (or channeled) scopes. We proposed to identify for each anatomical application: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. We proposed to classify the existing scopes in our direct PE database under this classification system, to improve the transparency of our review process and improve appropriate relativity among the services. We planned to propose input prices for these equipment items through future rulemaking.

We proposed these changes only for the reviewed codes for CY 2017 that made use of scopes, along with updated

prices for the equipment items related to scopes utilized by these services. We did not propose to apply these policies to codes with inputs reviewed prior to CY 2017. We also solicited comment on this separate pricing structure for scopes, scope video systems, and scope accessories, which we noted we could consider proposing to apply to other codes in future rulemaking. We did not finalize price increases for a series of other scopes and scope accessories, as the invoices submitted for these components indicated that they are different forms of equipment with different product IDs and different prices. We did not receive any data to indicate that the equipment on the newly submitted invoices was more typical in its use than the equipment that we were currently using for pricing.

We did not make further changes to existing scope equipment in CY 2017 to allow the RUC's PE Subcommittee the opportunity to provide feedback. However, we believed there was some miscommunication on this point, as the RUC's PE Subcommittee workgroup that was created to address scope systems stated that no further action was required following the finalization of our proposal. Therefore, we made further proposals in the CY 2018 PFS proposed rule (82 FR 33961 through 33962) to continue clarifying scope equipment inputs, and sought comments regarding the new set of scope proposals. We considered creating a single scope equipment code for each of the five categories detailed in this rule: (1) A rigid scope; (2) a semi-rigid scope; (3) a non-video flexible scope; (4) a non-channeled flexible video scope; and (5) a channeled flexible video scope. Under the current classification system, there are many different scopes in each category depending on the medical specialty furnishing the service and the part of the body affected. We stated our belief that the variation between these scopes was not significant enough to warrant maintaining these distinctions, and we believed that creating and pricing a single scope equipment code for each category would help provide additional clarity. We sought public comment on the merits of this potential scope organization, as well as any pricing information regarding these five new scope categories.

After considering the comments on the CY 2018 PFS proposed rule, we did not finalize our proposal to create and price a single scope equipment code for each of the five categories previously identified. Instead, we supported the recommendation from the commenters to create scope equipment codes on a per-specialty basis for six categories of scopes as applicable, including the addition of a new sixth category of multi-channeled flexible video scopes. Our goal was to create an administratively simple scheme that would be easier to maintain and help to reduce administrative burden. In 2018, the RUC convened a Scope Equipment Reorganization Workgroup to incorporate feedback from expert stakeholders with the intention of making recommendations to us on scope organization and scope pricing. Since the workgroup was not convened in time to submit recommendations for the CY 2019 PFS rulemaking cycle, we delayed proposals for any further changes to scope equipment until CY 2020 in order to incorporate the feedback from the aforementioned workgroup.

(2) Scope Video System

We proposed in the CY 2017 PFS proposed rule (81 FR 46176 through 46177) to define the scope video system as including: (1) A monitor; (2) a processor; (3) a form of digital capture; (4) a cart; and (5) a printer. We believe that these equipment components represent the typical case for a scope video system. Our model for this system was the ''video system, endoscopy (processor, digital capture, monitor, printer, cart)'' equipment item (ES031), which we proposed to re-price as part of this separate pricing approach. We obtained current pricing invoices for the endoscopy video system as part of our investigation of these issues involving scopes, which we proposed to use for this re-pricing. In response to comments, we finalized the addition of a digital capture device to the endoscopy video system (ES031) in the CY 2017 PFS final rule (81 FR 80188). We finalized our proposal to price the system at $33,391, based on component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, and $1,750 for the cart. In the CY 2018 PFS final rule (82 FR 52991 through 52993), we outlined, but did not finalize, a proposal to add an LED light source into the cost of the scope video system (ES031), which would remove the need for a separate light source in these procedures. We also described a proposal to increase the price of the scope video system by $1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.). With the addition of the LED light (equipment code EQ382 at a price of $1,915), the updated total price of the scope video system would be set at $36,306.

We did not finalize this updated pricing to the scope video system in CY 2018, but we did propose and finalize the updated pricing for CY 2019 to $36,306 along with changing the name of the ES031 equipment item to ''scope video system (monitor, processor, digital capture, cart, printer, LED light)'' to reflect the fact that the use of the ES031 scope video system is not limited to endoscopy procedures.

(3) Scope Accessories

We understand that there may be other accessories associated with the use of scopes. We finalized a proposal in the CY 2017 PFS final rule (81 FR 80188) to separately price any scope accessories outside the use of the scope video system, and individually evaluate their inclusion or exclusion as direct PE inputs for particular codes as usual under our current policy based on whether they are typically used in furnishing the services described by the particular codes.

(4) Scope Proposals for CY 2020

The Scope Equipment Reorganization Workgroup organized by the RUC submitted detailed recommendations to CMS for consideration in the CY 2020 rule cycle, describing 23 different types of scope equipment, the HCPCS codes associated with each scope type, and a series of invoices for scope pricing. Based on the recommendations from the workgroup, we proposed to establish 23 new scope equipment codes. For the eight new scope equipment items where we received submitted invoices for pricing, we proposed to replace the existing scopes with the new scope equipment at the same amount of equipment time. This scope replacement involved approximately 100 HCPCS codes in total and was detailed in a table published in the CY 2020 PFS proposed rule (84 FR 40495 through 40498). We noted that we did not receive pricing information along with the workgroup recommendations for the other 15 new scope equipment items. Therefore, although we proposed to establish new equipment codes for these scopes, we did not propose to replace existing scope equipment with the new equipment items as we did for the other eight new scope equipment items for CY 2020.

Following the publication of the CY 2020 PFS proposed rule, commenters provided additional information regarding pricing for the new scope equipment and their associated HCPCS

codes. Based on this information provided by the commenters, we finalized a price for eight additional new scope equipment items and finalized the replacement of the existing scopes with the new scope equipment at the same amount of equipment time for approximately two dozen additional HCPCS codes (84 FR 62593 through 62595). Table 5 lists the CY 2020 finalized price for the new scope equipment codes:

TABLE 5: CY 2020 New Scope Equipment Codes

CMS Code	Scope Equipment Description	Finalized Price
ES070	rigid scope, cystoscopy	
ES071	rigid scope, channeled, hysteroscopy	$6,795.00
ES072	rigid scope, otoscopy	$2,333.98
ES073	rigid scope, nasal/sinus endoscopy	$3,004.75
ES074	rigid scope, proctosigmoidoscopy	
ES075	rigid scope, laryngoscopy	$3,966.08
ES076	rigid scope, colposcopy	$14,500.00
ES077	non-channeled flexible digital scope, hysteroscopy	
ES078	non-channeled flexible digital scope, nasopharyngoscopy	$21,923.43
ES079	non-channeled flexible digital scope, bronchoscopy	
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
ES081	channeled flexible digital scope, cystoscopy	
ES082	channeled flexible digital scope, hysteroscopy	
ES083	channeled flexible digital scope, bronchoscopy	
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
ES089	multi-channeled flexible digital scope, ileoscopy	$34,585.35
ES090	multi-channeled flexible digital scope, pouchoscopy	$17,360.00
ES091	ultrasound digital scope, endoscopic ultrasound	$0.00
ES092	non-video flexible scope, laryngoscopy	$5,105.97

We noted that although we updated the scope equipment pricing for CY 2020 such that the ES087 and ES089 scopes shared the same price with the ES088 scope, and the ES090 scope shared the same price with the ES085 scope, we did not mean to suggest that these scopes that shared pricing were identical with one another. We assigned the same price to these scopes because they replaced the same current scope equipment codes, and because we did not have individual pricing information for them. We noted in the CY 2021 PFS proposed rule (85 FR 50087) that we remain open to the submission of additional invoices to establish individual pricing for these scopes, and we welcomed more data to help identify pricing for the remaining seven scope equipment codes that still lack invoices.

(5) Scope Proposals for CY 2021

We did not receive further recommendations from the Scope Equipment Reorganization Workgroup organized by the RUC following the publication of the CY 2020 PFS final rule. However, we did receive invoices associated with the pricing of the scope video system (monitor, processor, digital capture, cart, printer, LED light) (ES031) equipment item as part of the review of the Esophagogastroduodenoscopy (EGD) with Biopsy and the Colonoscopy code families. We previously finalized a price of $36,306 for the ES031 equipment based on the sum of component prices of $9,000 for the processor, $18,346 for the digital capture device, $2,000 for the monitor, $2,295 for the printer, $1,750 for the cart, $1,915 for the LED light, and $1,000 to cover the expense of miscellaneous small equipment associated with the system that falls below the threshold of individual equipment pricing as scope accessories (such as cables, microphones, foot pedals, etc.) We received 37 invoices associated with the components of the ES031 scope video system, which averaged out to prices of $21,988.89 for the processor, $16,175.87 for the digital capture device, $6,987.56 for the monitor, $7,922.80 for the printer, $4,945.45 for the cart, and $12,652.82 for the LED light. Based on the sum of these component prices, we proposed to update the price the ES031 scope video system equipment to $70,673.38. We did not propose to include an additional $1,000 to cover the expense of miscellaneous small equipment as the products listed on the component invoices indicated that cost of cables were already included in this significantly higher equipment pricing. We solicited additional comments from stakeholders regarding the pricing of the full ES031 scope equipment system as well as its components.

As part of our market-based supply and equipment pricing transition, we finalized a policy in CY 2019 to phase in any updated pricing established during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, even if invoices are provided as part of the formal review of a code family (83 FR 59473 through 59475). Because the ES031 scope equipment system is utilized by more than 250 HCPCS codes, we proposed to transition this pricing increase over the remaining 2 years of the pricing update,

such that the CY 2021 equipment price will be $53,489.69 before moving to its destination price of $70,673.38 in CY 2022. We noted that this transition policy also applies to the price of the suction machine (Gomco) (EQ235) equipment, which, although it is not a scope, is utilized by approximately 360 HCPCS codes, and therefore, is another example of this pricing transition policy. We proposed to transition the EQ235 pricing increase over the remaining 2 years of the pricing update, such that the CY 2021 equipment price would be $1,981.66 before moving to its destination price of $ $3,195.85 in CY 2022. As we stated previously, this policy was intended to minimize any potential disruptive effects during the pricing transition period due to the high number of services that make use of these very common supply and equipment items included in 100 or more HCPCS codes.

We also received invoices for the colonoscopy videoscope (ES033) and gastroscopy videoscopy (ES034) as part of the review of the Esophagogastroduodenoscopy (EGD) with Biopsy and the Colonoscopy code families. We finalized the replacement of both of these scope equipment items in the CY 2020 PFS final rule (84 FR 62588 through 62590), replacing the colonoscopy videoscope (ES033) with the multi-channeled flexible digital scope, colonoscopy (ES086) equipment item and the gastroscopy videoscopy (ES034) with the multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD) (ES087) equipment item. In both cases, the submitted invoices were nearly identical to the finalized prices for the ES086 ($38,058.81) and ES087 ($34,585.35) equipment. We believe that these invoices reinforce the prices finalized through rulemaking last year, and therefore, we did not propose to further update the prices of these scopes.

We noted that we remain open to further comments regarding the pricing of the remaining seven scope equipment codes that still lack invoices, as well as additional data regarding the pricing of the scope equipment codes that currently share the same price.

We received public comments on our proposals associated with equipment recommendations for scope systems. The following is a summary of the comments we received and our responses.

Comment: Several commenters thanked CMS for updating the prices of the scope video system (ES031) and Gomco suction machine (EQ235) to reflect the submitted invoices. Commenters stated that they supported the proposed transition in price increase for both pieces of equipment over the remaining 2 years of the pricing update and supported the ES031 price update to correctly account for the cost of the various components included in this scope video system.

Response: We appreciate the support for our proposals from the commenters.

Comment: A commenter stated that although they appreciated CMS's efforts to ensure the accuracy of the inputs for scope equipment, the price inputs for scope video systems do not capture all of the costs needed for near infrared fluorescence visualization with 4K monitors. The commenter stated that the actual cost of these processor, monitor, and digital capture device components are 45 to 97 percent higher than current CMS prices. The commenter encouraged CMS to seek additional price inputs for this newer technology and planned to submit invoices to demonstrate the costs related to the near infrared fluorescence scope video price inputs.

Response: We appreciate the feedback from the commenter regarding the costs associated with new technology being incorporated into scope video systems and we look forward to the submission of invoices or other data sources with additional pricing information. However, in the absence of information demonstrating these additional costs, we will continue to maintain our current scope pricing.

Comment: A commenter submitted invoices associated with three of the eight scope equipment items that still lacked a price: The cystoscopy rigid scope (ES070), the cystoscopy channeled flexible digital scope (ES081), and the hysteroscopy channeled flexible digital scope (ES082). The commenter stated that these invoices were representative of national pricing for these scopes and compiled a list of procedures associated with these scopes. This procedure list submitted by the commenter also included the hysteroscopy rigid scope, channeled (ES071) equipment item which was previously priced in CY 2020.

Response: We appreciate the additional pricing information submitted by the commenter in helping us assign a price to the remaining scope equipment codes. Based on this information, we are finalizing a price of $7,270.00 for the rigid scope, cystoscopy (ES070) equipment, a price of $22,274.36 for the channeled flexible digital scope, cystoscopy (ES081) equipment, and a price of $19,081.82 for the channeled flexible digital scope, hysteroscopy (ES082) equipment. When added to the previously finalized prices for the other scope equipment items from CY 2020, the total list is shown in Table 6.

TABLE 6: CY 2021 New Scope Equipment Codes

CMS Code	Scope Equipment Description	Finalized Price
ES070	rigid scope, cystoscopy	$7,270.00
ES071	rigid scope, channeled, hysteroscopy	$6,795.00
ES072	rigid scope, otoscopy	$2,333.98
ES073	rigid scope, nasal/sinus endoscopy	$3,004.75
ES074	rigid scope, proctosigmoidoscopy	
ES075	rigid scope, laryngoscopy	$3,966.08
ES076	rigid scope, colposcopy	$14,500.00
ES077	non-channeled flexible digital scope, hysteroscopy	
ES078	non-channeled flexible digital scope, nasopharyngoscopy	$21,923.43
ES079	non-channeled flexible digital scope, bronchoscopy	
ES080	non-channeled flexible digital scope, laryngoscopy	$21,485.51
ES081	channeled flexible digital scope, cystoscopy	$22,274.36
ES082	channeled flexible digital scope, hysteroscopy	$19,081.82
ES083	channeled flexible digital scope, bronchoscopy	
ES084	channeled flexible digital scope, laryngoscopy	$18,694.39
ES085	multi-channeled flexible digital scope, flexible sigmoidoscopy	$17,360.00
ES086	multi-channeled flexible digital scope, colonoscopy	$38,058.81
ES087	multi-channeled flexible digital scope, esophagoscopy gastroscopy duodenoscopy (EGD)	$34,585.35
ES088	multi-channeled flexible digital scope, esophagoscopy	$34,585.35
ES089	multi-channeled flexible digital scope, ileoscopy	$34,585.35
ES090	multi-channeled flexible digital scope, pouchoscopy	$17,360.00
ES091	ultrasound digital scope, endoscopic ultrasound	$0.00
ES092	non-video flexible scope, laryngoscopy	$5,105.97

With regard to the procedure list submitted by the commenter, we are not finalizing the replacement of any current scope equipment with the new scope equipment codes. We did not propose to make any such replacements in the proposed rule and we had reservations about some of the procedures on the submitted list, which included CPT codes that currently do not contain scopes or any direct PE inputs at all in some cases. We appreciate the submission of this additional information from the commenter and we will consider the procedure list for potential use in future rulemaking.

After consideration of the public comments, we are finalizing our proposal to update the price the ES031 scope video system equipment to $70,673.38 along with our proposed update to the price of the suction machine (Gomco) (EQ235) equipment. We are also finalizing the price for the three new scope equipment items as detailed above.

c. Technical Corrections to Direct PE Input Database and Supporting Files

For CY 2021, we proposed to address the following inconsistencies:

- Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and clarified that CPT code 0466T (Insertion of chest wall respiratory sensor electrode or electrode array, including connection to pulse generator) is always performed on an add-on basis and would never be used as a standalone code. Therefore, we proposed to update the global period for CPT code 0466T to add-on status (ZZZ) to more accurately reflect the way in which this service is performed.

We received public comments on the technical corrections to direct PE input database and supporting files. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they supported the proposed change to the global period of CPT code 0466T and agreed that this technical correction was appropriate.

Response: We appreciate the support for our proposal from the commenter.

Comment: Several commenters stated that in the direct PE inputs for CPT code 33202 (*Insertion of epicardial electrode(s); open incision (e.g., thoracotomy, median sternotomy, subxiphoid approach)*), there are two tables listed under the equipment inputs: An exam table (EF023) and a power table (EF031). Commenters stated that spreadsheet information from CPT 2007 listed a power table and an exam light for this service, not an exam table. Commenters stated that it seemed likely that this was an accidental data entry error and requested that the equipment inputs for CPT code 33202 be corrected in the CMS equipment database to include a power table and exam light.

Response: We agree with the commenters that this was likely a data entry error confusing the exam light with the exam table. Based on the information supplied by the commenters, we are finalizing the replacement of the exam table with an exam light (EQ168) at the same equipment time of 36 minutes for CPT code 33202.

Comment: Several commenters stated that in the 2020 CMS direct PE inputs supplies listing, the ''unit'' type is missing for the skin prep barrier wipes (SM029) supply. Commenters stated that although this omission does not affect pricing, it makes it ambiguous what the units mean and could have an unintended impact if there are multiple different possible unit types, such as a liquid, where it would be unclear if it were ounces, milliliters, or something else. Commenters recommended that each supply item in the CMS database should have a unit type and provided a list of the supply items in the CY 2020 PFS final rule that were missing a unit type, with potential unit type suggestions for each item.

Response: We agree with the commenters that each supply item in the CMS database should include a unit type in order to avoid potential confusion regarding pricing. We are finalizing the addition of the unit types as listed in Table 7.

TABLE 7: Addition of Supply Unit Types

CMS Code	Description	Unit Type
SA115	hemorrhoidal banding system	item
SA116	continuous peripheral nerve block tray	tray
SA119	kit, low frequency ultrasound wound therapy (MIST)	kit
SA122	Claravein Kit	kit
SA123	Hysteroscopic fluid management tubing kit	kit
SC101	ultrasound needle	item
SC102	EBUS, single use aspiration needle, 21g	item
SC103	catheter, RF ablation, endoscopic	item
SD290	electrode, BIS (bioimpedance spectroscopy)	item
SD291	Urolift Implant and implantation device	item
SD292	10g IVAS drill	item
SD293	10g cannulae	item
SD294	Balloon for Bronchoscopy Fiberscope	item
SH106	CavityShield 5% Varnish .25mL	item
SJ089	ultrasound transmission gel, sterile (single use)	item
SK126	Beck Depression Inventory, Second Edition	item
SL519	Urethane Foaming Agent	item
SM029	skin prep barrier wipes	item

All of the supply items in the CMS database should now include a unit type with the additions from this list. We note that we did not add a unit type for the ''No Supplies'' (SX007) category as the commenter requested since this is not a supply item.

Comment: Several commenters questioned the proposed RVUs associated with several occupational therapy evaluation procedures (CPT codes 97165–97167). Commenters stated that the PE valuation for these codes appeared to be illogical, with the proposed valuation of the codes demonstrating an inverse relationship between PE value and complexity. Commenters stated that it was counterintuitive for the PE RVU to go down as the level of complexity increased. Commenters stated that the distribution of code usage has not changed in any manner to justify a reduction in the code values and that all three evaluation codes should reimburse at the same rate.

Response: We appreciate the commenters bringing this issue to our attention. However, although we agree with the commenters that the proposed valuation of these services is somewhat illogical, we do not agree that their proposed valuation represents a technical error. Although the three codes in question share the same work RVU and the same direct PE inputs, they do not share the same specialty distribution in the claims data and therefore will not necessarily receive the same allocation of indirect PE. In response to the comments, we are implementing a technical change which should ensure that these three services receive the same allocation of indirect PE.

Following the publication of the proposed rule, we also discovered a technical error in the published RVUs for three HCPCS codes. Code G0102 (*Prostate cancer screening; digital rectal examination*) was assigned the same value as CPT code 99211, the lowest level E/M service, in the CY 2000 PFS final rule (64 FR 59414). Code G0102 was assigned a work RVU of 0.17 which matched the work RVU of CPT code 99211 at the time. However, when we increased the work RVU for CPT code 99211 to 0.18 in CY 2010 as part of the last E/M revalution, the work RVU for HCPCS code G0102 was not increased to match. We are correcting this technical oversight by finalizing an increase in the work RVU of code G0102 from 0.17 to 0.18 to match the previously finalized crosswalk to CPT code 99211.

We also previously finalized and valued in the CY 1998 PFS final rule (62 FR 59082) the following two G codes for use when a barium enema is being substituted for either a screening sigmoidoscopy or screening colonoscopy: HCPCS codes G0106 (*Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema*) and G0120 (*Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema*). We established the same RVUs for these screening G codes as for the diagnostic barium enema procedure, CPT code 74280 (*Radiologic examination, colon, including scout abdominal radiograph(s) and delayed image(s), when performed; double-contrast (e.g., high density barium and air) study, including glucagon, when administered*). The work RVU for codes G0106 and G0120 has matched the work RVU for CPT code 74280 for the last two decades; however, we reviewed CPT code 74280 last year and, in the CY 2020 PFS final rule, increased the work RVU for CPT code 74280 to 1.26. Through an oversight, we did not make corresponding changes in the work RVUs for HCPCS codes G0106 and G0120. We are therefore correcting this technical oversight by finalizing an increase in the work RVU for HCPCS codes G0106 and G0120 to match the previously finalized crosswalk to CPT code 74280.

After consideration of the public comments, we are finalizing our proposals along with the additions as detailed above.

d. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. For CY 2021, we proposed to update the price of one supply and four equipment items in response to the public submission of invoices. As these pricing updates were each part of the formal review for a code family, we proposed that the new pricing take effect for CY 2021 for these items instead of being phased in over 4 years. These supply and equipment items with updated prices associated with the formal review of a code family are listed in the valuation of specific codes section of the preamble under Table 31: CY 2021 Invoices Received for Existing Direct PE Inputs.

(1) Market-Based Supply and Equipment Pricing Update

Section 220(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) provides that the Secretary may collect or obtain information from any eligible professional or any other source on the resources directly or indirectly related to furnishing services for which payment is made under the PFS, and that such information may be used in the determination of relative values for services under the PFS. Such information may include the time involved in furnishing services; the amounts, types and prices of PE inputs; overhead and accounting information for practices of physicians and other suppliers, and any other elements that would improve the valuation of services under the PFS.

As part of our authority under section 1848(c)(2)(M) of the Act, we initiated a market research contract with StrategyGen to conduct an in-depth and robust market research study to update the PFS direct PE inputs (DPEI) for supply and equipment pricing for CY 2019. These supply and equipment prices were last systematically developed in 2004–2005. StrategyGen submitted a report with updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. This report is available as a public use file displayed on the CMS website under downloads for the CY 2019 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The StrategyGen team of researchers, attorneys, physicians, and health policy experts conducted a market research study of the supply and equipment items currently used in the PFS direct PE input database. Resources and methodologies included field surveys, aggregate databases, vendor resources, market scans, market analysis, physician substantiation, and statistical analysis to estimate and validate current prices for medical equipment and medical supplies. StrategyGen conducted secondary market research on each of the 2,072 DPEI medical equipment and supply items that CMS identified from the current DPEI. The primary and secondary resources StrategyGen used to gather price data and other information were:

- Telephone surveys with vendors for top priority items (Vendor Survey).
- Physician panel validation of market research results, prioritized by total spending (Physician Panel).
- The General Services Administration system (GSA).
- An aggregate health system buyers database with discounted prices (Buyers).
- Publicly available vendor resources, that is, Amazon Business, Cardinal Health (Vendors).
- The **Federal Register**, current DPEI data, historical proposed and final rules prior to CY 2018, and other resources; that is, AMA RUC reports (References).

StrategyGen prioritized the equipment and supply research based on current share of PE RVUs attributable by item provided by CMS. StrategyGen developed the preliminary Recommended Price (RP) methodology based on the following rules in hierarchical order considering both data representativeness and reliability.

(1) If the market share, as well as the sample size, for the top three commercial products were available, the weighted average price (weighted by percent market share) was the reported RP. Commercial price, as a weighted average of market share, represents a more robust estimate for each piece of equipment and a more precise reference for the RP.

(2) If no data were available for commercial products, the current CMS prices were used as the RP.

GSA prices were not used to calculate the StrategyGen recommended prices, due to our concern that the GSA system curtails the number and type of suppliers whose products may be accessed on the GSA Advantage website, and that the GSA prices may often be lower than prices that are available to non-governmental purchasers. After reviewing the StrategyGen report, we proposed to adopt the updated direct PE input prices for supplies and equipment as recommended by StrategyGen.

StrategyGen found that despite technological advancements, the average commercial price for medical equipment and supplies has remained relatively consistent with the current CMS price. Specifically, preliminary data indicated that there was no statistically significant difference between the estimated commercial prices and the current CMS prices for both equipment and supplies. This cumulative stable pricing for medical equipment and supplies appears similar to the pricing impacts of non-medical technology advancements where some historically high-priced equipment (that is, desktop PCs) has been increasingly substituted with current technology (that is, laptops and tablets) at similar or lower price points. However, while there were no statistically significant differences in pricing at the aggregate level, medical specialties would experience increases or decreases in their Medicare payments if we were to adopt the pricing updates recommended by StrategyGen. At the service level, there may be large shifts in PE RVUs for individual codes that happened to contain supplies and/or equipment with major changes in pricing, although we note that codes with a sizable PE RVU decrease would be limited by the requirement to phase in significant reductions in RVUs, as required by section 1848(c)(7) of the Act. The phase-in requirement limits the maximum RVU reduction for codes that are not new or revised to 19 percent in any individual calendar year.

We believe that it is important to make use of the most current information available for supply and equipment pricing instead of continuing to rely on pricing information that is more than a decade old. Given the potentially significant changes in payment that would occur, both for specific services and more broadly at the specialty level, in the CY 2019 PFS proposed rule we proposed to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY 2019), 50/50 percent (CY 2020), 75/25 percent (CY 2021), and 100/0 percent (CY 2022) split between new and old pricing. This approach is consistent with how we have previously incorporated significant new data into the calculation of PE RVUs, such as the 4-year transition period finalized in CY 2007 PFS final rule with comment period when changing to the ''bottom-

up'' PE methodology (71 FR 69641). This transition period will not only ease the shift to the updated supply and equipment pricing, but will also allow interested parties an opportunity to review and respond to the new pricing information associated with their services.

We proposed to implement this phase-in over 4 years so that supply and equipment values transition smoothly from the prices we currently include to the final updated prices in CY 2022. We proposed to implement this pricing transition such that one quarter of the difference between the current price and the fully phased-in price is implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 8.

TABLE 8: Example of Direct PE Pricing Transition

Current Price	$100	
Final Price	$200	
Year 1 (CY 2019) Price	$125	1/4 difference between $100 and $200
Year 2 (CY 2020) Price	$150	1/3 difference between $125 and $200
Year 3 (CY 2021) Price	$175	1/2 difference between $150 and $200
Final (CY 2022) Price	$200	

For new supply and equipment codes for which we establish prices during the transition years (CYs 2019, 2020 and 2021) based on the public submission of invoices, we proposed to fully implement those prices with no transition since there are no current prices for these supply and equipment items. These new supply and equipment codes would immediately be priced at their newly established values. We also proposed that, for existing supply and equipment codes, when we establish prices based on invoices that are submitted as part of a revaluation or comprehensive review of a code or code family, they will be fully implemented for the year they are adopted without being phased in over the 4-year pricing transition. The formal review process for a HCPCS code includes a review of pricing of the supplies and equipment included in the code. When we find that the price on the submitted invoice is typical for the item in question, we believe it would be appropriate to finalize the new pricing immediately along with any other revisions we adopt for the code valuation.

For existing supply and equipment codes that are not part of a comprehensive review and valuation of a code family and for which we establish prices based on invoices submitted by the public, we proposed to implement the established invoice price as the updated price and to phase in the new price over the remaining years of the proposed 4-year pricing transition. During the proposed transition period, where price changes for supplies and equipment are adopted without a formal review of the HCPCS codes that include them (as is the case for the many updated prices we proposed to phase in over the 4-year transition period), we believe it is important to include them in the remaining transition toward the updated price. We also proposed to phase in any updated pricing we establish during the 4-year transition period for very commonly used supplies and equipment that are included in 100 or more codes, such as sterile gloves (SB024) or exam tables (EF023), even if invoices are provided as part of the formal review of a code family. We would implement the new prices for any such supplies and equipment over the remaining years of the proposed 4-year transition period. Our proposal was intended to minimize any potential disruptive effects during the proposed transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply and equipment items (meaning that these items are included in 100 or more codes).

We believed that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. Updating the pricing of direct PE inputs for supplies and equipment over a longer timeframe will allow more opportunities for public comment and submission of additional, applicable data. We welcomed feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

We received many comments regarding the market-based supply and equipment pricing proposal following the publication of the CY 2019 PFS proposed rule. For a full discussion of these comments, we direct readers to the CY 2019 PFS final rule (83 FR 59475 through 59480). In each instance in which a commenter raised questions about the accuracy of a supply or equipment code's recommended price, the StrategyGen contractor conducted further research on the item and its price with special attention to ensuring that the recommended price was based on the correct item in question and the clarified unit of measure. Based on the commenters' requests, the StrategyGen contractor conducted an extensive examination of the pricing of any supply or equipment items that any commenter identified as requiring additional review. Invoices submitted by multiple commenters were greatly appreciated and ensured that medical equipment and supplies were re-examined and clarified. Multiple researchers reviewed these specified supply and equipment codes for accuracy and proper pricing. In most cases, the contractor also reached out to a team of nurses and their physician panel to further validate the accuracy of the data and pricing information. In some cases, the pricing for individual items needed further clarification due to a lack of information or due to significant variation in packaged items. After consideration of the comments and this additional price research, we updated the recommended prices for approximately 70 supply and equipment codes identified by the commenters. Table 9 in the CY 2019 PFS final rule lists the supply and equipment codes with price changes based on feedback from the commenters and the resulting additional research into pricing (83 FR 59479 through 59480).

After consideration of the public comments, we finalized our proposals

associated with the market research study to update the PFS direct PE inputs for supply and equipment pricing. We continue to believe that implementing the proposed updated prices with a 4-year phase-in will improve payment accuracy, while maintaining stability and allowing stakeholders the opportunity to address potential concerns about changes in payment for particular items. We continue to welcome feedback from stakeholders on the proposed updated supply and equipment pricing, including the submission of additional invoices for consideration.

For CY 2021, we received invoice submissions for approximately a dozen supply and equipment codes from stakeholders as part of the third year of the market-based supply and equipment pricing update. The submitted invoices were used in many cases to supplement the pricing originally proposed for the CY 2019 PFS rule cycle. We reviewed the invoices, as well as prior data for the relevant supply/equipment codes to make sure the item in the invoice was representative of the supply/equipment item in question and aligned with past research. Based on this research, we proposed to update the prices of the supply and equipment items listed in Table 7 of the CY 2021 PFS proposed rule.

We finalized a policy in CY 2019 to phase in the new supply and equipment pricing over 4 years so that supply and equipment values transition smoothly from their current prices to the final updated prices in CY 2022. We finalized our proposal to implement this pricing transition such that one quarter of the difference between the current price and the fully phased in price was implemented for CY 2019, one third of the difference between the CY 2019 price and the final price is implemented for CY 2020, and one half of the difference between the CY 2020 price and the final price is implemented for CY 2021, with the new direct PE prices fully implemented for CY 2022. An example of the transition from the current to the fully-implemented new pricing is provided in Table 8. For CY 2021, one half of the difference between the CY 2020 price and the final price will be implemented as per the previously finalized policy. Table 9 contains the list of proposed CY 2021 market-based supply and equipment pricing updates:

TABLE 9: CY 2021 Proposed Market-Based Supply and Equipment Updates

CMS CODE	Description	CMS 2020 Price	Prior CMS 2022 Price	Prior CMS 2021 Price	Updated CMS 2022 Price	Updated CMS 2021 Price
SA105	UroVysion test kit	$153.040	$129.280	$141.160	$187.490	$170.265
SD089	guidewire, hydrophilic	$39.435	$43.370	$41.403	$13.350	$26.393
SD136	vascular sheath	$36.650	$52.800	$44.725	$24.444	$30.547
SD155	catheter, RF endovenous occlusion	$637.500	$550.000	$593.750	$382.500	$510.000
EQ041	Vmax 22d and 62j (PFT equip, autobox, computer system)	$47,930.000	$47,930.000	$47,930.000	$47,406.540	$47,668.270
ER044	nuclide rod source set	$1,783.167	$2,171.333	$1,977.250	$2,081.167	$1,932.167

The prices for the supply and equipment items listed in Table 9 were calculated based on averaging together the prices on the submitted invoices. In the case of the vascular sheath (SD136) and RF endovenous occlusion catheter (SD155) supplies, the price was determined by removing the sheath or catheter from the eight submitted kit invoices and then averaging the resulting price together with the single standalone sheath/catheter invoice.

In addition to submitting invoices with information updating the price of the ''Vmax 22d and 62j (PFT equip, autobox, computer system)'' (EQ041) equipment, stakeholders also clarified that the ''Vmax 229 (spirometry testing equip, computer system)'' (EQ040) and ''Vmax 29s (spirometry testing equip, computer system)'' (EQ043) equipment items have become obsolete and are no longer typically used in any HCPCS codes. Based on the information supplied by the stakeholders, we proposed to remove the EQ040 and EQ043 equipment items, replacing them with the EQ041 equipment at the same number of minutes in the six HCPCS codes where they are utilized.

We did not propose to update the price of additional supply and equipment items for which invoices were submitted following the publication of the CY 2020 PFS final rule. We did not propose to update the price for the ''pipette, transfer 23ml'' (SL109), ''slide specimen mailer (1–5 microscope slides)'' (SL121), ''stain, hematoxylin'' (SL135), ''stain, eosin'' (SL201), and ''stain, PAP OG–6'' (SL491) supplies. In each case we received a single invoice for these five supplies detailing price increases ranging from 82 percent to 160 percent above the current pricing. These supplies are commonly used in cytopathology procedures and we disagree that the typical price for these supplies has more than doubled since being reviewed by the StrategyGen contractor 2 years ago for CY 2019.

We also did not propose to update the price for the ''embedding mold'' (SL060) supply or the ''microscope, compound'' (EP060) equipment based on the same rationale. The submitted invoices represent pricing increases of 339 percent for the compound microscope and 7800 percent for the embedding mold and, based on the recent review of the pricing of these items by our contractor, we do not believe that the submitted invoices reflect typical market-based pricing. The same stakeholder also submitted an invoice to update the price of the surgical mask (SB033) supply by 617 percent over the current price. However, the invoice in question contains the price for a surgical mask with face shield, which is described by the SB034 supply code, not the SB033 supply code. Therefore, we did not propose to update the price of the surgical mask (SB033) supply based on this invoice. Finally, we received an invoice for a ClosureFast Procedure Pack (CFP) but it was unclear

what supply or equipment item this invoice was intended to update. As a result, we noted in the CY 2021 PFS proposed rule that we were unable to use this invoice to make a pricing proposal.

We received public comments on the market-based supply and equipment pricing update. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they continued to support the engagement from the agency to work with CMS contractors and stakeholders to incorporate current pricing data based on invoices into the calculation of direct PE cost. Commenters stated that bringing in an outside vendor in addition to accepting invoices from stakeholders was a reasonable approach, and that the incorporation of this new data and the process for determining what is accepted and what is rejected should be done in a transparent manner. Several different commenters urged CMS to be more deliberate and transparent about this decision-making process regarding supply and equipment pricing.

Response: We appreciate the feedback from the commenters and share the desire for transparency in pricing. We continue to believe that it is important to make use of the most current information available for supply and equipment pricing through the use of market-based research, and we agree with the need to explain the rationale behind the adoption or rejection of invoices submitted by stakeholders. We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. We consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Stakeholders are encouraged to submit invoices as part of their public comments or, if outside the public comment process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

Comment: A commenter stated that they supported the proposed pricing for the UroVysion test kit (SA105) supply. The commenter stated that establishing a price that is in line with invoice pricing ensures that reimbursement for the service reflects accurately the cost of resources involved in providing the service.

Response: We appreciate the support for our proposed pricing from the commenter.

Comment: A commenter disagreed with the proposed pricing of the lysing reagent (FACS) (SL089) supply. The commenter submitted six invoices for the supply and requested that CMS use them to update the pricing.

Response: We appreciate the submission of these additional invoices for use in pricing the SL089 supply. Therefore, we are finalizing an update in the price of this supply to $3.645 as indicated on the submitted invoices. As part of our ongoing pricing transition, the CY 2021 price of the supply will be $3.764 before reaching the finalized price of $3.645 in CY 2022.

Comment: One commenter disagreed with the proposed pricing of the radiofrequency introducer kit (SA026). The commenter stated that although some vendors now include this supply in an overall catheter pack, it is still common that many practices purchase this item separately. The commenter submitted two invoices for the supply and requested that CMS use them to update the pricing.

Response: We appreciate the submission of these additional invoices for use in pricing the SA026 supply. Therefore, we are finalizing an update in the price of this supply to $28.575 based on an average of the prices on the two submitted invoices. As part of our ongoing pricing transition, the CY 2021 price of the SA026 supply will be $32.83 before reaching the finalized price of $28.575 in CY 2022.

Comment: Several commenters disagreed with the proposed pricing of the hydrophilic guidewire (SD089) supply. Commenters stated that $27.76 would be a more appropriate reimbursement rate and submitted an invoice in support of their suggested pricing.

Response: We appreciate the submission of these additional invoices for use in pricing the SD089 supply. We noted that the guidewire on the newly submitted invoice was a different size than the guidewire on the invoice that we previously used for pricing the SD089 supply. Since we do not have information currently available as to which of these guidewires would be more typical, we are averaging together the two submitted invoices for a price of $20.555. As part of our ongoing pricing transition, the CY 2021 price of the SD089 supply will be $29.995 before reaching the finalized price of 20.555 in CY 2022.

Comment: A commenter disagreed with the proposed pricing of the endovascular laser treatment kit (SA074). The commenter stated that they were not sure that the proposed pricing was typical for the average clinic due to the economy of scale advantages available for larger providers. The commenter submitted three invoices for the supply and requested that CMS use them to update the pricing.

Response: We appreciate the submission of these additional invoices for use in pricing the SA074 supply. The unit prices on the three submitted invoices were $431.08 (for a pack of five), $438.60 (for a pack of two), and $535.60 for an individual supply. The price for the individual endovascular laser treatment kit was significantly higher than the other invoice prices and we believe that this price would not be typical in light of the other pricing data that we have available. Therefore, we are finalizing an update in the price of this supply to $438.60 based on taking the median of the submitted invoices which we believe to be more representative of typical pricing. As part of our ongoing pricing transition, the CY 2021 price of the SA074 supply will be $429.88 before reaching the finalized price of $438.60 in CY 2022.

Comment: A commenter disagreed with the proposed pricing of the tubing set (Liposorber) (SC083) and plasma separator (Liposorber) (SD188) supplies. The commenter stated that the proposed prices did not accurately reflect the actual average prices paid by their U.S. provider customers. The commenter submitted 45 invoices for the two supplies and requested that CMS use them to update the pricing.

Response: We appreciate the submission of this large quantity of additional invoices for use in pricing the SC083 and SD188 supplies. After reviewing the invoices, we agree with the commenter that the average sales price matches the numbers listed in their comment letter. Therefore, we are finalizing an update in the price of the SC083 supply to $75.71 and an update in the price of the SD188 supply to $131.42 as indicated on the submitted invoices. As part of our ongoing pricing transition, the CY 2021 price of the SC083 supply will be $62.28 and the CY 2021 price of the SD188 supply will be $113.04 before reaching their finalized prices in CY 2022.

Comment: Several commenters disagreed with the proposed pricing for the RF endovenous ablation catheter (SD 155) and the vascular sheath (SD 136) supplies. Commenters stated that the proposed prices did not reflect the reality of their practice's economics and expressed concern that such reductions could encourage office-based physicians to curtail or cease performing these

procedures. Commenters stated that the proposed pricing for RF catheters and sheaths represented the price being paid by high-volume or large multi-location practices and did not reflect the prices paid by smaller providers who are more typical. Due to the greater negotiating power and high volume discounts available to larger practices, commenters stated that the proposed supply pricing did not seem be to what typical providers pay and that the current pricing of $52.80 was more representative for the vascular sheath. One commenter requested a more thorough review of the data CMS used to determine the updated pricing for the SD136 and SD155 supplies as well as the opportunity to provide additional data to validate their pricing. Several commenters submitted a series of invoices for the RF endovenous occlusion catheter (SD155) that they stated were more typical of pricing and urged CMS to update the supply pricing accordingly.

Response: We appreciate the additional information provided by the commenters regarding the pricing of these supplies, especially the invoices with additional pricing data for the SD155 catheter. The commenters are correct that the proposed pricing for the SD155 supply was based in part on a bulk order and that ordering the catheters on an individual basis resulted in higher prices. However, we do not agree that it would be accurate to base the pricing of the SD155 supply solely on the basis of individual orders with no discounts included, as it is clear from the submitted invoices that there exists a variety of discounts available for providers. Therefore, we are averaging together the newly submitted invoices together with our previous invoices for the SD155 supply and finalizing the resulting price of $487.92. As part of our ongoing pricing transition, the CY 2021 price of the supply will be $562.71 before reaching the finalized price of $487.92 in CY 2022.

We did not receive any invoices with updated pricing information for the vascular sheath (SD136) supply. In the absence of additional information, we believe that the proposed price for the vascular sheath accurately reflects the cost of this supply and we are finalizing the proposed price of $24.44. We continue to welcome the submission of invoices with additional information regarding the pricing of these two or any other supply items.

Comment: Several commenters stated that they believe the HDR Afterload System, Nucletron—Oldelft (ER003) and the SRS System, SBRT, Six Systems (ER083) equipment items remain significantly undervalued relative to fair market pricing. The commenters stated that it was imperative for CMS equipment pricing to accurately reflect marketplace pricing given the high cost of these items and their substantial utilization in certain radiation oncology delivery codes. One commenter stated that the pricing for this equipment may represent a less costly electronic brachytherapy system used to treat skin cancer or an equipment upgrade or refurbished equipment. The commenters requested that CMS conduct additional research regarding fair and accurate market pricing for these two equipment items and accept newly submitted invoices during the 60-day comment period. One commenter requested a one-year moratorium on phasing in the StrategyGen revised pricing inputs and maintain all direct PE inputs at 2020 levels.

Response: We share the desire of the commenter for fair and accurate market-based pricing for these two equipment items. However, both of these equipment items were priced based on research conducted by our StrategyGen contractor and then were updated in response to additional information supplied by commenters in the CY 2019 PFS final rule (83 FR 59478–59479). In the absence of additional information, we believe that the current prices accurately reflect the cost of these equipment items. We continue to welcome the submission of invoices with additional information regarding the pricing of these two or any other equipment items. We also note that the ongoing market-based supply and equipment pricing update was previously finalized in CY 2019 rulemaking and we do not agree that a one-year moratorium on the continuing pricing transition would facilitate our goal of ensuring current pricing.

After consideration of the public comments, we are finalizing our proposals associated with the market-based supply and equipment pricing update as detailed above. Table 10 contains the list of finalized CY 2021 market-based supply and equipment pricing updates:

TABLE 10: CY 2021 Finalized Market-Based Supply and Equipment Updates

CMS CODE	Description	CMS 2020 Price	Prior CMS 2022 Price	Prior CMS 2021 Price	Updated CMS 2022 Price	Updated CMS 2021 Price
SA026	kit, radiofrequency introducer	$37.080	$24.160	$30.620	$28.575	$32.828
SA074	kit, endovascular laser treatment	$421.165	$323.330	$372.248	$438.600	$429.883
SA105	UroVysion test kit	$153.040	$129.280	$141.160	$187.490	$170.265
SC083	tubing set (Liposorber)	$48.840	$47.680	$48.260	$75.710	$62.275
SD089	guidewire, hydrophilic	$39.435	$13.350	$26.393	$20.555	$29.995
SD136	vascular sheath	$36.650	$52.800	$44.725	$24.444	$30.547
SD155	catheter, RF endovenous occlusion	$637.500	$382.500	$510.000	$487.920	$562.710
SD188	plasma separator (Liposorber)	$94.660	$89.320	$91.990	$131.420	$113.040
SL089	lysing reagent (FACS)	$3.883	$3.280	$3.581	$3.645	$3.764
EQ041	Vmax 22d and 62j (PFT equip, autobox, computer system)	$47,930.000	$47,930.000	$47,930.000	$47,406.540	$47,668.270
ER044	nuclide rod source set	$1,783.167	$2,171.333	$1,977.250	$2,081.167	$1,932.167

(2) Invoice Submission

The full list of updated supply and equipment pricing as it will be implemented over the 4-year transition period will be made available as a public use file displayed on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

We routinely accept public submission of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the PFS proposed rule, and would consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Stakeholders are encouraged to submit invoices as part of their public comments or, if outside the public comment process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

(3) Updated Supply Pricing for Venous and Arterial Stenting Services

Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and presented additional information regarding supply pricing for certain venous and arterial stenting services. These stakeholders stated that the use of the ''stent, vascular, deployment system, Cordis SMART'' (SA103) supply was no longer typical in CPT codes 37238 (*Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein*) and 37239 (*Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein*). The stakeholders stated that a new venous stent system had become the typical standard of care for these services, and they supplied ten invoices for use in pricing this supply.

The stakeholders also requested additional information regarding the nature of the ''stent, balloon, implantable'' (SD299) supply included in CPT codes 37236 (*Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; initial artery*) and 37237 (*Transcatheter placement of an intravascular stent(s) (except lower extremity artery(s) for occlusive disease, cervical carotid, extracranial vertebral or intrathoracic carotid, intracranial, or coronary), open or percutaneous, including radiological supervision and interpretation and including all angioplasty within the same vessel, when performed; each additional artery*). The stakeholders specifically were unclear what the implantable stent balloon represented and sought guidance on whether pricing involved a stent, a balloon, or a combination of both.

In response to the additional information provided by the stakeholders, we proposed to remove the SA103 supply item from CPT codes 37238 and 37239. We proposed to replace it with a newly created ''venous stent system'' (SD340) supply at the same supply quantity. We proposed a price of $1,750.00 for the venous stent system based on the median price of the ten invoices supplied by the stakeholders. We proposed the use of the median price due to the presence of several invoices that appear to be outliers, which are not reflective of

market pricing for the venous stent system. With regards to the request for additional information regarding the nature of the ''stent, balloon, implantable'' (SD299) supply, the original invoice used to price this supply during the CY 2015 rule cycle listed an item named ''Renal and Biliary Stent System 7.0 mm × 15 mm × 135 cm''. We welcomed additional information from stakeholders regarding the nature and pricing of this supply item.

We received public comments on our proposals associated with updated supply pricing for venous and arterial stenting services. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they supported the proposed change to replace the stent for CPT codes 37238 and 37239. One commenter stated that they appreciated the additional information on the two CPT codes and looked forward to researching this issue further.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing our proposals associated with updated supply pricing for venous and arterial stenting services.

(4) Myocardial PET Equipment Inputs

Following the publication of the CY 2020 PFS final rule, stakeholders contacted CMS and presented additional information regarding the direct PE inputs for several codes associated with Myocardial PET services. The stakeholders stated that the nuclide rod source set (ER044) equipment was inadvertently excluded from the direct PE recommendations for CPT codes 78432 (*Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (eg, myocardial viability)*), 78459 (*Myocardial imaging, positron emission tomography (PET), metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), single study)*), 78491 (*Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); single study, at rest or stress (exercise or pharmacologic)*), and 78492 (*Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic)*), and requested that CMS add this equipment to the direct inputs for this group of CPT codes. The stakeholders also stated that the current useful life of 5 years for the ER044 equipment was incorrect as these sources are replaced every 9 months to 1 year. The stakeholders requested that CMS update the useful life of ER044 to 0.75 years. Finally, the stakeholders stated that the costs for the purchase of the Rubidium PET Generator (ER114) equipment are captured elsewhere through the billing of HCPCS supply code A9555, and the stakeholders recommended that we remove equipment item ER114 to avoid incorrect billing duplication.

We noted that we appreciate the additional information submitted by the stakeholders regarding the direct PE inputs for these Myocardial PET services. In response to this new information, we proposed to update the price for the nuclide rod source set (ER044) equipment to $2,081.17 based on averaging together the price of the three submitted invoices after removing the shipping and delivery costs according to our standard pricing methodology. We also proposed to add the ER044 equipment to CPT codes 78432, 78459, 78491, and 78492 as requested, assigning the same equipment time utilized by the ''PET Refurbished Imaging Cardiac Configuration'' (ER110) equipment in each service. We proposed to update the useful life of the ER044 equipment to one year in accordance with our proposed policy to treat equipment useful life durations of less than 1 year as having a duration of one year. As we stated previously in section II.B, we have concerns that assigning very low useful life durations of less than 1 year would fail to maintain relativity with other equipment on the PFS, and the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. We direct readers to the previous discussion regarding equipment cost per minute methodology earlier in section II.B. of this final rule. Finally, we are removing the ''PET Generator (Rubidium)'' (ER114) equipment from our database as requested by the stakeholders. We noted that since the technical components for CPT codes 78432, 78459, 78491, and 78492 are all contractor-priced, there will be no change to the national pricing of these codes.

We received public comments on our proposals associated with Myocardial PET equipment inputs. The following is a summary of the comments we received and our responses.

Comment: Several commenters stated that they agreed with and supported all four of the CMS proposals associated with Myocardial PET equipment inputs. Commenters also stated that they supported the decision to maintain contractor pricing for the technical components for all the new and revised Myocardial PET codes. Commenters stated that the standard CMS formula and RUC PE inputs do not allow for certain high-cost expenses that are generally part of overhead to be factored into the RVUs and requested that contractor pricing continue to be maintained for these services.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing our proposals associated with Myocardial PET equipment inputs.

(5) Autologous Platelet-Rich Plasma (HCPCS Code G0460) Supply Inputs

We did not make any proposals associated with HCPCS code G0460 (*Autologous platelet rich plasma for chronic wounds/ulcers, including phlebotomy, centrifugation, and all other preparatory procedures, administration and dressings, per treatment*) in the CY 2021 PFS proposed rule. Following the publication of the rule, stakeholders contacted CMS regarding the creation of a new 3C patch system supply which is topically applied for the management of exuding cutaneous wounds, such as leg ulcers, pressure ulcers, and diabetic ulcers and mechanically or surgically-debrided wounds. Stakeholders first sought clarification on how CMS calculated the underlying nonfacility PE RVUs for HCPCS code G0460. Stakeholders also stated that autologous platelet rich plasma administration procedures furnished in clinical trials (including the new 3C patch system) are reported using HCPCS code G0460 and requested that CMS revalue the service to reflect the PEs associated with the new patch system supply. The stakeholders stated that the use of the new 3C patch system will represent the typical case for HCPCS code G0460 and the therefore the cost inputs for this supply should be used to establish the RVUs for this code as the current MPFS rate is substantially less than the amount it costs to furnish the 3C patch.

We clarify for stakeholders that the valuation of the direct PE inputs increased for HCPCS code G0460 as a result of the ongoing market-based supply and equipment pricing update. However, there was also a minor

decrease in the indirect PE allocation associated with this service, with the net result that the proposed PE RVU coincidentally ended up remaining the same as in the previous year. We also clarify for stakeholders that HCPCS code G0460 is not included in the Anticipated Specialty Assignment for Low Volume Services list, and therefore, was unaffected by low utilization in the claims data.

We understand that the stakeholders originally believed that the new 3C patch system would be reported using new HCPCS coding before CMS issued a clarification that the clinical trials associated with this supply would be reported under HCPCS code G0460. We share the concerns of the stakeholders that patient access to the 3C patch will be materially impacted if CMS maintains reimbursement for HCPCS G0460 at the current rate. However, we note that we did not propose to increase the price of HCPCS code G0460 in the PFS proposed rule, and we have concerns about finalizing a fivefold increase in the pricing of this service without going through notice and comment rulemaking. Therefore, we are finalizing contractor pricing for HCPCS code G0460 for CY 2021 to allow for increased pricing for this service when it includes the 3C patch system without establishing a new national price. We believe that the use of contractor pricing will allow additional time to determine the most accurate pricing for HCPCS code G0460. We are also adding the 3C patch system to our supply database under supply code SD343 at a price of $625.00 based on an average of the submitted invoices.

(6) Adjustment to Allocation of Indirect PE for Some Office-Based Services

In the CY 2018 PFS final rule (82 FR 52999 through 53000), we established criteria for identifying the services most affected by the indirect PE allocation anomaly that does not allow for a site of service differential that accurately reflects the relative indirect costs involved in furnishing services in nonfacility settings. We also finalized a modification in the PE methodology for allocating indirect PE RVUs to better reflect the relative indirect PE resources involved in furnishing these services. The methodology, as described, is based on the difference between the ratio of indirect PE to work RVUs for each of the codes meeting eligibility criteria and the ratio of indirect PE to work RVU for the most commonly reported visit code. We refer readers to the CY 2018 PFS final rule (82 FR 52999 through 53000) for a discussion of our process for selecting services subject to the revised methodology, as well as a description of the methodology, which we began implementing for CY 2018 as the first year of a 4-year transition.

For CY 2021, we proposed to continue with the fourth and final year of the transition of this adjustment to the standard process for allocating indirect PE.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

e. Update on Technical Expert Panel Related to Practice Expense

The RAND Corporation is currently studying potential improvements to CMS' PE allocation methodology and the data that underlie it. As we noted earlier in this section, our current system for setting PE RVUs relies in part on data collected in the Physician Practice Information Survey (PPIS), which was administered by the AMA in CY 2007 and 2008.

RAND, in its first phase of research, available at *https://www.rand.org/pubs/research_reports/RR2166.html*, found that the PPIS data are outdated and may no longer reflect the resource allocation, staffing arrangements, and cost structures that describe practitioners' resource requirements in furnishing services to Medicare beneficiaries, and consequently may not accurately capture the indirect PE resources required to furnish services to Medicare FFS beneficiaries. For example, the PPIS preceded the widespread adoption of electronic health records, quality reporting programs, billing codes that promote team-based care, and hospital acquisition of physician practices. Notably, RAND found that practice ownership was strongly associated with indirect PE, with physician-owned practices requiring 190% higher indirect PE compared to facility-owned practices, suggesting a need to potentially update demographic information. Additionally, RAND found that aggregating Medicare provider specialties into broader categories resulted in small specialty-level impacts relative to the current system, suggesting that specialty-specific inputs may not be required to accurately reflect resource costs.

To follow up on these and other issues raised in the first phase of RAND's research, in the CY 2020 PFS, we announced that RAND was convening a technical expert panel (TEP) to obtain input from stakeholders including physicians, practice and health system managers, health care accountants, and health policy experts. The TEP occurred on January 10, 2020 and its report is available at *https://www.rand.org/pubs/working_papers/WR1334.html*. Topics discussed included identifying issues with the current system; changes in medicine that have affected PE; how PE inputs could be updated, including through a potential new survey instrument; how best to aggregate PE categories if there were to be new survey instrument; ways to maximize response rates in a potential new survey; and using existing data to inform PFS PE rates. In addition, RAND has issued the results of its subsequent phase of research, available at *www.rand.org/t/RR3248*. This report is also available as a public use file displayed on the CMS website under downloads for the CY 2021 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Based on the results of the TEP and RAND's other ongoing research, we are interested in potentially refining the PE methodology and updating the data used to make payments under the PFS. We believe that potential refinements could improve payment accuracy and strengthen Medicare. Our goals are to balance obtaining the data as soon as practicable and in a way that would allow stakeholders and CMS to collectively examine many of the issues the TEP and RAND's research identified. We noted that we were considering several questions, including how to best incorporate market-based information, which could be similar to the market research that we recently conducted to update supply and equipment pricing used to determine direct PE inputs under the PFS payment methodology. For example, stakeholders have expressed an interest in updating the clinical labor data that we use for direct PE inputs based on current salaries and compensation for the health care workforce. We solicited comment regarding how we might update the clinical labor data. We noted that historically we have used data from the Bureau of Labor Statistics and sought comment to determine if this is the best data source or if there is an alternative. We also noted that we are interested in hosting a Town Hall meeting at a date to be determined to provide an open forum for discussion with stakeholders on our ongoing research to potentially update the PE methodology and the underlying inputs. Finally, we welcomed feedback from all interested parties regarding RAND's report and clarified that we were not making any proposals based on this report for this rulemaking cycle We encouraged stakeholders to submit feedback as part

of their public comments or, if outside the public comment process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

We received public comments on the update on technical expert panel related to PE. The following is a summary of the comments we received and our responses.

Comment: In response to the RAND report, commenters encouraged CMS to work with stakeholders on any new PE data collection effort.

Response: We agree that we would want to engage with stakeholders as part of any new PE data collection effort. Our public notice and comment rulemaking process is the venue we would use for any potential future proposals.

Comment: Commenters were supportive of CMS convening a Town Hall meeting.

Response: We appreciate and are encouraged by commenters' support. We continue to believe that a Town Hall would provide open forum for discussions with stakeholders. We remain interested in hosting this meeting at a date to be determined.

C. Potentially Misvalued Services Under the PFS

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section II.H. of this final rule, Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA) Resource-Based Relative Value Scale (RVS) Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and other stakeholders. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by law. We may also consider analyses of work time, work RVUs, or direct PE inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recently available data, we assess the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*http://www.medpac.gov/docs/default-source/reports/Mar06_Ch03.pdf?sfvrsn=0*), MedPAC discussed the importance of appropriately valuing physicians' services, noting that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases or PE costs rises.

As MedPAC noted in its March 2009 Report to Congress (*http://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to

facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we intend to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well. Individuals and stakeholder groups may submit codes for review under the potentially misvalued codes initiative to CMS in one of two ways. Nominations may be submitted to CMS via email or through postal mail. Email submissions should be sent to the CMS emailbox *Medicare PhysicianFeeSchedule@cms.hhs.gov*, with the phrase ''Potentially Misvalued Codes'' and the referencing CPT code number(s) and/or the CPT descriptor(s) in the subject line. Physical letters for nominations should be sent via the U.S. Postal Service to the Centers for Medicare & Medicaid Services, Mail Stop: C4–01–26, 7500 Security Blvd., Baltimore, Maryland 21244. Envelopes containing the nomination letters must be labeled ''Attention: Division of Practitioner Services, Potentially Misvalued Codes''. Nominations for consideration in our next annual rule cycle should be received by our February 10th deadline. Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,700 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; final rule (76 FR 73052 through 73055) (hereinafter referred to as the ''CY 2012 PFS final rule with comment period''). In the CY 2012 PFS final rule with comment period (76 FR 73055 through 73958), we finalized our policy to consolidate the review of physician work and PE at the same time, and established a process for the annual public nomination of potentially misvalued services.

In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (77 FR 68892) (hereinafter referred to as the ''CY 2013 PFS final rule with comment period''), we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In the Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions; Proposed Rule (73 FR 38589) (hereinafter referred to as the ''CY 2009 PFS proposed rule''), we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes. In the fourth Five-Year Review (76 FR 32410), we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 services. In the CY 2013 PFS final rule with comment period, we identified specific Harvard-valued services with annual allowed charges that total at least $10,000,000 as potentially misvalued. In addition to the Harvard-valued codes, in the CY 2013 PFS final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time and codes with no physician work that have listed work time). We continue each year to consider and finalize a list of potentially misvalued codes that have or will be reviewed and revised as appropriate in future rulemaking.

3. CY 2021 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058), we finalized a process for the public to nominate potentially misvalued codes. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: Technique, knowledge and technology, patient population, site-of-service, length of hospital stay, and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and

organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a potentially misvalued code. The public has the opportunity to comment on these and all other proposed potentially misvalued codes. In that year's final rule, we finalize our list of potentially misvalued codes.

a. Public Nominations

We received submissions nominating codes for review under the potentially misvalued code initiative, and several requests for review of PE related inputs prior to our February 10, 2020 deadline. We refer readers to section II.B. of this final rule, Determination of Practice Expense RVUs, for further discussion on the PE-related submissions. The summary of the submissions reviewed under the potentially misvalued code initiative is discussed below.

We received multiple submissions requesting that CMS consider CPT code 22867 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without fusion, including image guidance when performed, with open decompression, lumbar; single level*) for nomination as potentially misvalued. In their request, the submitters suggested that the physician work assigned to this code significantly undervalues the procedure relative to the value of CPT code 63047 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar*). The submitters stated that the work performed during the surgical steps to perform a laminectomy for both procedures is generally similar except for the additional intensity and complexity involved in CPT code 22867 to implant the interspinous stabilization device. The submitters also requested that the malpractice RVUs assigned to this code be increased to better align with similar spine procedures, in terms of specialty-level and service-level risk factors, in addition to the intensity and complexity of the procedure. After considering the information provided by the submitter, which suggests that the current valuation for the service may not reflect the level of intensity inherent in furnishing the service relative to other similar services with inputs that exceed those for the nominated service, we proposed to nominate CPT code 22867 as potentially misvalued and welcomed public comment on this code.

We received public comments on the CY 2021 identification and review of potentially misvalued services. The following is a summary of the comments we received and our responses.

Comment: The AMA RUC has indicated that CPT code 22867 will be placed on a list they call the ''next Level of Interest for review.''

Response: We acknowledge and thank the AMA RUC's placement of CPT code 22867 on their ''next Level of Interest for review'' list and look forward to their input, as well as input from the initial submitters of CPT code 22867 and all other parties.

Comment: Some commenters expressed support for the nomination of CPT code 22867 as a potentially misvalued code, but disagreed with the comparison to CPT code 63047. Some commenters stated that CPT code 22867 was misvalued from its last review in 2016, when CMS determined a work RVU of 13.50 over the AMA RUC recommended work RVU of 15.00. Commenters stated that CMS already has the necessary survey data from the specialties who perform this service—which had been surveyed and reviewed twice by the AMA RUC with the same outcome, and that the procedure's technology has not changed since the last survey. One commenter also highlighted differences between CPT code 63047 and CPT code 22867, noting that CPT code 63047 involves more postoperative work (as an inpatient service), spends more time with intense imaging services and device sizing, and that the decompression performed is more extensive than CPT code 22867, all of which supports the relative greater RVU amount for CPT code 63047.

Response: We acknowledge and appreciate comments and feedback from CPT code 22867 stakeholders who have expressed their reasons both for and against the nomination of this code as potentially misvalued.

Comment: Some commenters requested that CMS nominate HCPCS codes G0442 (*Annual alcohol misuse screening, 15 minutes*) and G0444 (*Annual depression screening, 15 minutes*) as potentially misvalued due to the possible misinterpretation of their descriptors. These commenters highlighted that the descriptors may appear to convey that the physician providing the service must provide a full 15 minutes of screening to report either of these services. The commenters stated their understanding of the descriptor to mean ''up to 15 minutes'' to perform the screenings, and suggested that CMS adjust the official descriptors to say G0442 (*Annual alcohol misuse screening, up to 15 minutes*) and G0444 (*Annual depression screening, up to 15 minutes*), and for CMS to provide an educational announcement to clarify the proposed change.

Response: We thank the commenters for these suggestions for clarifications on HCPCS codes G0442 and G0444 descriptors and welcome comments and continued engagement with stakeholders on all aspects of coding that improves accuracy and promotes clarity.

Comment: Several commenters nominated CPT code 49436 (*Delayed creation of exit site from embedded subcutaneous segment of intraperitoneal cannula or catheter*) as being potentially misvalued, due to the PFS presently only making payment for this service in the facility setting and not in the office setting. Commenters requested that CMS review this code, and value the required resources for correct payment in the office setting. They contend that the procedure can be performed in the office, just as safely as it is done in an ASC or outpatient setting, and that it might be a more convenient site of service for the physician and for the patient. CPT code 49436 helps promote home peritoneal dialysis, which falls in line with the President's Executive Order (E.O.) on Advancing American Kidney Health and keeps patients at home during the PHE for COVID–19 rather than having to travel to a dialysis center three times a week.

Response: While CMS had decided not to nominate CPT code 49436 in the proposed rule as being potentially misvalued, commenters resubmitted their nomination during this comment period. We appreciate all of the comments and feedback that we have received for nominating CPT code 49436 as potentially misvalued and further to consider valuing CPT code 49436 in the office setting. We intend to research the information provided and understand more about the potential impact of valuing CPT code 49436 in the office setting and may consider for future rulemaking.

Comment: Commenters referenced codes that were publicly nominated in CY 2019 as misvalued by a national commercial insurer. The commenter expressed disappointment that CMS accepted these public nominations from a private national commercial insurer, as they could potentially represent a possible conflict of interest in their role

as a private commercial medical insurance and Medicare Advantage payer to the providers of physician services. The commenter urged CMS to evaluate how it considers public nominations from parties with possible conflicts in payment determinations.

Response: CMS will accept and review all public nomination of services that may be potentially misvalued, as appropriate. As we had stated in our CY 2019 PFS final rule, we also reiterate that we continue to be open to reviewing additional and supplemental sources of data furnished by stakeholders, and providing such information to CMS is not limited to the public nomination process for potentially misvalued codes. We encourage stakeholders to continue to provide such information for our consideration, as this information may support CMS' review and refinement of work RVUs that are the basis for payment for many services under the PFS.

Comment: One commenter urged CMS to use its authority to adjust CY 2018 Medicare payments for physicians' services to increase the current rate for managing home patients (CPT code 90966 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older*) 6.77 RVU) and to the maximum payment amount for managing in-center patients (CPT code 90960 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month*) 8.07 RVU); however, no supporting documentation was included with this nomination request.

Response: Should there be compelling evidence of substantial change in the nature of CPT codes 90966 and 90960 and their relationship to each other since their 2018 review, the commenter is free to nominate these codes as potentially misvalued and lend support and evidence to that effect for the next proposed rule.

After consideration of the public comments, we are finalizing our proposal to nominate CPT code 22867 as potentially misvalued. We appreciate all of the comments and information we have received from stakeholders about services that they believe to be potentially misvalued and look forward to receiving new and additional information prior to our February 10th deadline for our next round of rulemaking.

D. Telehealth and Other Services Involving Communications Technology, and Interim Final Rule With Comment Period for Coding and Payment of Virtual Check-In Services

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act

As discussed in the CY 2021 PFS proposed rule (85 FR 50095) and in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the PFS. For further details, see the full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006) and in 42 CFR 410.78 and 414.65.

a. Adding Services to the Medicare Telehealth Services List

In the CY 2003 PFS final rule with comment period (67 FR 79988), we established a regulatory process for adding services to or deleting services from the Medicare telehealth services list in accordance with section 1834(m)(4)(F)(ii) of the Act (§ 410.78(f)). This process provides the public with an ongoing opportunity to submit requests for adding services, which are then reviewed by us and assigned to categories established through notice and comment rulemaking. Specifically, we assign any submitted request to add to the Medicare telehealth services list to one of the following two categories:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the Medicare telehealth services list. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to those on the current Medicare telehealth services list. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The Medicare telehealth services list, including the additions described later in this section, is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

For CY 2021, requests to add services to the Medicare telehealth services list must have been submitted and received by February 10, 2020. Each request to add a service to the Medicare telehealth services list must have included any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as the vehicle to make changes to the Medicare telehealth services list, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request in the future to add services to the Medicare telehealth services list, including where to mail these requests, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. Requests To Add Services to the Medicare Telehealth Services List for CY 2021

Under our current policy, we add services to the Medicare telehealth services list on a Category 1 basis when we determine that they are similar to

services on the existing Medicare telehealth services list for the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73098), we believe that the Category 1 criteria not only streamline our review process for publicly requested services that fall into this category, but also expedite our ability to identify codes for the Medicare telehealth services list that resemble those services already on the Medicare telehealth services list. We received several requests to add various services as Medicare telehealth services effective for CY 2021. We also conducted an internal review of potential services to add to the Medicare telehealth services list.

In response to the public health emergency (PHE) for Coronavirus Disease 2019 (COVID–19), CMS undertook emergency rulemaking to add a number of services to the Medicare telehealth services list on an interim final basis. In the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (IFC), (which was issued on March 31, 2020 and appeared in the April 6, 2020 **Federal Register** (85 FR 19230, 19234 through 19241) (hereinafter referred to as the ''March 31st COVID–19 IFC''), on an interim final basis for the duration of the PHE for COVID–19, we also finalized the addition of a number of services to the Medicare telehealth services list on a Category 2 basis. The following is a list of those services:

- Emergency Department (ED) Visits, Levels 1–5 (CPT codes 99281–99285).
- Initial and Subsequent Observation and Observation Discharge Day Management (CPT codes 99217–99220; CPT codes 99224–99226; CPT codes 99234–99236).
- Initial Hospital Care and Hospital Discharge Day Management (CPT codes 99221–99223; CPT codes 99238–99239).
- Initial nursing facility visits, All levels (Low, Moderate, and High Complexity) and nursing facility discharge day management (CPT codes 99304–99306; CPT codes 99315–99316).
- Critical Care Services (CPT codes 99291–99292).
- Domiciliary, Rest Home, or Custodial Care services, New and Established patients (CPT codes 99327–99328; CPT codes 99334–99337).
- Home Visits, New and Established Patient, All levels (CPT codes 99341–99345; CPT codes 99347–99350).
- Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT codes 99468–99472; CPT codes 99475–99476).
- Initial and Continuing Intensive Care Services (CPT code 99477–994780).
- Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483).
- Group Psychotherapy (CPT code 90853).
- End-Stage Renal Disease (ESRD) Services (CPT codes 90952, 90953, 90959, and 90962).
- Psychological and Neuropsychological Testing (CPT codes 96130–96133; CPT codes 96136–96139).
- Therapy Services, Physical and Occupational Therapy, All levels (CPT codes 97161–97168; CPT codes 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521–92524, 92507).
- Radiation Treatment Management Services (CPT codes 77427).

When we previously considered adding these services to the Medicare telehealth services list, either through a public request or through our own internal review, we considered whether these services met the Category 1 or Category 2 criteria. In many cases, we reviewed requests to add these services on a Category 1 basis, but did not receive or identify information that allowed us to review the services on a Category 2 basis. While we stated in the March 31st COVID–19 IFC that we did not believe the context of the PHE for COVID–19 would change the assessment of these services as Category 1, we did reassess all of these services on a Category 2 basis in the context of the widespread presence of COVID–19 in the community.

Given the exposure risks for beneficiaries, the health care work force, and the community at large, we stated that in-person interactions between professionals and patients posed an immediate potential risk that would not have been present when we previously reviewed these services. We were concerned that this new risk created a unique circumstance where health care professionals might have to choose between mitigating exposure risk for themselves and for their patients or seeking Medicare payment for the service. For example, certain persons, especially older adults who are particularly vulnerable to complications from this specific viral infection; those considered at risk because of underlying health conditions; and those known to be recently exposed or diagnosed, and therefore, likely to spread the virus to others, were often being directed by local public health officials to self-isolate as much as possible. At the same time, we noted that the risk to medical professionals treating patients is high and we considered it likely that medical professionals would try to treat patients as effectively as possible without exposing themselves or their patients unnecessarily. We explained that, in some cases, the use of telecommunications technology could mitigate the exposure risk; and in such cases, there is a clear clinical benefit of using such technology in furnishing the service. In other words, patients who should not be seen by a professional in-person due to the exposure risk were highly likely to be without access to clinically appropriate treatment or diagnostic options unless they have access to services furnished through interactive communication technology.

Therefore, in the context of the PHE for COVID–19, we believed that all of the services we added met the Category 2 criteria to be added to the Medicare telehealth services list on the basis that there was a patient population that would otherwise not have access to clinically appropriate treatment. We noted that, as with other services on the Medicare telehealth services list, it may not be clinically appropriate or possible to use telecommunications technology to furnish these particular services to every person or in every circumstance. In the context of the PHE for COVID–19, with specific regard to the exposure risks noted above, we recognized the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology as opposed to the potential lack of access that could occur to mitigate the risk of disease exposure.

The following presents a discussion of these services and the related proposals.

After reviewing the requests we received and the services we identified for consideration, we identified the services listed in Table 11 as being sufficiently similar to services currently on the Medicare telehealth services list to be added on a Category 1 basis. Therefore, we proposed to add the services in Table 11 to the Medicare telehealth services list on a Category 1 basis for CY 2021.

TABLE 11: CY 2021 Proposed and Final Additions to the Medicare Telehealth Services List on a Category 1 Basis

HCPCS Code	Long Descriptor
G2211	Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)
90853	Group psychotherapy (other than of a multiple-family group)
96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [e.g., acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
G2212	Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (e.g., basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (e.g., functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (e.g., home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (e.g., rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.
99334	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent with the patient and/or family or caregiver.
99335	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent with the patient and/or family or caregiver.
99347	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 15 minutes are spent face-to-face with the patient and/or family.

HCPCS Code	Long Descriptor
99348	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.

We noted that we believe the services described by the HCPCS codes in Table 11 are similar to services currently on the Medicare telehealth services list. The HCPCS codes G2211 and G2212 are add-on codes to the office/outpatient evaluation and management (O/O E/M) services and are, by definition, part of the O/O E/M services with which they are billed; they cannot be billed with any other codes. These codes were previously described by placeholder HCPCS codes GPC1X and 99XXX (for G2211 and G2212, respectively). For further discussion of these codes, please see section II.F.2.c of this rule. The Assessment of and Care Planning for Patients with Cognitive Impairment was defined as a service meant to be billed in specific clinical scenarios in lieu of a level 5 O/O E/M visit. As such, these services fall within the Category 1 criteria, because they are similar to the office visits that are already on the Medicare telehealth services list. As it describes group therapy, CPT code 90853 is similar to the other group therapy services currently on the Medicare telehealth services list.

While the patient's home cannot serve as an originating site (where the patient is located) for purposes of most Medicare telehealth services, the SUPPORT for Patients and Communities Act amended section 1834(m)(4)(C) of the Act and added a new paragraph at section 1834(m)(7) of the Act to remove geographic limitations and authorize the patient's home to serve as a telehealth originating site for purposes of treatment of a substance use disorder (SUD) or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a SUD diagnosis. These domiciliary/home visits contain the same elements and similar descriptors to the O/O E/M visits, and therefore, we noted that there is sufficient justification to add them to the Medicare telehealth services list on a Category 1 basis. Additionally, we noted that, due to the vulnerability of this particular patient population that are receiving treatment for a diagnosed SUD or co-occurring mental health disorder, we should maximize the availability of telehealth services for the treatment of SUDs and co-occurring mental health disorders. We also noted that, because the home is not generally a permissible telehealth originating site, these services could be billed when furnished as telehealth services only for treatment of a SUD or co-occurring mental health disorder.

Finally, we received a request to add CPT code 96121 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [e.g., acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)*) on the basis that this is an add-on code to CPT code 96116 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [e.g., acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour*), which is currently on the Medicare telehealth services list. In the past, we have added services to the Medicare telehealth services list that are add-on codes that describe a continuation or additional elements of services currently on the Medicare telehealth services list since the services would only be considered telehealth services when billed as an add-on to codes already on the Medicare telehealth services list (82 FR 53008). Therefore, we proposed to add CPT code 96121 to the Medicare telehealth services list.

We also received a request to add services to the Medicare telehealth services list that do not meet our criteria for addition to the Medicare telehealth services list. We did not propose to add the services listed in Table 12 to the Medicare telehealth services list.

TABLE 12: Services Requested for Addition to the Medicare Telehealth Services List Not Proposed for Addition

Service Type	HCPCS	Long Descriptor
Medical Genetics	96040	Medical genetics and genetic counseling services, each 30 minutes face-to-face with patient/family
	S0265	Genetic counseling, under physician supervision, each 15 minutes

We received a request to add Medical Genetics services to the Medicare telehealth services list. We note that CPT code 96040 is considered bundled into O/O E/M visits, which are already on the Medicare telehealth services list. Therefore, we do not believe it is necessary to add CPT code 96040. As we stated in the CY 2012 PFS final rule

with comment period (76 FR 73096 through 73097), physicians and NPPs who may independently bill Medicare for their services and who are counseling individuals would generally report office or other outpatient E/M CPT codes for office visits that involve significant counseling, including genetic counseling, and these office visit CPT codes are already on the Medicare telehealth services list. CPT code 96040 would only be reported by genetic counselors for genetic counseling services. Genetic counselors are not among the practitioners who can bill Medicare directly for their professional services, and they are also not practitioners who can furnish telehealth services as specified in section 1834(m)(4)(E) of the Act. As such, we noted that we do not believe that it would be necessary or appropriate to add CPT code 96040 to the Medicare telehealth services list.

HCPCS code S0265 is a Medication, Supplies, and Services code. There is no separate payment under the PFS for this category of codes. Therefore, we did not propose to add this service to the Medicare telehealth services list.

We received public comments on the requests to add services to the Medicare telehealth services list for CY 2021. The following is a summary of the comments we received and our responses.

Comment: Commenters broadly supported our proposal to add HCPCS codes and CPT codes 90853, 96121, G2212, 99483, 99334, 99335, 99347, and 99348 to the Medicare telehealth list on a Category 1 basis.

Response: We thank the commenters for their support and feedback.

Comment: One commenter opposed the addition of G2211 to the Medicare telehealth list on the basis they do not agree the creation of the code.

Response: We thank the commenter for their feedback and refer them to section II.F.2.c. of this final rule for further discussion of payment policies for HCPCS code G2211. We note that HCPCS codes G2211 and G2212 replace GPC1X and 99XXX respectively, please see section II.F.2.c in this final rule.

Comment: One commenter requested clarification on the addition of CPT codes 99347 and 99348 (*Home visit for the evaluation and management of an established patient*). Specifically, the commenter requested clarification from CMS on the situations in which a home visit after the end of the PHE for COVID–19 would be allowed via telehealth.

Response: While the patient's home cannot serve as an originating site (where the patient is located) for purposes of most Medicare telehealth services, the SUPPORT for Patients and Communities Act amended section 1834(m)(4)(C) of the Act and added a new paragraph at section 1834(m)(7) of the Act to remove geographic limitations and authorize the patient's home to serve as a telehealth originating site for purposes of treatment of a SUD or a co-occurring mental health disorder, furnished on or after July 1, 2019, to an individual with a SUD diagnosis. These domiciliary/home visits contain the same elements and similar descriptors to the O/O E/M visits, and therefore, we believe there is sufficient justification to add them to the Medicare telehealth services list on a Category 1 basis. We are adding these to the telehealth services list because an office/outpatient visit might not always most accurately or specifically describe the type of visit furnished to treat an individual in their home for an SUD or co-occuring mental health disorder; and that sometimes one of the domiciliary/home visit codes would more accurately describe the service.

Comment: One commenter stated that Assessment and Care Planning for Patients with Cognitive Impairment (CPT Code 99483) should not be added at this time until more study can be done to assess the appropriateness of this service being delivered in the telehealth context given that many cognitive impairments and symptoms may require in-person assessment.

Response: We continue to believe that CPT code 99483 is sufficiently similar to an office visit to warrant addition to the Medicare telehealth list on a permanent basis in that it involves evaluating and managing a patient's cognitive impairment in an office/outpatient setting. When the AMA CPT Editorial Panel created this code, they assumed that the work associated with assessment and care planning for patients with cognitive impairment had been reported with CPT code 99215 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family*), which is currently on the Medicare telehealth list.

After considering the public comments received, we are finalizing our proposal and adding HCPCS codes G2211 and CPT codes 90853, 96121, G2212, 99483, 99334, 99335, 99347, and 99348 to the Medicare telehealth list for CY 2021.

Comment: Commenters expressed opposition to CMS' decision not to propose to add Medical Genetics services (CPT code 96040) to the Medicare telehealth services list.

Response: We note that CPT code 96040 is not separately billable under the PFS; it is considered bundled into O/O E/M visits, which are already on the Medicare telehealth services list. Therefore, we believe it is unnecessary, and could potentially be confusing, to add CPT code 96040 to the list. Only codes that are separately billable can be added to the Medicare telehealth list. As we stated in the CY 2012 PFS final rule with comment period (76 FR 73096 through 73097), physicians and NPPs who furnish and bill Medicare for these services would generally report office or other outpatient E/M CPT codes for office visits that involve significant counseling, including genetic counseling; and the office visit CPT codes are already on the Medicare telehealth services list. CPT code 96040 would only be reported by genetic counselors for genetic counseling services. Genetic counselors are not among the practitioners who can bill Medicare directly for their professional services, and they are also not practitioners who can furnish telehealth services as specified in section 1834(m)(4)(E) of the Act. As such, we do not believe that it would be necessary or appropriate to add CPT code 96040 to the Medicare telehealth services list.

c. Proposed Temporary Addition of a Category 3 Basis for Adding to or Deleting Services From the Medicare Telehealth Services List

Legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act, as added by section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020) and subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020)), to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19. We established several flexibilities to accommodate these

changes in the delivery of care. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as the restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for COVID–19.[1] We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. In the March 31st COVID–19 IFC, we added 89 services to the Medicare telehealth services list on an interim basis. Through the ''Medicare and Medicaid Programs; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (IFC), (which was issued on May 1, 2020, and was effective upon publication in the May 8, 2020 **Federal Register** (85 FR 27550 through 27649)) (hereinafter referred to as the ''May 8th COVID–19 IFC''), on an interim basis for the duration of the PHE for COVID–19, we removed the requirement in our regulations that we undertake rulemaking to add or delete services on the Medicare telehealth services list so that we could consider the addition of services on a subregulatory basis as they were recommended by the public or identified internally. On a subregulatory basis, we simultaneously added 46 more services to the Medicare telehealth services list on an interim basis when we issued the May 8th COVID–19 IFC. Finally, on October 14, 2020 we added 11 more services to the Medicare telehealth list on a subregulatory basis. For a full list of Medicare telehealth services please see the CMS website: *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes*.

At the conclusion of the PHE for COVID–19, these waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the Act, and we will return to the policies established through the regular notice and comment rulemaking process, including the previously established Medicare telehealth services list, as modified by subsequent changes in policies and additions to the telehealth services list adopted through rulemaking, including in this final rule. We believe that the experiences of clinicians who are furnishing telehealth services during the PHE for COVID–19 will be useful to inform decisions about which of the services we added temporarily to the Medicare telehealth services list might be appropriate to add on a permanent basis. However, we also recognize that the annual PFS rulemaking schedule may not align perfectly with the expiration of the PHE for COVID–19, and that the clinicians providing services via telehealth during the PHE may not have the opportunity to conduct the kinds of review or develop the kind of evidence we usually consider when adding services to the Medicare telehealth services list on a permanent basis. In the event that the PHE for COVID–19 ends prior to the end of CY 2021, stakeholders might not have the opportunity to use our current consideration process for telehealth services to request permanent additions to the Medicare telehealth services list prior to those services being removed from the Medicare telehealth services list. This is especially true for those services that might need to be considered on a Category 2 basis, which involves providing supporting documentation to illustrate the clinical benefit of such services. Recognizing the extent to which practice patterns are shifting as a result of the PHE for COVID–19 from a model of care based on in-person services to one that relies on a combination of in-person services and virtual care, we noted that we believe that it would be disruptive to both clinical practice and beneficiary access to abruptly eliminate Medicare payment for these services when furnished via telehealth as soon as the PHE for COVID–19 ends without first providing an opportunity to use information developed during the PHE to support requests for permanent changes to the Medicare telehealth services list.

As previously noted, in response to the PHE for COVID–19, we added a broad range of services to the Medicare telehealth services list. Before eliminating the full range of these services from the Medicare telehealth services list and potentially jeopardizing beneficiary access to those services that have been clinically beneficial, based primarily on the timing of annual rulemaking, we noted that we believe it would be prudent to collect information from the public regarding which, where, and how various telehealth services have been in use in various communities during the COVID–19 response. Feedback from patients and clinicians is essential to helping CMS understand how the use of telehealth services may have contributed positively to, or negatively affected, the quality of care provided to beneficiaries during the PHE for COVID–19, enabling us to better determine which services should be retained on the Medicare telehealth services list until we can give them full consideration under our established rulemaking process.

Therefore, we proposed to create a third category of criteria for adding services to the Medicare telehealth services list on a temporary basis. This new category would describe services that would be included on the Medicare telehealth services list on a temporary basis. We would include in this category the services that were added during the PHE for COVID–19 for which there is likely to be clinical benefit when furnished via telehealth, but for which there is not yet sufficient evidence available to consider the services as permanent additions under Category 1 or Category 2 criteria. Recognizing that the services we would add on a temporary basis under Category 3 would ultimately need to meet the criteria under categories 1 or 2 in order to be permanently added to the Medicare telehealth services list, and the potential for evidence development that could continue through the Category 3 temporary addition period, we considered each of the services we added on an interim final basis during the PHE for COVID–19.

In developing the proposal to add specific services on a Category 3 basis, we conducted a clinical assessment to identify those services for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth outside the circumstances of the PHE for COVID–19 and that we anticipate would be able to demonstrate that clinical benefit in such a way as to meet our Category 2 criteria in full. Any service added under the proposed Category 3 would remain on the Medicare telehealth services list through the calendar year in which the PHE for COVID–19 ends. When assessing whether there was a potential likelihood of clinical benefit for a service such that it should be added to the Medicare telehealth services list on a Category 3 basis, we considered the following factors:

- Whether, outside of the circumstances of the PHE for COVID–19, there are increased concerns for patient safety if the service is furnished as a telehealth service.
- Whether, outside of the circumstances of the PHE for COVID–19, there are concerns about whether the provision of the service via telehealth is likely to jeopardize quality of care.

[1] *https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.*

• Whether all elements of the service could fully and effectively be performed by a remotely located clinician using two-way, audio/video telecommunications technology.

We recognized that the circumstances of the PHE for COVID–19 have provided clinicians with the opportunity to use telecommunications technology in health care delivery in a scope and manner far surpassing the telehealth services described under section 1834(m) of the Act, particularly as a result of the removal of geographic and site of service restrictions, and the addition of many services to the Medicare telehealth services list. When adding services to the Medicare telehealth services list on an interim basis during the PHE for COVID–19, we reassessed services on a Category 2 basis in the context of the widespread presence of COVID–19 in the community. We recognized that healthcare access issues could arise due to the immediate potential exposure risks to patients and healthcare workers, and that the use of telecommunication technology could mitigate risk and facilitate clinically appropriate treatment. In the context of the PHE for COVID–19. We found that all of the added services met the Category 2 criteria on the basis that there is a patient population who would otherwise not have access to clinically appropriate care (85 FR 19234). While the interim addition of a broad swath of services to the Medicare telehealth services list is responsive to critical needs during the PHE for COVID–19, the impact of adding these services to the Medicare telehealth services list on a permanent basis is currently unknown. Specifically, although it is possible to assess the uptake among health care practitioners of the added telehealth services, the extent to which service delivery via telehealth demonstrates clinical benefit outside the conditions of the PHE for COVID–19 is not known. Adding services to the Medicare telehealth services list on a Category 3 basis will give the public the opportunity to gather data and generate requests to add certain services to the Medicare telehealth services list permanently, which would be adjudicated on a Category 1 or Category 2 basis during future PFS annual rulemaking, while maintaining access to telehealth services with potential likelihood of clinical benefit. We proposed that the Category 3 criteria and the basis for considering additions to the Medicare telehealth services list would be temporary, to expire at the end of the calendar year in which the PHE for COVID–19 expires.

We identified a number of services that we believe, based on our clinical assessment, fit the Category 3 criteria enumerated above in that we did not identify significant concerns over patient safety, quality of care, or the ability of clinicians to provide all elements of the service remotely if these services were to remain on the Medicare telehealth services list for an additional period beyond the PHE for COVID–19. Therefore, we proposed to continue including the services listed in Table 13 on the Medicare telehealth services list through the calendar year in which the PHE for COVID–19 ends. We solicited public comment on the services we identified for temporary addition to the Medicare telehealth services list through the Category 3 criteria, including whether some should not be considered as Category 3 temporary additions to the Medicare telehealth services list, or whether services currently not proposed as Category 3 additions to the Medicare telehealth services list should be considered as such. We noted that while our clinical assessment indicated that the services in Table 13 demonstrate potential likelihood of clinical benefit when furnished as telehealth services and, as such, the potential to meet the Category 1 or Category 2 criteria for permanent addition to the Medicare telehealth services list with the development of additional evidence, we solicited information from the public that would supplement our clinical assessment and assist us in consideration of our proposals regarding the Category 3 addition of services, even though we recognize that formal analyses may not yet be available. The following are examples of the types of information we sought from the public to help inform our decisions about proposed additions under Category 3:

• By whom and for whom are the services being delivered via telehealth during the PHE;

• What practical safeguards are being employed to maintain safety and clinical effectiveness of services delivered via telehealth; and how are practices quickly and efficiently transitioning patients from telehealth to in-person care as needed;

• What specific health outcomes data are being or are capable of being gathered to demonstrate clinical benefit;

• How is technology being used to facilitate the acquisition of clinical information that would otherwise be obtained by a hands-on physical examination if the service was furnished in person. Certain services on the Medicare telehealth services list prior to the PHE, specifically the O/O E/M code set, involve a physical exam. With the telehealth expansions during the PHE, clinicians may have had valuable experience providing other telehealth services to patients in higher acuity settings of care, such as an emergency department, that involve a hands-on physical examination when furnished in person.

• Whether patient outcomes are improved by the addition of one or more services to the Medicare telehealth services list, including whether inclusion on the Medicare telehealth services list increases access, safety, patient satisfaction, and overall quality of care;

• Whether furnishing this service or services via telecommunication technology promotes prudent use of resources;

• Whether the permanent addition of specific, individual services or categories of services to the Medicare telehealth services list supports quick responses to the spread of infectious disease or other emergent circumstances that may require widespread use of telehealth; and

• What is the impact on the health care workforce of the inclusion of one or more services or categories of services on the Medicare telehealth services list (for example, whether the health care workforce and its capabilities to provide care are expanded).

In addition, we noted that CMS is committed to the following broad goals, and these weigh heavily in our decision-making around the addition, whether temporary or permanent, of a service or services to the Medicare telehealth services list. We requested that commenters consider these goals in conjunction with their comments on the proposals for the treatment of the telehealth services we added on an interim basis during the PHE for COVID–19:

• Maintaining the capacity to enable rapid assessment of patterns of care, safety, and outcomes in the Medicare, Medicaid, CHIP, and Marketplace populations;

• Establishing system safeguards to detect and avert unintended patient harms that result from policy adjustments;

• Ensuring high quality care is maintained;

• Demonstrating ongoing quality improvement efforts by Medicare participating providers, while maintaining access to necessary care;

• Establishing protections for vulnerable beneficiary populations (those with multiple chronic conditions, functional limitations, heart failure,

COPD, diabetes, dementia), and sites of heightened vulnerability (such as nursing homes, rural communities) with high risk of adverse outcomes;

- Ensuring appropriate resource utilization and supporting cost efficiency;
- Supporting emergency preparedness and maintaining capacity to surge for potential coronavirus resurgence or other healthcare issues; and
- Considering timing and pace of policy corrections in light of local and regional variations in systems of care and the impact of the PHE for COVID–19.

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TABLE 13: Services Proposed for Temporary Addition to the Medicare Telehealth Services List

Service Type	HCPCS	Long Descriptor
Domiciliary, Rest Home, or Custodial Care services, Established patients	99336	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.
	99337	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.
Home Visits, Established Patient	99349	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
	99350	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.
Emergency Department Visits	99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.
	99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.
	99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.
Nursing facilities discharge day management	99315	Nursing facility discharge day management; 30 minutes or less
	99316	Nursing facility discharge day management; more than 30 minutes

Service Type	HCPCS	Long Descriptor
Psychological and Neuropsychological Testing	96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)

TABLE 14: Final Services for Temporary Addition to the Medicare Telehealth Services List

Service Type	HCPCS	Long Descriptor
End-Stage Renal Disease Monthly Capitation Payment Services	90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
	90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
	90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
	90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
	90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month
Emergency Department Visits	99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.
	99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care

Service Type	HCPCS	Long Descriptor
		professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.
	99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.
	99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.
	99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.
Domiciliary, Rest Home, or Custodial Care services, Established patients	99336	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.
	99337	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.
Home Visits, Established Patient	99349	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
	99350	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.

Service Type	HCPCS	Long Descriptor
Nursing facilities discharge day management	99315	Nursing facility discharge day management; 30 minutes or less
	99316	Nursing facility discharge day management; more than 30 minutes
Psychological and Neuropsychological Testing	96121	Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)
	96130	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96131	Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96132	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour
	96133	Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)
	96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes
	96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
	96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
	96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
Therapy Services, Physical and Occupational Therapy, All levels	97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures

Service Type	HCPCS	Long Descriptor
		addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
	97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
	97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
	97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.
	97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
	97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility

Service Type	HCPCS	Long Descriptor
	97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
	97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
	97535	Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
	97750	Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes
	97755	Assistive technology assessment (eg, to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
	97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
	97761	Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes
	92521	Evaluation of speech fluency (eg, stuttering, cluttering)
	92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);
	92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)
	92524	Behavioral and qualitative analysis of voice and resonance
	92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
Subsequent Observation and Observation Discharge Day Management	99217	Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital "observation status" if the discharge is on other than the initial date of "observation status." To report services to a patient designated as "observation status" or "inpatient status" and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234-99236 as appropriate.])
	99224	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; Problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99225	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99226	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication

Service Type	HCPCS	Long Descriptor
		or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.
Initial hospital care and hospital discharge day management	99221	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99222	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99223	Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.
	99238	Hospital discharge day management; 30 minutes or less
	99239	Hospital discharge day management; more than 30 minutes
Critical Care Services	99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes
	99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)
Inpatient Neonatal and Pediatric Critical Care, Subsequent	99469	Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger
	99472	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age
	99476	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age
Continuing Neonatal Intensive Care Services	99478	Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams)
	99479	Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams)
	99480	Subsequent intensive care, per day, for the evaluation and management of the recovering infant (present body weight of 2501-5000 grams)

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We received public comments on the proposed temporary addition of a category 3 basis for adding to or deleting services from the Medicare telehealth services list. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to use a third, temporary category of criteria for adding services to the Medicare telehealth list on a provisional basis. Commenters agreed that keeping certain services added on an interim basis during the PHE for COVID–19 on the Medicare telehealth list on a temporary basis after the end of the PHE will give the medical community time to gather much needed data on services in this category to support Category 2 requests through the regular process for considering additions to the telehealth services list, while maintaining beneficiary access and allowing practitioners to transition back to models of care focused primarily on in-person, rather than virtual, services. The majority of commenters also supported adding the services CMS proposed to add to the Medicare telehealth list on a Category 3 basis.

Response: We appreciate commenters' support for these proposals.

Comment: Most commenters supported the proposed timeframe for services added on a Category 3 basis to remain on the Medicare telehealth list; however, a few commenters stated that adding services to the Medicare telehealth list on a temporary basis would create unnecessary burden for clinicians who are attempting to both treat patients in the midst of a pandemic and develop an evidence base to

support adding these services to the Medicare telehealth list permanently. In addition, by stipulating that certain codes would remain on the list through the year in which the PHE ends, commenters suggested that CMS was creating ambiguity as to when services added to the list on a Category 3 basis would expire. The commenters stated that this would be an impediment to investing in the infrastructure necessary to furnish these services. Some commenters requested that CMS fund the studies necessary to demonstrate whether a given service should be added permanently to the Medicare telehealth list, or at least articulate clear standards CMS would use to assess efficacy.

Response: While we understand commenters' concerns that adding services temporarily to the Medicare telehealth list without a fixed end date would create ambiguity that could serve as a disincentive to providing the services as telehealth services, we would note that the PHE for COVID–19 has now been extended into CY 2021.[2] The extension of the PHE into CY 2021 ensures that clinicians will have at least the entirety of 2021 to collect evidence to support a request to add these services permanently to the Medicare telehealth list.

Comment: Some commenters also expressed concern with the timeframe for which services added on a Category 3 basis will be on the Medicare telehealth list after the conclusion of the PHE. Some commenters suggested alternative timeframes, ranging between 90 days and 2 years after the end of the PHE. Some commenters suggested that CMS should specify a year in which the category 3 additions to the telehealth list will expire, such as 2022.

Response: As stated above, the PHE for COVID–19 has been extended into CY 2021, allowing for services added to the Medicare telehealth list on a Category 3 basis to remain there for at least the entirety of 2021. Any potential extension of this timeframe would be proposed in future rulemaking.

After considering the public comments, we are finalizing the additions in Table 14 to the telehealth list on a Category 3 basis through the later of the end of the year in which the PHE ends or December 31, 2021, as proposed.

[2] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx.*

d. Comment Solicitation on Medicare Telehealth Services Added on an Interim Basis During the PHE for COVID–19 That CMS Did Not Propose To Retain After the PHE Ends

In the March 31st COVID–19 IFC and the May 8th COVID–19 IFC, we finalized on an interim basis during the PHE for COVID–19 the addition of a number of services to the Medicare telehealth services list. While a number of these services were previously requested by external stakeholders and reviewed for addition as part of our standard process for updating the Medicare telehealth services list, a few were identified through internal review. As discussed above, we conducted a clinical assessment of each of the services added on an interim basis during the PHE for COVID–19 to the Medicare telehealth services list to identify those for which we could foresee a reasonable potential likelihood of clinical benefit when furnished via telehealth outside the circumstances of the PHE for COVID–19. In our clinical review of these services, we did not identify sufficient information to suggest there is a potential likelihood of clinical benefit for the services described below such that they could meet the Category 1 or Category 2 criteria outside the circumstances of the PHE for COVID–19. We specifically considered the potential for these services to be furnished, outside the circumstances of the PHE for COVID–19, without increased concerns for patient safety or jeopardizing quality of care; and furnished fully and effectively, including all elements of the service, by a remotely located clinician via two-way, audio/video telecommunications technology. After assessing these factors, we did not find a potential likelihood that the services could meet Category 2 criteria even with development of additional evidence. As such, we proposed not to extend them on the Medicare telehealth services list beyond the end of the PHE for COVID–19. However, we solicited public comment on whether any service added to the Medicare telehealth services list on an interim basis for the duration of the PHE for COVID–19 should be added to the Medicare telehealth services list on a temporary, Category 3 basis, based on the criteria outlined above. We welcomed additional information from commenters about these services.

We also sought comment on the following considerations associated with particular services. We noted that comments on these specific concerns would inform our final decisions on whether these services should be added to the Medicare telehealth services list on a temporary, Category 3 basis:

- *Initial and final/discharge interactions (CPT codes 99234–99236 and 99238–99239):* We noted that we believe that the potential acuity of the patient described by these codes would require an in-person physical exam in order to fulfill the requirements of the service. We expressed concerns that, without an in-person physical examination, the need for the physician or health care provider to fully understand the health status of the person with whom they are establishing a clinical relationship would be compromised. We noted that we believe the need for an in-person interaction would rise beyond any specific diagnosis, and serves as the foundation upon which any and all clinical decisions are based for these services. We noted that, without an in-person interaction, care planning that includes risk-benefit considerations and clinical decision-making will be less well-informed and create risk of patient harm.
- *Higher level emergency department visits (CPT codes 99284–99285):* We expressed concern that the full scope of service elements of these codes cannot be met via two-way, audio/video telecommunications technology as higher levels are indicated by patient characteristics, clinical complexity, urgency for care, and require complex decision-making. We also noted that we believe, due to the acuity of the patient described by these codes, that an in-person physical examination is necessary to fulfill the service requirements.
- *Hospital, Intensive Care Unit, Emergency care, Observation stays (CPT codes 99217–99220; 99221–99226; 99484–99485, 99468–99472, 99475–99476, and 99477–99480):* These codes describe visits that are furnished to patients who are ill enough to require hospital evaluation and care. We noted that we believe that the codes describe an evaluation for these potentially high acuity patients that is comprehensive and includes an in-person physical examination. Our view that in-person care is necessary to fulfill the requirements of the code is driven by the need for the physician or health provider to fully understand the health status of the person with whom they are establishing a clinical and therapeutic relationship. We also noted that we believe that the need for an in-person interaction would rise above any specific diagnosis, and serves as the foundation upon which any and all clinical decisions are based for these services. We noted that, without an in-

person interaction, care planning that includes risk-benefit considerations and clinical decision-making would be less well-informed and create risk of patient harm. With regard to the physical therapy, occupational therapy, and speech-language pathology services in Table 13, we have received a number of requests that we add therapy services to the Medicare telehealth services list. In the CY 2017 PFS final rule, we noted that section 1834(m)(4)(E) of the Act specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C) of the Act. Physical therapists (PTs), occupational therapists (OTs) and speech-language pathologists (SLPs) are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We stated in the CY 2017 PFS final rule (81 FR 80198) that because these services are predominantly furnished by PTs, OTs, and SLPs, we did not believe it would be appropriate to add them to the Medicare telehealth services list at that time. In a subsequent request to consider adding these services for 2018, the original requester suggested that we might propose these services to be added to the Medicare telehealth services list so that payment can be made for them when furnished via telehealth by physicians or practitioners who can serve as distant site practitioners. We stated that since the majority of the codes are furnished over 90 percent of the time by therapy professionals who are not included on the statutory list of eligible distant site practitioners, we believed that adding therapy services to the Medicare telehealth services list could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth.

In the proposed rule, we noted that we continue to believe this is generally the case, and we did not propose to add these services permanently to the Medicare telehealth services list. We solicited comment on whether these services should be added to the Medicare telehealth services list so that, in instances when a practitioner who is eligible to bill for telehealth services furnishes these services via telehealth, they could bill and receive payment for them. We also solicited comment on whether all aspects of these services can be fully and effectively furnished via two-way, audio/video telecommunications technology. We noted that given our clarification regarding telehealth services furnished incident to the professional services of a physician or practitioner (85 FR 27562), if these services were added to the Medicare telehealth services list, they could be furnished by a therapist and billed by a physician or practitioner who can furnish and bill for telehealth services provided that all of the ''incident to'' requirements are met.

Comment: Commenters expressed concern that we did not propose to add the vast majority of the interim PHE telehealth services to the telehealth list on a Category 3 basis. Commenters stated that, by limiting the availability of these interim PHE telehealth services to the duration of the PHE, CMS would jeopardize access to care for beneficiaries who have come to rely on the provision of these services virtually, and would disrupt practice patterns for those clinicians who were accustomed to furnishing a broader array of telehealth services than included in the proposed permanent and temporary Category 3 additions to the Medicare telehealth list.

Response: We appreciate commenters' concerns. In response, we are finalizing the addition of a broader array of services to the Medicare telehealth list on a Category 3 basis, as described below.

Comment: Many commenters requested that CMS add specific interim PHE telehealth services that we did not propose to the Medicare telehealth list on a Category 3 basis. Most commenters did not provide sufficient (or in some cases, any) evidence to support their requests to be considered under Category 3 criteria. Other commenters did provide additional evidence sufficient to consider certain services on a Category 3 basis. Table 15 includes the complete list of services commenters requested for addition to the CMS Medicare telehealth list on a Category 3 basis.

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TABLE 15: All Category 3 Requests

Code	Long Descriptor
77427	Radiation treatment management, 5 treatments
90952	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month
90953	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month
92521	Evaluation of speech fluency (e.g., stuttering, cluttering)
92522	Evaluation of speech sound production (e.g., articulation, phonological process, apraxia, dysarthria);
92523	Evaluation of speech sound production (e.g., articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (e.g., receptive and expressive language)
92524	Behavioral and qualitative analysis of voice and resonance
92526	Treatment of swallowing dysfunction and/or oral function for feeding
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming
93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording.
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
96112	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; first hour
96113	Developmental test administration (including assessment of fine and/or gross motor, language, cognitive level, social, memory and/or executive functions by standardized developmental instruments when performed), by physician or other qualified health care professional, with interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)
96136	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes

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96137	Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
96138	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes
96139	Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97116	Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)
97151	Behavior identification assessment, administered by a physician or other qualified health care professional, each 15 minutes of the physician's or other qualified health care professional's time face-to-face with patient and/or guardian(s)/caregiver(s) administering assessments and discussing findings and recommendations, and non-face-to-face analyzing past data, scoring/interpreting the assessment, and preparing the report/treatment plan
97152	Behavior identification-supporting assessment, administered by one technician under the direction of a physician or other qualified health care professional, face-to-face with the patient, each 15 minutes
97153	Adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with one patient, each 15 minutes
97154	Group adaptive behavior treatment by protocol, administered by technician under the direction of a physician or other qualified health care professional, face-to-face with two or more patients, each 15 minutes
97155	Adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, which may include simultaneous direction of technician, face-to-face with one patient, each 15 minutes
97156	Family adaptive behavior treatment guidance, administered by physician or other qualified health care professional (with or without the patient present), face-to-face with guardian(s)/caregiver(s), each 15 minutes
97157	Multiple-family group adaptive behavior treatment guidance, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of guardians/caregivers, each 15 minutes
97158	Group adaptive behavior treatment with protocol modification, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.
97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An

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	examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.
97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.
97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (i.e., relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (e.g., physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes

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97755	Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
97761	Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes
99217	Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital "observation status" if the discharge is on other than the initial date of "observation status." To report services to a patient designated as "observation status" or "inpatient status" and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234-99236 as appropriate.])
99224	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; Problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.
99225	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.
99226	Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.
99234	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit.
99235	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.
99236	Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high

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	complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit.
99238	Hospital discharge day management; 30 minutes or less
99239	Hospital discharge day management; more than 30 minutes
99281	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.
99282	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.
99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.
99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.
99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.
99291	Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes
99292	Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)
99324	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent with the patient and/or family or caregiver.
99325	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or

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	family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent with the patient and/or family or caregiver.
99326	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent with the patient and/or family or caregiver.
99327	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.
99328	Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/or family or caregiver.
99336	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.
99337	Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.
99341	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.
99342	Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.
99343	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of

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	moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.
99344	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.
99345	Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.
99349	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.
99350	Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.
99468	Supervision by a control physician of interfacility transport care of the critically ill or critically injured pediatric patient, 24 months of age or younger, includes two-way communication with transport team before transport, at the referring facility and during the transport, including data interpretation and report; each additional 30 minutes (List separately in addition to code for primary procedure)
99469	Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger
99472	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99474	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99476	Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age
99478	Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams)
99479	Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams)
99480	Subsequent intensive care, per day, for the evaluation and management of the recovering infant (present body weight of 2501-5000 grams)
G0422	Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session
G0423	Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session
G0424	Pulmonary rehabilitation, including exercise (includes monitoring), one hour, per session, up to two sessions per day

BILLING CODE 4120–01–C

The following is a summary of these comments and our responses.

Comment: Some commenters requested that we consider adding

initial nursing facility visits, which are currently interim PHE telehealth services, to the telehealth list on a Category 3 basis. Commenters did provide information regarding how telehealth is used in long-term care facilities; however, they did not provide information indicating how the full scope of service elements of an initial nursing facility visit could be furnished via two-way, audio/telecommunications technology.

Response: We continue to believe that there are components of the initial visit, such as the physical exam, that in the vast majority of circumstances can only be properly performed in person given the vulnerability and frailty of this particular patient population. Commenters did not provide evidence to indicate otherwise. We note that patients in a nursing facility may still receive subsequent visits as telehealth services; however, we are not persuaded that these services, in general, could be furnished via telehealth as described by the CPT codes based upon information provided by commenters.

Comment: Many commenters requested that we add physical therapy, occupational therapy, and speech language pathology services to the Medicare telehealth list on a category 3 basis. Commenters provided extensive information on how they furnish these services via two-way, audio/video telecommunications technology. In response to CMS's longstanding concerns that the practitioners who furnish and bill for the overwhelming majority of these services are, outside of the circumstances of the PHE for COVID–19, not among the statutorily authorized practitioners who may independently bill Medicare for telehealth services, commenters pointed to our proposed clarification that telehealth services could be furnished by a therapist incident to the professional services of a billing clinician in accordance with our regulations at § 410.26.

Response: We appreciate the additional information commenters provided suggesting a possible scenario whereby services furnished by therapists may be provided and billed incident to the professional services of a physician or practitioner who is authorized to furnish and bill for telehealth services. While we continue to have concerns as to whether certain elements of therapy services, particularly when provided to new patients, could be furnished in total via two-way, audio/video telecommunications technology, we recognize that the clarification of billing requirements for these services may allow for additional information to be collected and submitted for consideration by CMS. We are therefore finalizing addition of these services to the Medicare telehealth list on a Category 3 basis.

Comment: Some commenters requested that we add several audiology services to the Medicare telehealth list on a Category 3 basis. These codes are currently interim PHE telehealth services. Commenters explained that including CPT codes for device evaluation and therapeutic services with a device is necessary to support access for patients in needs of these assistive technologies, and that not including them would inhibit the ability of speech language pathologists to perform the evaluation and therapeutic services via telehealth.

Response: We note that, outside of the circumstances of the PHE, speech language pathologists are not eligible to independently bill for Medicare telehealth services, although these services could possibly be furnished by a therapist incident to an eligible billing practitioner. Furthermore, we do not agree that the information provided by commenters demonstrates that, under most circumstances, these services can be furnished, in full, via two-way audio/video communication technology given that these codes describe a new patient interaction which would likely require hands-on, clinical assessment and direct, one-on-one interaction/observation.

Comment: Some commenters requested that we add ESRD MCP services with 1 monthly visit to the Medicare telehealth list on a Category 3 basis. Commenters cited information that they say demonstrates that retaining the ESRD-specific telehealth flexibilities post-pandemic would be valuable to both patients and health care providers and would pose no material detriments to patient safety or quality of care. Commenters further offered that technology exists that would enable physicians and other practitioners to deliver effective ESRD care on a virtual basis beyond the PHE for COVID–19. Additionally, commenters noted that it may take time for medically complex and vulnerable patients to travel for in-person care, and that determining when a patient should return to a physician's office should be left to the patient and the physician.

Response: We did not propose to add these services to the Medicare telehealth list on a Category 3 basis due to concerns regarding the patient receiving an adequate physical examination of the vascular access site and in-person evaluation of the patient's fluid status when a patient is only receiving 1 visit per month. We appreciate the additional information provided by commenters, particularly the information on how ESRD services are furnished using audio/video technology outside of the circumstances of the PHE for COVID–19. Based upon this information, we are finalizing the addition of the ESRD MCP services with a single face-to-face visit per month to the Medicare telehealth list on a Category 3 basis. We would note that, during the PHE for the COVID–19 pandemic, section 3705 of the CARES Act allowed for a waiver of the statutory provision in section 1881(b)(3)(B)(ii) of the Act, which requires that an individual determined to have ESRD receiving home dialysis must receive certain face-to-face clinical assessments without the use of telehealth. Therefore, outside of the PHE for COVID–19, for beneficiaries receiving home dialysis services, a face-to-face ESRD-related clinical assessment must be provided in person (without the use of telehealth) for the first 3 months of home dialysis, and once every 3 months thereafter.

Comment: Some commenters requested that we add hospital observation and discharge day management services to the Medicare telehealth list on a Category 3 basis. Commenters cited information that they believe demonstrates that telehealth services in the emergency setting have proven to be successful and add clinical benefit to patients, and that they should be added on a Category 3 basis, if not permanently. Commenters stated that furnishing these services as telehealth services can be helpful or even essential to enable patients to receive high-quality specialty care in isolated rural communities, communities affected by natural disasters, communities affected by local disease outbreaks, and similar situations. Commenters also requested that we add critical care services and established patient neonatal critical care services to the Medicare telehealth list on a Category 3 basis, stating that there are certain situations where it is appropriate to provide higher level and critical care to patients via telehealth. Commenters further offered that the clinical value of telehealth is particularly clear for patients being treated in rural EDs or at rural hospitals where effective telehealth collaboration for high-level cases could facilitate clinical collaboration and decrease unnecessary transfers. Commenters stated that there is a shortage of rural board-certified emergency physicians, and that, if shortages of these physicians continue, more critical care services

may need to be delivered via telehealth over time to ensure that patients receive timely and necessary care. Finally, we received requests to add level four and five emergency department visits to the Medicare telehealth list on a Category 3 basis.

All of these requests were accompanied by robust supporting evidence including information on teleICU and tele-stroke models of care. Commenters also submitted clinical studies pointing to the efficacy of telehealth in more acute care settings.

Response: We are responding to the comments on these codes together because they are all E/M services that are furnished in a hospital or ED setting. We did not propose to add these services to the Medicare telehealth list on a Category 3 basis due to the presumption that in-person assessment and care, particularly an in-person physical exam, was necessary for patients at this level of acuity. Based upon a review of the information provided by commenters, which included information on how distant site practitioners could collaborate with individuals at the originating site (which, outside of the circumstances of the PHE, must be a medical facility) to obtain an accurate and comprehensive evaluation of the patient, we agree that telehealth in the acute settings described by these codes could offer an excellent opportunity for care to patients if both the distant site and originating site facilities/teams have the appropriate infrastructure, technology, and training to effectively conduct such visits via telehealth. We continue to believe that in most instances, in order to fulfill the full scope of service elements described by codes for new patients, an in-person physical exam is necessary; however, we agree that, for services provided to established patients, such as established patient observation services and established patient neonatal critical care, and for emergency department visits and critical care services (the latter of which is being used extensively during the PHE to support surge capacity), more data are needed to understand how these E/M code families are being used in the field and whether their addition to the telehealth services list ultimately could be supported on a Category 2 basis. Therefore, we are finalizing the addition of established patient observation services and established patient neonatal critical care services to the Medicare telehealth list on a Category 3 basis. We are also finalizing the addition of critical care services to the Medicare telehealth list on a Category 3 basis.

Comment: Some commenters requested that we add electronic device management and treatment services to the Medicare telehealth list on a Category 3 basis, stating that safeguards are being developed to deliver safe and effective remote management of neuromodulation technologies during the PHE and beyond. The commenter suggested rationale for monitoring the provision of these services through use of these codes to ensure improved outcomes.

Response: While we appreciate the additional information as to the safeguards being developed to ensure safe access to these services and the information on improved outcomes, it was not clear whether the capability for clinicians to remotely connect to a patient's hand-held device for the purposes of electronic assessment and analysis is widely available. It is also not within CMS's mandate under the PFS to ensure improved outcomes. Therefore, we remain unconvinced by the evidence provided by the commenter that these services can, in most instances, be conducted in full using two-way, audio/video communication technology. We were also uncertain as to which of these services involve a direct, clinical interaction between the patient and practitioner such that, if the service is furnished as a telehealth service, the interaction would be facilitated by audio/video technology; and those that do not involve such an interaction. To the extent these services do not involve a direct, clinical interaction between the patient and practitioner facilitated by audio/video technology, the services would not be subject to the statutory requirements for telehealth services under section 1834(m) of the Act, and there would be no need to consider adding them to the telehealth services list.

Comment: Most commenters supported CMS not adding CPT code 77427 (*Radiation treatment management, 5 treatments*) to the Medicare telehealth list on a Category 3 basis. These commenters stated that, given that most radiation oncology practices have been able to secure adequate PPE, it was no longer necessary for radiation treatment management to be available as a telehealth service. A few commenters disagreed, but did not provide supporting information.

Response: We did not propose to add this service to the Medicare telehealth list on a Category 3 basis due to concerns over whether the full service elements described by CPT code 77427 could, in most cases, be furnished in full via two way, audio-video communication technology. We continue to believe this is the case and appreciate the additional information provided by commenters as to the necessity of adding this service to the Medicare telehealth list on a Category 3 basis.

After considering the public comments, we are finalizing the addition of services to the Medicare telehealth list on a Category 3 basis as explained above and detailed in Table 16.

2. Analysis and Response to the Comment Solicitation on Coding and Payment for Tele-ICU

With regard to the critical care services listed in A–D 5 we have received a number of requests in prior years to add these services to the Medicare telehealth services list. In response to one such request, we finalized creation of two HCPCS G codes, G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth*) and G0509 *(Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*), to describe the work associated with furnishing consultation services via Medicare telehealth to critically ill patients in the CY 2017 PFS final rule (81 FR 80196 through 80197). We stated that CPT guidance makes clear that a variety of other services are bundled into the payment rates for critical care, including gastric intubations and vascular access procedures, among others. While we are adding critical care services to the Medicare telehealth list temporarily, on a Category 3 basis, we also solicited comment on whether current coding (either through the CPT codes describing in-person critical care or the HCPCS G codes describing critical care consults furnished via telehealth) does not reflect additional models of critical care delivery, specifically, models of care delivery that utilize a combination of remote monitoring and clinical staff at the location of the beneficiary to allow, when an onsite practitioner is not available, for a practitioner at a distant site to monitor vital signs and direct in-person care as needed.

We sought comment on the definition, potential coding and valuation for this kind of remote service. Specifically, we sought comment on the following concerns:

- How to distinguish the technical component of the remote monitoring portion of the service from the

diagnosis-related group (DRG) payment already being provided to the hospital.

- How to provide payment only for monitoring and interventions furnished to Medicare beneficiaries when the remote intensivist is monitoring multiple patients, some of which may not be Medicare beneficiaries.
- How this service intersects with both the critical care consult G codes and the in-person critical care services.

Comment: One commenter stated that, generally, there are two models of remote critical care services; the first of which is more of a telehealth consultant. Services performed under this scenario may be accurately reported via existing critical care consult G codes. The other model of care includes physicians providing tele-ICU services, which may be enhanced through the use of robotic technology or other methods to complete a remote clinical assessment of the critically ill patient. Commenters stated current critical care consult G-codes may be used for an episodic evaluation and recommendation to the bedside team or may be used for episodic telemedicine consults and do not reflect current models of care. One commenter noted the tele-ICU is involved both before and after the bedside intensivist or physician arrives and leaves the bedside. Several commenters also stated that current CPT and HCPCS coding does not adequately reflect the additional component of monitoring, surveillance, coaching of bedside nurses, physicians who are not intensivists, and active management in real-time and over extended timeframes by tele-ICU Intensivists. Many commenters encouraged CMS to adopt a coding proposal currently under consideration by the CPT editorial panel and the AMA RUC.

Response: We appreciate the feedback regarding the different tele-ICU models. As noted by commenters, the AMA is currently engaged in evaluating coding and valuation for services similar to those identified by commenters. We will keep these comments in mind and look forward to evaluating any new CPT coding and AMA RUC recommendations as part of our future annual rulemaking process.

After considering the public comments, we will consider all of the feedback on the different tele-ICU models of care as well as potential gaps in coding for possible future rulemaking.

TABLE 16: Summary of CY 2021 Services Added to the Medicare Telehealth Services List

Type of Service	Specific Services and CPT Codes
1. Services we are finalizing for permanent addition as Medicare Telehealth Services	• Group Psychotherapy (CPT 90853) • Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99334-99335) • Home Visits, Established Patient (CPT 99347- 99348) • Cognitive Assessment and Care Planning Services (CPT 99483) • Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS G2211) • Prolonged Services (HCPCS G2212) • Psychological and Neuropsychological Testing (CPT 96121)
2. Services we are finalizing to remain temporarily on the Medicare telehealth list through the end of the year in which the PHE for COVID-19 ends (Category 3 services), to allow for continued development of evidence to demonstrate clinical benefit and facilitate post-PHE care transitions.	• Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99336-99337) • Home Visits, Established Patient (CPT 99349-99350) • Emergency Department Visits, Levels 1-5 (CPT 99281-99285)* • Nursing facilities discharge day management (CPT 99315-99316) • Psychological and Neuropsychological Testing (CPT 96130- 96133; CPT 96136- 96139) • Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161- 97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507)* • and Hospital discharge day management (CPT 99238- 99239)* • Inpatient Neonatal and Pediatric Critical Care, Subsequent (CPT 99469, 99472, 99476)* • Continuing Neonatal Intensive Care Services (CPT 99478- 99480)* • Critical Care Services (CPT 99291-99292)* • End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962)* • Subsequent Observation and Observation Discharge Day Management (CPT 99217; CPT 99224- 99226)*
3. Services we are not adding to the Medicare telehealth list either permanently or temporarily.	• Initial Nursing Facility Visits, All Levels (Low, Moderate, and High Complexity) (CPT 99304-99306) • Initial hospital care (CPT 99221-99223) • Radiation Treatment Management Services (CPT 77427) • Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324- 99328) • Home Visits, New Patient, all levels (CPT 99341- 99345) • Inpatient Neonatal and Pediatric Critical Care, Initial (CPT 99468, 99471, 99475, 99477) • Initial Neonatal Intensive Care Services (CPT 99477) • Initial Observation and Observation Discharge Day Management (CPT 99218 – 99220; CPT 99234- 99236) • Medical Nutrition Therapy (CPT G0271)

* Services that were not proposed as Category 3 additions to the Medicare telehealth list but are being finalized as such.

3. Technical Refinement to the Medicare Telehealth Services List To Reflect Current Coding

For CY 2020, the CPT Editorial Panel deleted the six existing Health and Behavior Assessment and Intervention procedure CPT codes and replaced them with nine new CPT codes. The six deleted CPT codes include CPT code 96150 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health oriented questionnaires), each 15 minutes face-to-face with the patient;*

initial assessment), CPT code 96151 (*Health and behavior assessment (e.g., health-focused clinical interview, behavioral observations, psychophysiological monitoring, health oriented questionnaires), each 15 minutes face-to-face with the patient; reassessment*), CPT code 96152 (*Health and behavior intervention, each 15 minutes, face-to-face; individual*), CPT code 96153 (*Health and behavior intervention, each 15 minutes, face-to-face; group (2 or more patients)*), CPT code 96154 (*Health and behavior intervention, each 15 minutes, face-to-face; family (with the patient present)*), and CPT code 96155 (*Health and behavior intervention, each 15 minutes, face-to-face; family (without the patient present)*). However, we inadvertently neglected to make the corresponding update to reflect these coding changes on the Medicare telehealth services list in CY 2020 PFS rulemaking. Therefore, we proposed to delete CPT codes 96150–96155 from the Medicare telehealth services list and replace them with the following successor codes: CPT code 96156 (*Health behavior assessment, including reassessment (i.e., health-focused clinical interview, behavioral observations, clinical decision making)*); CPT code 96158 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*); CPT code 96159 (*Health behavior intervention, individual, face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*); CPT code 96164 (*Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes*); CPT code 96165 (*Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*); CPT code 96167 (*Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes*); CPT code 96168 (*Health behavior intervention, family (with the patient present), face-to-face each additional 15 minutes (list separately in addition to code for primary service)*); CPT code 96170 (*Health behavior intervention, family (without the patient present), face-to-face; initial 30 minutes*); and CPT code 96171 (*Health behavior intervention, family (without the patient present), face-to-face; each additional 15 minutes (list separately in addition to code for primary service)*).

We also proposed to amend our regulations to stipulate that when new codes are issued to replace codes that describe the same clinical services that are currently on the Medicare telehealth services list, we would consider those new codes to be successor codes to those that are on the Medicare telehealth services list, and would update the Medicare telehealth services list accordingly. At § 410.78(f), we proposed to revise the final sentence of the paragraph to read: CMS maintains on the CMS website the Medicare telehealth services list under this section, including the current HCPCS codes that describe the services.

We received public comments on the technical refinement to the Medicare telehealth services list to reflect current coding. The following is a summary of the comments we received and our responses.

Comment: Commenters supported this proposal.

Response: We are finalizing this technical refinement as proposed.

4. Furnishing Telehealth Visits in Inpatient and Nursing Facility Settings, and Critical Care Consultations

The long term care facility regulations at § 483.30(c) require that residents of SNFs receive an initial visit from a physician, and periodic personal visits subsequently by either a physician or other NPP. In the CY 2010 PFS final rule with comment period (74 FR 61762), we stated that these regulations ensure that at least a minimal degree of personal contact between a physician or a qualified NPP and a resident is maintained, both at the point of admission to the facility and periodically during the course of the resident's stay. In that rule we stated that we believe that these federally-mandated visits should be conducted in-person, and not as Medicare telehealth services. Therefore, we revised § 410.78 to restrict physicians and practitioners from using telehealth to furnish the physician visits required under § 483.30(c).

During the PHE for COVID–19, we waived the requirement in 42 CFR 483.30 for physicians and NPPs to perform in-person required visits for nursing home residents, and allowed visits to be conducted via telehealth (*https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf*).

We solicited public comment on whether it would be appropriate to maintain this flexibility on a permanent basis outside of the PHE for COVID–19. We invited public comment on whether the in-person visit requirement is necessary, or whether two-way, audio/video telecommunications technology would be sufficient in instances when, due to continued exposure risk, workforce capacity, or other factors, the clinician determines an in-person visit is not necessary.

We also received requests to revise our frequency limitations for telehealth subsequent inpatient and nursing facility visits. We limit the provision of subsequent inpatient visits via Medicare telehealth to once every 3 days and subsequent nursing facility visits to once every 30 days. We received a request to remove the frequency limitation on the subsequent inpatient services and a separate request to revise the subsequent nursing facility visits to once every 3 days, rather than 30 days.

As we stated in the CY 2019 PFS final rule, we believed the potential acuity of illness of hospital inpatients is greater than that of patients who are likely to receive services that were on the Medicare telehealth services list at that time. We also stated that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth to ensure that hospitalized patients have sufficiently frequent encounters with their admitting practitioner. In addition, we expressed our belief that the majority of these visits should be furnished in person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis. Because of our concerns regarding the potential acuity of illness of hospital inpatients, we finalized the addition of CPT codes 99231–99233 to the Medicare telehealth services list, but limited the provision of these subsequent hospital care services through telehealth to once every 3 days. We noted that we continue to believe that admitting practitioners should continue to make appropriate in-person visits to all patients who need such care during their hospitalization. Our concerns with, and position on, the provision of subsequent hospital care services via telehealth have not changed (83 FR 59493). Therefore, we did not propose to modify the current policy.

In the CY 2018 PFS final rule, we reiterated that we believed it would be appropriate to permit some subsequent nursing facility (NF) care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, but because of our concerns regarding the potential acuity and complexity of NF inpatients, we limited the provision of subsequent NF care services furnished through telehealth to once every 30 days. We also stated that we continued to have concerns regarding more routine use of telehealth given the potential acuity and complexity of NF inpatients, and therefore, we were not proposing to

remove the frequency limitation for subsequent NF care services (83 FR 59494). We received comments from stakeholders who stated that the once every 30-day frequency limitation for subsequent NF visits furnished via Medicare telehealth limits access to care for Medicare beneficiaries in the NF setting. Stakeholders stated that the use of Medicare telehealth is crucial to maintaining a continuum of care in this setting and that CMS should leave it up to clinicians to decide how frequently a visit may be furnished as a Medicare telehealth service rather than in person depending on the needs of specific patients. We noted that we were persuaded by the comments from these stakeholders, and therefore, we proposed to revise the frequency limitation from one visit every 30 days to one visit every 3 days. We noted that we believe this interval strikes the right balance between requiring in-person visits and allowing flexibility to furnish services via telehealth when clinically appropriate to do so. We solicited comment on whether frequency limitations broadly are burdensome and limit access to necessary care when services are available only through telehealth, and how best to ensure that patients are receiving necessary in-person care.

We received public comments on furnishing telehealth visits in inpatient and nursing facility settings, and critical care consultations. The following is a summary of the comments we received and our responses.

Comment: Many commenters requested that CMS revise the long term care facility regulations at § 483.30(c), which require that residents of NFs receive an initial visit from a physician, and periodic personal visits subsequently by either a physician or other NPP, to allow the initial visit to be conducted via Medicare telehealth.

Response: As we stated in the CY 2010 PFS final rule with comment period (74 FR 61762), we continue to believe that in-person contact between a physician or a qualified NPP and a resident is needed at the point of admission to the facility to ensure the appropriate level of care.

Comment: Many commenters have stated their support for revising the frequency limitation for subsequent nursing facility visits furnished via telehealth from once every 30 days to once every 3 days, while other commenters encouraged CMS to remove frequency limitations entirely. A few commenters stated that CMS should maintain some frequency limitations so as to not to create a disincentive for in-person care.

Response: We thank all the commenters for their feedback. As discussed in the proposed rule, we have received requests to revise the frequency limitations on subsequent nursing facility visits from one every 30 days to one every 3 days to align with the frequency limitations in the inpatient setting; however, after additional consideration of the issue, we noted that patients in the nursing facility setting tend to have a longer lengths of stay compared to the patients in the inpatient setting. As such, we have further considered whether the frequency limitations for subsequent nursing facility visits furnished via telehealth should be the same as for the inpatient setting. Additionally, we acknowledge commenters' concerns about creating a disincentive for in-person care in the absence of any frequency limitations on services furnished through telehealth, and that a broader view of our frequency limitation policies across the different Part A and B care settings could potentially lead to inadequate in-person care in certain scenarios. While we appreciate that, in some cases, a subsequent nursing facility visit furnished via telehealth may allow flexibility for practitioners to appropriately treat patients, there are also situations where an in-person visit may be more appropriate. In seeking to find the right balance between providing greater access to care through more telehealth visits and ensuring adequate in-person care, especially given the longer length of stays for NF patients, we believe that one telehealth visit every 30 days may be too infrequent and once every 3 days poses a risk of creating a disincentive for in-person care. Therefore, we believe it is appropriate to revise the frequency limitation for subsequent nursing facility visits to permit one Medicare telehealth visit every 14 days. This limitation provides an appropriate balance between increased access to care through telehealth and maintaining appropriate in-person care.

After consideration of the public comments, we are finalizing a policy to allow subsequent nursing visits to be furnished via Medicare telehealth once every 14 days in the NF setting. We are not finalizing any revisions to the frequency limitations on inpatient visits or critical care consultations provided as telehealth services.

5. Proposed Technical Amendment To Remove References to Specific Technology

The final sentence of our regulation at § 410.78(a)(3) prohibits the use of telephones, facsimile machines, and electronic mail systems for purposes of furnishing Medicare telehealth services. In the March 31st COVID–19 IFC, we added a new § 410.78(a)(3)(i) (and reserved § 410.78(a)(3)(ii) for later use) to provide for an exception that removes application of that sentence during the PHE for COVID–19. We added the new section on an interim final basis because we believe that the first sentence of § 410.78(a)(3) adequately describes the technology requirements for an interactive telecommunication system that may be used to furnish a Medicare telehealth service. That sentence defines interactive telecommunication system as ''multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication.'' We noted that we were also concerned that the reference to ''telephones'' in the second sentence of the regulation as impermissible technology could cause confusion in instances where otherwise eligible equipment, such as a smart phone, may also be used as a telephone Because these concerns are not situation- or time-limited to the PHE for COVID–19, we proposed to remove the second sentence of the regulation at § 410.78(a)(3) that specified that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system. As we proposed to adopt this change on a permanent basis, we also proposed to delete the paragraphs at § 410.78(a)(3)(i) and (ii). We noted that we believe these amendments to our regulations would remove outdated references to specific types of technology and provide a clearer statement of our policy.

We received public comments on proposed technical amendment to remove references to specific technology. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to amend the regulation. One commenter cited our statement in the March 31st COVID–19 IFC that mobile computing technology colloquially referred to as ''phones'' are now ubiquitous, and the wording of the regulatory text could be construed to prevent their use for purposes of conducting a telehealth service. According to another commenter, advances in digital communication technology should not be unnecessarily excluded as communication methods for patients and clinicians to utilize for telehealth services. Commenters agreed that the reference in the current regulation creates confusion about use

of equipment such as a smart phone or even an interactive telehealth platform operating within an electronic health information system. Commenters agreed that the reference to ''telephones'' in the regulation as an impermissible technology in the final sentence of regulation at § 410.78(a)(3) has caused confusion in instances where equipment, such as smartphones, are also used as a telephone. They state that the references in these sections of the CFR are not situation- or time-limited to the PHE for COVID–19 and should be deleted.

Response: We thank commenters for their support and agree with their stated points. .

After consideration of the comments, we are finalizing this proposed technical amendment.

6. Communication Technology-Based Services (CTBS)

In the CY 2019 PFS final rule, we finalized separate payment for a number of services that could be furnished via telecommunications technology, but that are not considered Medicare telehealth services. Specifically, we finalized HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*), and HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*). We finalized maintenance of these codes as part of the set of codes that is only reportable by those practitioners that can furnish E/M services. We stated that we believed this was appropriate since the service describes a check-in directly with the billing practitioner to assess whether an office visit is needed. However, we did note that similar check-ins provided by nurses and other clinical staff can be important aspects of coordinated patient care (83 FR 59486).

In the CY 2020 PFS final rule, we finalized separate payment for HCPCS codes G2061 (*Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), G2062 (*Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and G2063 (*Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*). In that rule, we stated that these codes may be billed by NPPs consistent with the definition of their respective benefit category, although we did not provide specific examples (84 FR 62796).

We received a number of questions regarding which benefit categories HCPCS codes G2061 through G2063 fall under. In the March 31st COVID–19 IFC (85 FR 19244–19245) we established on an interim basis for the duration of the PHE for COVID–19 that these services could be billed for example, by licensed clinical social workers and clinical psychologists, as well as PTs, OTs, and SLPs who bill Medicare directly for their services when the service furnished falls within the scope of these practitioner's benefit categories. In the CY 2021 PFS proposed rule (85 FR 50112 and 50113), we proposed to adopt that policy on a permanent basis. We noted that this is not an exhaustive list and we solicited comment on other benefit categories into which these services may fall.

We also proposed to allow billing of other CTBS by certain NPPs, consistent with the scope of these practitioners' benefit categories, through the creation of two additional HCPCS G codes that can be billed by practitioners who cannot independently bill for E/M services:

- G2250 (*Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.*)
- G2251 (*Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*).

We proposed to value the services identically to HCPCS codes G2010 and G2012, respectively. We acknowledged that it has been agency policy, in general, to differentially value similar services that are performed by practitioners who can and cannot, respectively, bill independently for E/M services, with higher values for the service performed by practitioners who can independently bill E/M services. However, given the relatively low values for HCPCS codes G2010 and G2012, we noted that we did not believe that there was a significant differential in resource costs to warrant different values, but solicited comment on whether we should value these services differentially, including potentially increasing the valuation of HCPCS codes G2010 and G2012.

Further, to facilitate billing of the CTBS by rehabilitative therapists, we proposed to designate HCPCS codes G2250, G2251, G2061, G2062, and G2063 as ''sometimes therapy'' services. When billed by a private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to signify that the CTB are furnished as therapy services furnished under an OT, PT, or SLP plan of care.

We also noted that we proposed for CY 2021 to replace the eVisit G-codes with corresponding CPT codes, and that this policy would also apply to those codes.

For all of these CTBS, we also clarified that the consent from the patient to receive these services can be documented by auxiliary staff under general supervision, as well as by the billing practitioner. While we continue to believe that beneficiary consent is necessary so that the beneficiary is notified of cost sharing when receiving these services, we noted that we did not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services. We retained the requirement that, in instances when the brief CTBS originates from a related E/M service (including one furnished as a telehealth service) provided within the previous 7 days by the same physician or other qualified health care professional, this service would be considered bundled into that previous E/M service and would not be separately billable.

We received public comments on the CTBS proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to replace the eVisit G codes (G2061–G2063) with corresponding CPT codes 98970–98972 for qualified nonphysician health care professional online digital E/M service.

Response: We thank commenters for their feedback. After consideration of the comments received, we are finalizing our proposal to replace G2061–G2063 with CPT codes 98970–98972.

Comment: Many commenters were supportive of the proposal to allow NPPs, such as licensed clinical social workers, clinical psychologists, PTs, OTs, and SLPs to bill HCPCS codes G2061 through G2063, consistent with the definition of their respective benefit category.

Response: We thank the commenters for their support and feedback. After consideration of the comments received, we are finalizing our proposal to allow NPPs, such as licensed clinical social workers, clinical psychologists, PTs, OTs, and SLPs to bill HCPCS codes G2061 through G2063, consistent with the definition of their respective benefit category.

Comment: Commenters requested that CMS clarify that HCPCS codes G2061 through G2063 fell within the scope of the audiology diagnostic benefit category or the medical nutrition therapist benefit category.

Response: We disagree with the commenter. HCPCS codes G2061–G2063 describe online assessment and management while the audiology benefit is for diagnostic testing. Therefore, we believe these services fall outside the audiologists' benefit category. The benefit for medical nutrition therapists is limited by statute to a few specific services described by certain HCPCS codes, which do not include G2061–G2063.

Comment: Many commenters were supportive of the proposal to allow billing of HCPCS codes G2250 and G2251 by certain NPPs, consistent with the scope of these practitioners' benefit categories.

Response: We thank the commenters for their support and feedback. After consideration of the comments received, we are finalizing our proposal to allow billing of HCPCS codes G2250 and G2251 by certain NPPs, consistent with the scope of these practitioners' benefit categories.

Comment: Many commenters supported the proposal to identically value HCPCS codes G2250 and G2251 to G2010 and G2012, respectively.

Response: We thank commenters for their support and feedback.

Comment: One commenter disagreed with the proposal to identically value HCPCS codes G2250 and G2251 to G2010 and G2012, respectively. The commenter stated that services furnished by NPPs should not be valued the same as those provided by physicians and encouraged CMS to increase the valuation of G2010 and G2012 while not offering recommended value for G2250 and G2251.

Response: As we stated in the proposed rule, given the relatively low values for HCPCS codes G2010 and G2012, we do not believe that there is a significant differential in resource costs to warrant differential values for codes G2250 and G2251, and codes G2010 and G2012.

After consideration of the comments, we are finalizing our proposal to identically value HCPCS codes G2250 and G2251 to G2010 and G2012, respectively.

Comment: Several commenters urged CMS to consider increasing the value of G2010 and G2012.

Response: We thank commenters for their feedback and will consider this matter and propose any potential changes through future rulemaking.

Comment: Many commenters supported the proposal to designate HCPCS codes G2250, G2251, G2061, G2062, and G2063 as ''sometimes therapy'' services to facilitate billing of these CTBS by therapists. Including when billed by a private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to signify that the CTB are furnished as therapy services furnished under an OT, PT, or SLP plan of care.

Response: We thank the commenters for their support and feedback. After consideration of the comments received, we are finalizing our proposal to designate HCPCS codes G2250, G2251, G2061, G2062, and G2063 as ''sometimes therapy'' services to facilitate billing of the CTBS by therapists. Additionally, we note that when billed by a private practice PT, OT, or SLP, the codes would need to include the corresponding GO, GP, or GN therapy modifier to signify that the CTB are furnished as therapy services furnished under an OT, PT, or SLP plan of care.

Comment: Many commenters supported and thanked CMS for the clarification that consent from the patient to receive CTBS services can be documented by auxiliary staff under general supervision as well as by the billing practitioner.

Response: We thank commenters for their feedback.

Comment: Several commenters encouraged CMS to permanently allow the use of virtual check-ins and e-visits for new as well as established patients.

Response: In the CY 2019 PFS proposed rule (83 FR 35724), we created HCPCS code G2012 and stated our expectation that these services would be initiated by the patient, especially since many beneficiaries would be financially liable for sharing in the cost of these services. Additionally, MedPAC noted particular concern regarding potential increases in volume that are not related to ongoing, informed patient care. CMS remains concerned about these issues outside of the PHE for COVID–19. As such, we did not propose, and do not anticipate proposing, to permanently allow billing for HCPCS codes G2020 and G2012 when furnished to new patients.

Comment: One commenter suggested it may be helpful for CMS to provide data on specialty-specific uptake of CTBS and e-Visits, both before and after the PHE for COVID–19, in order to determine if there are access challenges in specific specialties.

Response: We thank the commenter for their suggestion and will take this into future consideration after the PHE for COVID–19 ends.

7. Continuation of Payment for Audio-Only Visits

a. Background

In the March 31st COVID–19 IFC, we established separate payment for audio-only telephone E/M services (85 FR 19264 through 19266). The telephone E/M services are CPT codes 99441 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*); 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*); and 99443 (*Telephone evaluation and management service by a physician or other qualified health*

care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion). We noted that, although these services were previously considered non-covered under the PFS, in the context of the PHE for COVID–19 and with the goal of reducing exposure risks associated with COVID–19, especially in the case that two-way, audio and video technology is not available to furnish a Medicare telehealth service, we believed there are circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate, yet not fully replace a face-to-face visit. For example, an established patient who was experiencing an exacerbation of their condition could have a 25-minute phone conversation with their physician during which the physician determines that an adjustment to the patient's medication would alleviate their symptoms. The use of CPT code 99443 in this situation prevents a similar in-person service as the evaluation of the patient's symptoms and determination to adjust medication could be conducted without patient and the practitioner being in the same location. We stated our belief that these telephone E/M codes, with their established description and valuation, were the best way to recognize the relative resource costs of these kinds of services and make payment for them under the PFS. For these codes, we initially finalized on an interim basis during the PHE for COVID–19, work RVUs as recommended by the American Medical Association (AMA) Relative Value Scale Update Committee (RUC), as discussed in the CY 2008 PFS final rule with comment period (72 FR 66371), of 0.25 for CPT code 99441, 0.50 for CPT code 99442, and 0.75 for CPT code 99443. We also finalized the RUC-recommended direct PE inputs which consist of 3 minutes of post-service Registered Nurse/Licensed Practical Nurse/Medical Technical Assistant clinical labor time for each code.

In the May 8th COVID–19 IFC, we noted that in the time since we established these payment amounts, stakeholders had informed us that use of audio-only services was more prevalent than we had previously considered, especially because many beneficiaries were not utilizing video-enabled communication technology from their homes. In other words, there were many cases where practitioners would under ordinary circumstances utilize telehealth or in-person visits to evaluate and manage patients' medical concerns, but were instead using audio-only interactions to manage more complex care (85 FR 27589 through 27590). While we had previously acknowledged the likelihood that, under the circumstances of the PHE for COVID–19, more time would be spent interacting with the patient via audio-only technology, we stated that the intensity of furnishing an audio-only visit to a beneficiary during the unique circumstances of the PHE for COVID–19 was not accurately captured by the valuation of these services we established in the March 31st COVID–19 IFC. This would be particularly true to the extent that these audio-only services are actually serving as a substitute for office/outpatient Medicare telehealth visits for beneficiaries not using video-enabled telecommunications technology contrary to the situation we anticipated when establishing payment for them in the March 31st COVID–19 IFC. We stated that, given our understanding that these audio-only services were being furnished primarily as a replacement for care that would otherwise be reported as an in-person or telehealth visit using the O/O E/M codes, we established new RVUs for the telephone E/M services based on crosswalks to the most analogous O/O E/M codes, based on the time requirements for the telephone codes and the times assumed for valuation for purposes of the O/O E/M codes. Specifically, we crosswalked CPT codes 99212, 99213, and 99214 to CPT codes 99441, 99442, and 99443, respectively. We therefore finalized, on an interim basis and for the duration of the PHE for COVID–19, the following work RVUs: 0.48 for CPT code 99441; 0.97 for CPT code 99442; and 1.50 for CPT code 99443. We also finalized the direct PE inputs associated with CPT code 99212 for CPT code 99441, the direct PE inputs associated with CPT code 99213 for CPT code 99442, and the direct PE inputs associated with CPT code 99214 for CPT code 99443. We did not finalize increased payment rates for CPT codes 98966–98968 as these codes describe services furnished by practitioners who cannot independently bill for E/M services and so these telephone assessment and management services, by definition, are not being furnished in lieu of an O/O E/M service. We noted that to the extent that these extended phone services are taking place instead of O/O E/M visits (either in-person or via telehealth), the direct crosswalk of RVUs also better maintains overall budget neutrality and relativity under the PFS. We stated that we believed that the resources required to furnish these services during the PHE for COVID–19 are better captured by the RVUs associated with the level 2–4 established patient O/O E/M visits. Additionally, we stated that, given our understanding that these audio-only services were being furnished as substitutes for O/O E/M services, we recognized that they should be considered as telehealth services, and added them to the Medicare telehealth services list for the duration of the PHE for COVID–19. For these audio-only E/M services, we separately issued a waiver under section 1135(b)(8) of the Act, as amended by section 3703 of the CARES Act, of the requirements under section 1834(m) of the Act and our regulation at § 410.78 that Medicare telehealth services must be furnished using video technology.

b. Summary of Comments Received in Response to Comment Solicitation on Continuation of Payment for Audio-Only Visits

In the CY 2021 PFS proposed rule (85 FR 50113–50114), we did not propose to continue to recognize CPT codes 99441, 99442, and 99443 for payment under the PFS after conclusion of the PHE for COVID–19 because, outside of the circumstances of the PHE, we are not able to waive the requirement that telehealth services be furnished using an interactive telecommunications system that includes two-way, audio/video communication technology. However, we recognized that the need for audio-only interaction could remain as beneficiaries continue to try to avoid sources of potential infection, such as a doctor's office; and in that circumstance, a longer phone conversation may be needed to determine if an in-person visit is necessary rather than what is described by the virtual check-in. We solicited comment on whether CMS should develop coding and payment for a service similar to the virtual check-in but for a longer unit of time and with an accordingly higher value. We sought input from the public on the appropriate duration interval for such services and the resources in both work and PE that would be associated with furnishing them. We also solicited comment on whether separate payment for such telephone-only services should be a provisional policy to remain in effect until a year or some other period after the end of the PHE for COVID–19 or if

it should be PFS payment policy permanently.

We received public comments on the comment solicitation on continuation of payment for audio-only visits. The following is a summary of the comments we received and our responses.

Comment: Commenters broadly supported maintaining the availability of certain audio-only services after the duration of the PHE for COVID–19. Commenters stated that many beneficiaries may not have access to or choose not to use two-way, audio/video communication technology, and therefore, maintaining some form of payment for audio-only services would be crucial for ensuring access to care for this vulnerable population. Some commenters urged CMS to continue payment for audio-only evaluation or assessment and management services beyond the end of the PHE for COVID–19. Other commenters stated that allowing practitioners to furnish certain behavioral health and counseling services via audio-only communication technology has been crucial to ensuring access to these services and that CMS should continue payment for these audio-only services after the conclusion of the PHE for COVID–19. Commenters further suggested, in response to both this proposal and in the context of the proposed revision to the agency's regulation at § 410.78(a)(3), that the statutory text laying out the telehealth services benefit uses the term ''telecommunications system'' but does not include an explicit definition of that term, except to say that in the case of federal telemedicine demonstrations in Alaska or Hawaii, the term ''includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.'' Therefore, the statute leaves it up to the Department of Health and Human Services (HHS) to determine whether a telehealth telecommunications system must include both audio and video capabilities, and HHS is free to make the modification it proposes under this heading. Based on this assessment, commenters stated that CMS has the authority to redefine our longstanding regulatory interpretation of ''interactive telecommunications system'' at § 410.78 to include audio-only services.

While the majority of commenters stated that they preferred CMS continuing to recognize the audio evaluation/assessment and management services outside of the PHE for COVID–19, some commenters did state that, in the absence of continuing to recognize those codes, CMS should provide coding and payment for a longer virtual check-in. With regard to the valuation of a longer virtual check in, commenters provided a few recommendations. One commenter suggested that we value this service the same as CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family*), other commenters suggested a range of times for a new virtual check in, such as 11–22 minutes or 15–20 minutes. Another commenter suggested that CMS could create more than one additional virtual check-in code.

Response: We appreciate these comments. Section 1834(m)(2)(A) of the Act expressly provides payment to the distant site physician or practitioner of an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system. This means that we pay an equal amount for a service furnished using a ''telecommunications system'' as for a service furnished in person (without the use of a telecommunications system). Section 1834(m)(1) of the Act specifies that telehealth services must be furnished via a ''telecommunications system,'' and it includes an exception to allow ''store and forward'' technology to be considered a telecommunications system only for purposes of certain federal demonstrations. CMS has in place a longstanding interpretation of ''telecommunications system'' that includes only technology that enables a visit that is analogous to an in person visit—which aligns closely with our resource-based payment policy under the PFS, given that payment is made for a telehealth service at the same rate as an in-person visit. Our criteria for considering the addition of services to the telehealth services list also rely on an assessment of whether the service furnished via telehealth is analogous to one furnished in person. We continue to believe that our longstanding regulatory definition of ''telecommunications system'' reflects the intent of statute.

As the audio-only assessment and management or E/M visits are by definition replacements for in-person office visits, they would be subject to the statutory restrictions outlined in section 1834(m) of the Act. Outside of the circumstances of the PHE for COVID–19, we continue to believe that our longstanding regulatory interpretation of ''telecommunications system'' precludes the use of audio-only technology for purposes of Medicare telehealth services.

Comment: Some commenters stated that if CMS continues payment for the audio-only E/M visits, these should continue to be paid at rates commensurate to the level 2–4 established patient office visits, consistent with how these services have been paid during the PHE for COVID–19. Other commenters disagreed, stating that outside the circumstances of the PHE for COVID–19, these services should not have the same payment rate as in-person services.

Response: After the end of the PHE, there will be no separate payment for the audio-only E/M visit codes. At the conclusion of the PHE, we will assign a status of ''bundled'' and post the RUC-recommended RVUs for these codes in accordance with our usual practice.

Comment: A few commenters requested that, if CMS continues to recognize the audio-only evaluation/assessment and management services or if CMS creates a longer virtual check-in service, the service should be available to both new and established patients. A few commenters, including MedPAC, suggested that if CMS creates a longer virtual check-in, the policy should be provisional rather than permanent—for example, through the calendar year in which the PHE for COVID–19 ends.

Response: We continue to believe that, outside of the circumstances of the PHE for COVID–19, CTBS services broadly should be billed only for established patients.

c. Interim Final Rule With Comment Period for Coding and Payment of Virtual Check-In Services (HCPCS Code GSADX1)

i. Background

We note that we have historically established coding and payment on an interim final basis for truly new services when it is in the public interest to do so. Outside of the circumstances of the PHE for COVID–19, Medicare does not provide separate payment for a service that would be a substitute for an in-person visit but is furnished using synchronous audio-only technology. However, we recognize that commenters were clear about the continuing need for coding and payment to reflect the

provision of lengthier audio-only services outside of the PHE for COVID–19, if not as substitutes for in-person services, then as a tool to determine whether an in-person visit is needed, particularly as beneficiaries may still be cautious about exposure risks associated with in-person services.

ii. Interim Final Policy

Given the widespread concerns expressed by commenters about the continuing need for audio-only conversations with patients, we believe it would be expedient to establish additional coding and payment for an extended audio-only assessment service on an interim basis for CY 2021. We believe that establishing payment for this service on an interim basis will support access to care for beneficiaries who may be reluctant to return to in-person visits unless absolutely necessary, and allow us to consider whether this policy should be adopted on a permanent basis. Therefore, for CY 2021, on an interim basis, we are establishing HCPCS code G2252 (*Brief communication technology-based service, e.g., virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion*.). We are finalizing a direct crosswalk to CPT code 99442, the value of which we believe most accurately reflects the resources associated with a longer service delivered via synchronous communication technology, which can include audio-only communication. This is consistent with our approach to valuing the virtual check-in service (HCPCS code G2012), which used CPT code 99441 as the basis for valuation. In the case of HCPCS code G2252 and CPT code 99442, both codes describe 11–20 minutes of medical discussion when the practitioner may not necessarily be able to visualize the patient, and is used when the acuity of the patient's problem is not necessarily likely to warrant a visit, but when the needs of the particular patient require more assessment time from the practitioner. In the case of HCPCS code G2252, the additional time would be used to determine the necessity of an in person visit result in a work time/intensity that is similar to the crosswalk code. We are finalizing a work RVU of 0.50, direct PE inputs of 3 minutes of clinical labor code L037D, and 1 minute, 15 minutes, and 5 minutes of pre, intra and post service time, respectively. As this service is not a substitute for an in-person visit, but rather an assessment to determine the need for one, the restrictions in section 1834(m) of the Act do not apply and the only technological requirement is that the communication technology must be synchronous. If this service originates from a related E/M service provided within the previous 7 days or leads to an E/M service or procedure within the next 24 hours or soonest available appointment it would be considered bundled into that in-person service. We would consider this service to be a CTBS and refer readers to the CY 2019 PFS final rule for additional discussion as to why these fall outside of the restrictions in 1834(m) of the Act (83 FR 59482 through 59491). We also note that HCPCS code GSADX1 is subject to the same billing requirements as HCPCS code G2012.

iii. Waiver of Proposed Rulemaking for Provisions

Under the Administrative Procedure Act (APA), 5 U.S.C. 553(b), an agency is generally required to publish a notice and solicit comment on a proposed rule in the **Federal Register** before issuing a final rule. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. The APA provides for exceptions from the notice and comment requirements *see* 5 U.S.C. 553(b)(B); in cases in which the APA exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of Title 5 and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements if the agency for good cause finds that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) due to widespread concerns expressed by commenters about the continuing need for audio-only conversations with patients. We believe that establishing payment for this service on an interim basis will support access to care for beneficiaries who may be reluctant to return to in-person visits unless absolutely necessary, and allow us to consider whether this policy should be adopted on a permanent basis. We find that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing these payment policies on an interim basis. We also find that delaying implementation of these policies is unnecessary because the impact on other PFS services for 2021 is negligible and the practical alternative for this treatment is no payment under Medicare Part B. In either case, payments for 2022 and beyond would be informed by public comments.

Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section 1871(b)(2)(C) of the Act and section 533(b)(B) of the APA and to issue this interim final rule with an opportunity for public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document.

8. Comment Solicitation on Coding and Payment for Virtual Services

The health care community uses the term ''telehealth'' broadly to refer to medical services furnished via communications technology. Under current PFS payment rules, Medicare routinely pays for many of these kinds of services. This includes some kinds of remote patient monitoring (either as separate services or as parts of bundled services), interpretations of diagnostic tests when furnished remotely and, under conditions specified in section 1834(m) of the Act, services that would otherwise be furnished in person but are instead furnished via real-time, interactive communication technology. Over the past several years, we have also established several PFS policies to make separate payment for non-face-to-face services included as part of ongoing care management. Although all of the kinds of services stated above might be called ''telehealth'' by patients, payers of health care services, and health care providers, we have generally used the term ''Medicare telehealth services'' to refer to the subset of services defined in section 1834(m) of the Act. Section 1834(m) of the Act defines Medicare telehealth services and specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real time telecommunication technology.

In the CY 2021 PFS proposed rule, we noted that we believe that the provisions in section 1834(m) of the Act apply particularly to the kinds of professional services explicitly enumerated in the statutory provisions,

like professional consultations, office visits, and office psychiatry services. Generally, the services we have added to the Medicare telehealth services list are similar to these kinds of services. As has long been the case, certain other kinds of services that are furnished remotely using communications technology are not considered ''Medicare telehealth services'' and are not subject to the restrictions articulated in section 1834(m) of the Act. This is true for services that were routinely paid separately prior to the enactment of the provisions in section 1834(m) of the Act and do not usually include patient interaction (such as remote interpretation of diagnostic imaging tests), and for services that were not discretely defined or separately paid for at the time of enactment and that do include patient interaction (such as chronic care management services).

In recent years, we have begun making separate payment for a number of services that use telecommunications technology but are not considered Medicare telehealth services. These CTB services include, for example, certain kinds of remote patient monitoring (either as separate services or as parts of bundled services), a virtual check-in, and a remote asynchronous service. These services are different than the kinds of services specified in section 1834(m) of the Act, in that they are not the kind of services that are ordinarily furnished in person but are routinely furnished using a telecommunications system.

In the past, we have received requests to add certain services, such as chronic care management or remote physiologic monitoring to the Medicare telehealth services list. However, as these services fall outside the scope of services addressed, and the enumerated list of services included, in section 1834(m) of the Act, they are not considered telehealth services and, therefore, are not subject to the same restrictions. We solicited comment on whether there are additional services that fall outside the scope of telehealth services under section 1834(m) of the Act where it would be helpful for us to clarify that the services are inherently non-face-to-face, so do not need to be on the Medicare telehealth services list in order to be billed and paid when furnished using telecommunications technology rather than in person with the patient present. We also solicited comment on physicians' services that use evolving technologies to improve patient care that may not be fully recognized by current PFS coding and payment, including, for example, additional or more specific coding for care management services. Finally, we solicited comment on any impediments that contribute to healthcare provider burden and that may result in practitioners being reluctant to bill for CTBS. We noted that we appreciate the ongoing engagement and additional information from stakeholders as we work to improve coding and payment for these services that utilize telecommunications technology.

We received public comments on the comment solicitation on coding and payment for virtual services. The following is a summary of the comments we received and our responses.

Comment: Some commenters stated that CMS should provide utilization information for CTBS services before, during, and after the PHE. Others suggested that CMS establish separate coding and payment for additional consultations that may be furnished using communication technology. Other comments suggested that CMS issue clear and consistent guidance on how to code for and appropriately document both telehealth and CTBS. Commenters recommended that CMS collaborate with the AMA to accurately value services furnished using communication technology.

Response: We thank commenters for their input and will consider them for potential future rulemaking or future subregulatory guidance, as appropriate.

9. Clarification of Current PFS Policies for Telehealth Services

In response to the waiver of statutory requirements and the relaxation of regulatory requirements for telehealth during the PHE for COVID–19, we received a number of requests to clarify existing PFS policy for telehealth. For example, we received questions as to whether Medicare allows incident-to billing for telehealth services, particularly for practitioners such as counselors who are supervised by a physician in private practice. We noted that there are no Medicare regulations that explicitly prohibit eligible distant site practitioners from billing for telehealth services provided incident to their services. However, we also noted that our existing definition of direct supervision requires on-site presence of the billing clinician when the service is provided. That requirement could make it difficult for a billing clinician to provide the direct supervision of services provided via telehealth that is required for services furnished incident to their professional services by auxiliary personnel. Under the proposed revision to the definition of direct supervision to permit virtual presence (FR 85 50114 and 50115), we acknowledged that billing practitioners could more easily meet the direct supervision requirements for telehealth services provided incident to their services. Consequently, we noted that we believe services provided incident to the professional services of an eligible distant site physician or practitioner could be reported when they meet direct supervision requirements at both the originating and distant site through the virtual presence of the billing physician or practitioner. Therefore, we proposed to clarify that services that may be billed incident-to may be provided via telehealth incident to a physicians' (or authorized NPP's) service and under the direct supervision of the billing professional. This is consistent with a policy clarification that we made through the May 8th COVID–19 IFC (85 FR 27562).

We also received questions as to whether services should be reported as telehealth services when the individual physician or practitioner furnishing the service is in the same location as the beneficiary; for example, if the physician or practitioner furnishing the service is in the same institutional setting but is utilizing telecommunications technology to furnish the service due to exposure risks. We also clarified, as we did in the May 8th COVID–19 IFC (85 FR 27562), that if audio/video technology is used in furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person, and the service would not be subject to any of the telehealth requirements under section 1834(m) of the Act or § 410.78 of our regulations.

We received public comments on these proposed clarifications of current policies for telehealth services. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to amend the definition of direct supervision to permit supervision through virtual presence because it would allow billing practitioners to more easily meet the direct supervision requirements for telehealth services provided ''incident to'' their services. Commenters stated that this policy would expand access to needed care in communities that may not have a supervising physician on site, and could make available services that another qualified healthcare professional could provide within their scope of practice if only they had the necessary direct supervision.

Response: We appreciate commenters' support for this clarification. We are

finalizing our proposed clarification that telehealth services may be furnished and billed when provided incident to a distant site physicians' (or authorized NPP's) service under the direct supervision of the billing professional provided through virtual presence in accordance with our regulation at § 410.26.

Comment: One commenter requested that we specify in detail how time should be counted for services furnished and billed incident to the commenter's professional services when the required direct supervision is provided through virtual presence.

Response: As we do not provide specific coding guidance, we suggest that this commenter refer to the AMA CPT guidelines for using time to bill for services furnished and also contact their Medicare Administrative Contractor for further assistance. We further note that time should be counted for telehealth services furnished by auxiliary personnel incident to a billing professional's services in the same way time is counted for other ''incident to'' services.

Comment: Commenters supported our clarification that, if audio/video technology is used while furnishing a service when the beneficiary and the practitioner are in the same institutional or office setting, then the practitioner should bill for the service furnished as if it was furnished in person. In addition, the service would not be subject to any of the telehealth requirements, such as geographic or site restrictions. Commenters state that this flexibility helps conserve personal protective equipment (PPE) and supports access to care.

Response: We appreciate commenters' support for this clarification.

Comment: One commenter recommended that CMS institute tracking methods to accurately attribute services to the professional who delivered the care when submitting services using Medicare's ''incident to'' billing provision. They reasoned that, when there is a lack of transparency regarding which clinicians are providing what services, it is difficult, if not impossible, to appropriately measure the type or volume of services or the quality of care delivered by each health professional.

Response: We thank commenters for their feedback and suggestions. We note that CMS has very clear rules about when a physician or practitioner is permitted to bill for services furnished incident to their own. When practitioners bill for their services, they attest to the accuracy of the information they provide; and failure to provide accurate information can result in civil and criminal liability.

10. Direct Supervision by Interactive Telecommunications Technology

Many services for which payment is made under the PFS can be furnished under a level of physician or NPP supervision rather than being performed directly by the billing practitioner. In many cases, the supervision requirements necessitate the presence of the physician or NPP in a particular location, usually in the same location as the beneficiary when the service is provided. For example, as described at § 410.26, services furnished by auxiliary personnel incident to a physician's or NPP's professional service usually require the direct supervision of the physician or NPP. In addition to these ''incident to'' services, there are a number of diagnostic services under the PFS that also must be furnished under direct supervision. As currently defined in §§ 410.26 and 410.32(b)(3)(ii), direct supervision means that the physician or NPP must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. Direct supervision does not require the physician or NPP to be present in the room when the service or procedure is performed.

For the duration of the PHE for COVID–19, for purposes of limiting exposure to COVID–19, we adopted an interim final policy revising the definition of direct supervision to include virtual presence of the supervising physician or practitioner using interactive audio/video real-time communications technology (85 FR 19245). We recognized that in some cases, the physical proximity of the physician or practitioner might present additional infection exposure risk to the patient and/or practitioner. In the context of the PHE for COVID–19, given the risks of exposure, the immediate risk of foregone medical care, the increased demand for healthcare professionals, and the widespread use of telecommunications technology, we believed that individual practitioners were in the best position to make decisions about how to meet the requirement to provide appropriate direct supervision based on their clinical judgment in particular circumstances.

We proposed to extend the policy until the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021, to recognize the different and unique circumstances faced by individual communities that may continue after the PHE ends, and provide time to solicit public input on circumstances where the flexibility to use interactive audio/video real-time communications technology to provide virtual direct supervision could still be needed and appropriate. The extension of this flexibility would allow time for clinicians to make adjustments and for us to obtain public input on services and circumstances for which this policy might be appropriate on a permanent basis. We noted that if the proposal were finalized and the PHE for COVID–19 ended before the CY 2021 PFS final rule takes effect, the interim policy adopted during the PHE to allow direct supervision using real-time, interactive audio and video technology would no longer be in effect during the period between expiration of the PHE and the date the final policy takes effect.

Given our continued interaction with practitioners during the PHE for COVID–19 and our growing understanding of how services may be furnished remotely and safely, we noted that we have a better understanding of how, in some cases, depending upon the unique circumstances of individual patients and billing practitioners or physicians, telecommunications technology could safely allow the practitioner or physician's immediate availability to furnish assistance and direction without necessarily requiring the supervising practitioner's or physician's physical presence in the location where the service is being furnished. In such cases, the use of real-time, audio and video telecommunications technology may allow the supervising practitioner or physician to observe the beneficiary and the auxiliary staff performing the service or be engaged (Direct supervision does not require the physician or NPP to be present in the room when the service or procedure is performed) to provide assistance and direction of the service through virtual means, and without the supervising practitioner or physician being physically present.

Consequently, we proposed to revise § 410.32(b)(3)(ii) to allow direct supervision to be provided using real-time, interactive audio and video technology through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021. Specifically, we proposed to continue our current rule that ''Direct supervision'' in the office setting would mean the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It would not mean that the physician (or other

supervising practitioner) must be present in the room when the procedure is performed. We proposed to add that, until the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021, the presence of the physician (or other practitioner) may include virtual presence through audio/video real-time communications technology (excluding audio-only) subject to the clinical judgement of the supervising physician or (other supervising practitioner). In response to questions received since we issued the interim policy for the PHE for COVID–19, we clarified that, to the extent our policy allows direct supervision through virtual presence using audio/video real-time communications technology, the requirement could be met by the supervising physician (or other practitioner) being immediately available to engage via audio/video technology (excluding audio-only), and would not require real-time presence or observation of the service via interactive audio and video technology throughout the performance of the procedure.

While flexibility to provide direct supervision through audio/video real-time communications technology was adopted to be responsive to critical needs during the PHE for COVID–19 to ensure beneficiary access to care, reduce exposure risk and to increase the capacity of practitioners and physicians to respond to COVID–19, we expressed concern that direct supervision through virtual presence may not be sufficient to support PFS payment on a permanent basis, beyond the PHE for COVID–19, due to issues of patient safety. For instance, in complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change, and we believe it is necessary for such services to be furnished or supervised in person to allow for rapid on-site decision-making in the event of an adverse clinical situation. For example, there could be a case in which a practitioner or physician uses audio/video interactive communications to virtually supervise a nurse performing a post-op evaluation following surgery for hip fracture, and the nurse might note that the patient is uncooperative. In this scenario, had a full exam been performed directly by the practitioner or physician, or under the in-person supervision of a practitioner or physician who was physically or immediately available in the clinic to provide the necessary direction, the physician or practitioner would have recognized that the patient exhibited signs of crystal-mediated acute arthritis, and that the patient's lack of cooperation was likely due to hypoactive delirium. Instead, the supervising practitioner or physician may not have been able to identify this clinical issue as a result of being available only via audio/video interactive communications technology. In this case, the presence of the supervising practitioner or physician through audio/video interactive communications technology would have been insufficient. There also may be certain patient populations that require greater clinical attentiveness and skill than the supervising practitioner or physician could provide via audio/video interactive communications technology. For example, patients with cognitive impairment or dementia, or patients with communication disabilities, may require the experience and skill of a physically present supervising practitioner or physician to recognize needs such as the need for specialized testing. It may not be possible for a supervising practitioner or physician to recognize or meet these clinical needs while being present for the service only through audio/video interactive communications technology. Moreover, the virtual connection between the individual performing the service and the supervising practitioner or physician could be disrupted, making it challenging for the supervising practitioner or physician to remain immediately available to provide assistance and direction to the physically present clinical staff or auxiliary personnel to furnish appropriate care to the patient.

We solicited information from commenters as to whether there should be any additional ''guardrails'' or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use if we were to finalize a policy to permit direct supervision through audio/video interactive communications technology, with consideration of relevant patient safety, clinical appropriateness criteria or other restrictions, on a temporary basis through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021, or consider it beyond the time specified. We solicited information on what risks this policy might introduce to beneficiaries as they receive care from practitioners that would supervise care virtually in this way. Further, we solicited comment on potential concerns around induced utilization and fraud, waste, and abuse and how those concerns might be addressed. We also invited commenters to provide data and information about their implementation experience with direct supervision using virtual presence during the PHE for COVID–19, and are interested in comments on the degree of aging and disability competency training that is required for effective use of audio/video real-time communications technology.

We received public comments on the direct supervision by interactive telecommunications technology. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to revise the definition of direct supervision to allow virtual presence of the supervising physician or practitioner using real-time, interactive audio-video technology until the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021, stating that this revision will greatly help reduce barriers to access, and that allowing physicians and auxiliary personnel to provide services from two separate locations will work to support the expansion of telehealth services and protects frontline workers by allowing appropriate social distancing.

Response: We thank the commenters for their support and feedback.

Comment: Many commenters requested that CMS make permanent the current temporary regulatory flexibility allowing physicians to provide direct supervision of clinical staff virtually, using real-time audio/video technology. Others opposed the use of virtual direct supervision following the termination of the PHE due to issues of patient safety, stating it may not be possible for a supervising physician to recognize or meet urgent clinical needs while being present for the service, and potentially other services at the same time, only through audio/video interactive communications technology.

We also received a variety of responses to our stated concerns that direct supervision through virtual presence may not be sufficient to support PFS payment on a permanent basis, beyond the PHE for COVID–19, due to issues of patient safety. Many commenters did not share these concerns, stating that there is no situation whereby clinical staff or auxiliary personnel would conduct complex, high-risk, surgical, interventional, or endoscopic procedures under any circumstance other than in-person. Many other commenters shared our patient-safety concerns, citing increased utilization and spending, and the potential for

fraud and abuse. Many stressed that virtual supervision can be done safely in certain scenarios, but it is not warranted in other scenarios. More specifically, some commenters said remote supervision would not be appropriate for in-person diagnostic or therapeutic procedures since the physician would not be physically available to help the individual being supervised if the need arises. Similarly, commenters suggested that it may not be appropriate when a remote physician is not on-site for an E/M service that requires finesse when performing the physical examination in person. According to some commenters, virtual direct supervision would not be appropriate for data interpretation, such as imaging studies or certain physiologic studies, where the patient is not physically present. A commenter agreed with the agency's assessment that anesthesia services must be furnished or supervised in person to allow for rapid, on-site decision-making in the event of an adverse clinical situation. One commenter recommended that CMS provide clarifying language in the final rule to ensure that the supervising physician is in the United States when using audio-visual technology for purposes of direct supervision.

Commenters offered a range of responses and suggestions in the interest of patient safety and program integrity in response to our request for information as to whether there should be any additional ''guardrails'' or limitations to ensure patient safety/clinical appropriateness, beyond typical clinical standards, as well as restrictions to prevent fraud or inappropriate use, if we were to finalize a policy to permit direct supervision through audio/video interactive communications technology on a temporary basis. According to some commenters, we should defer entirely to physician judgment to determine clinical appropriateness. Others offered suggestions including that we should closely monitor the use of virtual direct supervision during the interim period to gain information on potential induced utilization or fraud, waste, and abuse concerns. Some commenters stated that virtual direct supervision should be robustly documented to ensure that patients are safely receiving clinically appropriate care from members of the care team. A commenter stated that program integrity concerns could be addressed through provider enrollment rather than through administrative barriers. Other suggestions included: That CMS develop a list of high risk procedures and complex patient populations for whom this policy may not be appropriate; that CMS limit the number of clinicians with whom a supervising physician may simultaneously engage, as well as the number of incident-to relationships in which a supervising physician may be involved at a given time, via audio/video technology; that testing sites that use interactive technologies rely on documentation and training; that we require that a caregiver be present physically with the patient when the services are furnished virtually; and that CMS identify conditions under which the extension of the virtual direct supervision policy may be revoked if evidence suggests such supervision is inadequate.

Response: We appreciate the information and suggestions we received in response to this request for comment. This information will allow us to consider safety and program integrity issues in the context of virtual supervision, and to what degree and on what basis this flexibility could be continued following the PHE. We will consider this and other information as we determine future policy regarding use of communication technology to satisfy direct supervision requirements as well as the best approach for safeguarding patient safety while promoting use of technology to enhance access.

After consideration of the comments, we are finalizing our proposal to allow direct supervision to be provided using real-time, interactive audio and video technology through the later of the end of the calendar year in which the PHE for COVID–19 ends or December 31, 2021.

11. Comment Solicitation on PFS Payment for Specimen Collection for COVID–19 Tests

When physicians and other practitioners collect specimens for clinical diagnostic laboratory tests as part of their professional services, Medicare generally makes payment for the services under the PFS, though often that payment is bundled into the payment rate for other services, including office and outpatient visits. Typically, collection of a specimen via nasal swab or other method during the provision of a service might be reported as part of (bundled with) an O/O E/M visit (CPT codes 99201 through 99205, 99211 through 99215). In visits where a patient has a face-to-face interaction with a billing professional with whom they have an established relationship, these services are generally reported with a level 2 through a level 5 visit (CPT codes 99212 through 99215). In cases where the specimen is collected during a visit where the face-to-face interaction only involves clinical staff of the billing professional with whom the patient has an established relationship, these services are generally reported using CPT code 99211.

In the May 8th COVID–19 IFC (85 FR 27604–27605), we finalized on an interim basis that physicians and NPPs may use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing, if the billing practitioner does not also furnish a higher level E/M service to the patient on the same day. In the CY 2021 PFS proposed rule, we noted that we considered whether to extend or make permanent the policy to allow physicians and NPPs to use CPT code 99211 to bill for services furnished incident to their professional services, for both new and established patients, when clinical staff assess symptoms and collect specimens for purposes of COVID–19 testing, and solicited public comments on whether we should continue this policy for a period of time, or permanently, after the PHE for COVID–19 ends.

We received public comments in response to our comment solicitation on PFS payment for specimen collection for COVID–19 tests. We appreciate the information and feedback provided. We will consider this information for potential future rulemaking.

12. Finalization of Interim Final Rule Provisions Related to Requirements of the Substance Use Disorder (SUD) Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

a. Expanding Medicare Telehealth Services for the Treatment of Opioid Use Disorder and Other SUDs

In the CY 2019 PFS interim final rule with comment period (83 FR 59452, 59496, Nov. 23, 2018), we implemented on an interim final basis the amendments made by section 2001(a) of the SUPPORT for Patients and Communities Act (Pub. L. 115–271, October 24, 2018) (the SUPPORT Act) to section 1834(m) of the Act. First, section 2001(a) of the SUPPORT Act removed the originating site geographic requirements under section 1834(m)(4)(C)(i) of the Act for telehealth services furnished on or after July 1, 2019 for the purpose of treating individuals diagnosed with a SUD or a co-occurring mental health disorder, as determined by the Secretary, at an originating site described in section

1834(m)(4)(C)(ii) of the Act, other than an originating site described in subclause (IX) of section 1834(m)(4)(C)(ii) of the Act. Subclause (IX) of section 1834(m)(4)(C)(ii) of the Act refers to a renal dialysis facility, which is only an allowable originating site for purposes of home dialysis monthly ESRD-related clinical assessments in section 1881(b)(3)(B) of the Act. Section 2001(a) of the SUPPORT Act also added the home of an individual as a permissible originating site for telehealth services for the purpose of treating individuals diagnosed with a SUD or a co-occurring mental health disorder. Section 2001(a) of the SUPPORT Act also amended section 1834(m)(2)(B)(ii) of the Act to require that no originating site facility fee will be paid in instances when the individual's home is the originating site. Section 2001(b) of the SUPPORT Act granted the Secretary specific authority to implement the amendments made by section 2001(a) through an interim final rule, and under that authority, we issued such an interim final rule. In accordance with section 1834(m)(4)(C)(ii)(X) of the Act, as amended by section 2001(a) of the SUPPORT for Patients and Communities Act, we revised § 410.78(b)(3) on an interim final basis, by adding § 410.78(b)(3)(xii), which adds the home of an individual as a permissible originating site for telehealth services furnished on or after July 1, 2019 to individuals with a SUD diagnosis for purposes of treatment of a SUD or a co-occurring mental health disorder. We amended § 414.65(b)(3) on an interim final basis to reflect the requirement in section 1834(m)(2)(B)(ii) of the Act that there is no originating site facility fee paid when the originating site for these services is the individual's home. Additionally, we added § 410.78(b)(4)(iv)(C) on an interim final basis to specify that the geographic requirements in section 1834(m)(4)(C)(i) of the Act do not apply for telehealth services furnished on or after July 1, 2019, to individuals with a SUD diagnosis for purposes of treatment of a SUD or a co-occurring mental health disorder at an originating site other than a renal dialysis facility. We noted that section 2001 of the SUPPORT Act did not amend section 1834(m)(4)(F) of the Act, which limits the scope of telehealth services to those on the Medicare telehealth list. We also noted that practitioners would be responsible for assessing whether individuals have a SUD diagnosis and whether it would be clinically appropriate to furnish telehealth services for the treatment of the individual's SUD or a co-occurring mental health disorder. By billing codes on the Medicare telehealth list with the telehealth place of service code, practitioners would be indicating that the codes billed were used to furnish telehealth services to individuals with a SUD diagnosis for the purpose of treating the SUD or a co-occurring mental health disorder.

Comment: Several commenters expressed support for the changes authorized by section 2001(a) of the SUPPORT Act, noting that these changes that will benefit beneficiaries and advance the use of telehealth as a critical tool to improving access to care. One commenter noted that the changes will mitigate barriers to treatment for this patient population, decreasing stigma associated with seeking mental health and SUD services caused by presenting at a qualified originating site, allow patients to receive services at home, and open access to telehealth services for patients living in urban areas.

Response: We thank the commenters for their comments.

Comment: A few commenters urged CMS to consider expanding this flexibility to beneficiaries without SUDs, particularly those with mental health disorders without a co-occurring SUD.

Response: The interim final changes we adopted to our regulations under § 410.78 described above were based on amendments to the statute made by section 2001(a) of the SUPPORT Act. These amendments were limited to telehealth services furnished to individuals diagnosed with a SUD for purposes of treatment of the SUD or a co-occurring mental health disorder. We do not have the statutory authority at this time to expand these changes to include treatment of mental health disorders that are not co-occurring with a SUD diagnosis.

Comment: A few commenters urged CMS to ensure that the full scope of both SUD treatment services and applicable services for the treatment of co-occurring mental health disorders are included in the Medicare telehealth list in the future, citing examples such as screening, counseling, consultation, psychiatric services, care planning, initiation and continued management of Medication-Assisted Treatment (MAT), and others.

Response: Thank you for your comment. We note that HCPCS codes G2086, G2087, and G2088 were added to the Medicare Telehealth list beginning in CY 2020 (84 FR 62628). These codes describe bundled payments for office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy, and group therapy and counseling. We note that for CY 2021, we are finalizing a revision to these code descriptions to include the treatment of any substance use disorder rather than just OUD. See discussion in this final rule describing expansion of these codes to be inclusive of all SUDs beginning in CY 2021. Also, as discussed earlier in this final rule, we are finalizing the addition of CPT codes 99347 and 99348 (*Home visit for the evaluation and management of an established patient*) to the Medicare Telehealth list for CY 2021, which could be appropriately billed for treatment of an SUD or co-occurring mental health disorder, as well as CPT code 90853 (*Group psychotherapy*). We welcome recommendations of other codes for addition to the Medicare Telehealth list through our usual process by the February 10th deadline.

Comment: One commenter encouraged CMS to amend section 1834(m)(4)(f) of the Act to include MAT and remote opioid treatment as covered services on the Medicare telehealth list in order to provide the care needed to all patients with SUDs, including Opioid Use Disorder.

Response: We do not have the authority to amend the statute; however, the services associated with the provision of MAT in the office setting, such as E/M visits and psychotherapy, are on the Medicare Telehealth List.

Comment: One commenter cautioned against creating any administrative procedures that would complicate billing for these services when furnished via telehealth, which could create a barrier to implementation and stifle the ability of telehealth to be used effectively to facilitate SUD and co-occurring mental health services, while another commenter stated that CMS should publish clear sub-regulatory guidance on how the current Medicare telehealth services can be billed when treating SUD.

Response: As discussed in the CY 2019 PFS interim final rule with comment period (83 FR 59496), we noted that practitioners are responsible for assessing whether individuals have a SUD diagnosis and whether it would be clinically appropriate to furnish telehealth services for the treatment of the individual's SUD or a co-occurring mental health disorder. By billing codes on the Medicare telehealth list with the telehealth place of service code, practitioners would be indicating that the codes billed were used to furnish telehealth services to individuals with a SUD diagnosis for the purpose of

treating the SUD or a co-occurring mental health disorder.

In summary, after consideration of the comments, we are finalizing the interim revisions to the regulation text at §§ 410.78(b)(3) and 414.65(b)(3) described above.

E. Care Management Services and Remote Physiologic Monitoring Services

1. Background

In recent years, we have updated PFS policies to improve payment for care management and coordination. Working with the CPT Editorial Panel and other clinicians, we have expanded the suite of codes describing these services. New CPT codes were created that describe services that involve direct patient contact (for some services, in-person) or do not involve direct patient contact; represent a single encounter, monthly service, or both; are timed services; address specific conditions; and represent the work of the billing practitioner, auxiliary personnel (specifically, clinical staff), or both (*see* Table 17). In this final rule for CY 2021, we continue our work to improve payment for care management services through code refinements related to remote physiologic monitoring (RPM), transitional care management (TCM), and psychiatric collaborative care model (CoCM) services.

TABLE 17: Summary of Care Management Codes

Service	Summary
Care Plan Oversight (CPO) (also referred to as Home Health Supervision, Hospice Supervision) (HCPCS codes G0181, G0182)	Supervision of home health, hospice, per month
ESRD Monthly Services (CPT codes 90951-70)	ESRD management, with and without face-to-face visits, by age, per month
Transitional Care Management (TCM) (adopted in 2013) (CPT codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit, once per patient within 30 days post-discharge
Chronic Care Management (CCM) (adopted in 2015, 2017, 2019, 2020, 2021) (CPT codes 99487, 99489, 99490, 99491, HCPCS code G2058 to be replaced by CPT code 99439, in CY 2021)	Management of all care for patients with two or more serious chronic conditions, timed, per month
Advance Care Planning (ACP) (adopted in 2016) (CPT codes 99497, 99498)	Counseling/discussing advance directives, face-to-face, timed
Behavioral Health Integration (BHI) (adopted in 2017) (CPT codes 99484, 99492, 99493, 99494, HCPCS code G2214)	Management of behavioral health conditions(s), timed, per month
Cognitive Impairment Assessment and Care Planning (adopted in 2017) (CPT code 99483)	Assessment and care planning of cognitive impairment, face-to-face visit
Prolonged Evaluation & Management (E/M) Without Direct Patient Contact (adopted in 2017) (CPT codes 99358, 99359)	Prolonged non-face-to-face E/M work related to a face-to-face visit (other than office/outpatient visits beginning in 2021), timed
Prolonged Office/Outpatient E/M Visit (adopted for 2021) (HCPCS code G2212)	Prolonged face-to-face and/or non-face to face E/M work related to an office/outpatient E/M visit, timed
Remote Physiologic Monitoring Treatment Management Services (RPM) (adopted in 2020) (CPT codes 99457, 99458)	Development and management of a plan of treatment based upon patient physiologic data
Interprofessional Consultation (adopted in 2019) (CPT codes 99446, 99447, 99448, 99449, 99451, 99452)	Inter-practitioner consultation
Principal Care Management (adopted in 2020) (HCPCS codes G2064, G2065)	Management of a single, high risk disease

2. Digitally Stored Data Services/Remote Physiologic Monitoring/Treatment Management Services (RPM)

RPM involves the collection and analysis of patient physiologic data that are used to develop and manage a treatment plan related to a chronic and/or acute health illness or condition. In recent years, we have finalized payment for seven CPT codes in the RPM code family. Five of the seven codes have been the focus of frequent questions from stakeholders.

In response to proposals in the CY 2019 PFS proposed rule (83 FR 35771) and the CY 2020 PFS proposed rule (84 FR 40555 through 40556), stakeholders requested that we clarify how we interpret aspects of the RPM code descriptors for CPT codes 99453, 99454, 99091, and 99457. Commenters asked us, for example, to identify who can furnish RPM services, what kinds of devices can be used to collect data, how data should be collected, and how ''interactive communication'' is defined. We stated in the CY 2020 PFS final rule (84 FR 62697) that we would provide guidance in the future about the codes. For CY 2021, we are clarifying how we

read CPT code descriptors and instructions associated with CPT codes 99453, 99454, 99091, and 99457 (and the add-on code, CPT code 99458) and their use for remote monitoring of physiologic parameters of a patient's health.

The RPM process begins with two PE only codes, CPT codes 99453 and 99454, finalized in the CY 2019 PFS final rule (83 FR 59574 through 59576). As PE only codes, they are valued to include clinical staff time, supplies, and equipment, including the medical device for the typical case of remote monitoring. CPT code 99453 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*) is valued to reflect clinical staff time that includes instructing a patient and/or caregiver about using one or more medical devices. CPT code 99454 (*Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*) is valued to include the medical device or devices supplied to the patient and the programming of the medical device for repeated monitoring. We reviewed the PE inputs for CPT code 99454 in the proposed rule and clarified that the medical devices that are supplied to the patient and used to collect physiologic data are considered equipment and, as such, are direct PE inputs for the code.

Review of CPT prefatory language (CPT® 2021 Professional Codebook (hereafter, CPT Codebook), pp. 52–53) provides additional information about the two PE-only codes. For example, the CPT prefatory language indicates that monitoring must occur over at least 16 days of a 30-day period in order for CPT codes 99453 and 99454 to be billed. Additionally, these two codes are not to be reported for a patient more than once during a 30-day period. This language suggests that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed only once per patient per 30-day period and only when at least 16 days of data have been collected. We also noted that CPT code 99453 can be billed only once per episode of care where an episode of care is defined as ''beginning when the remote physiologic monitoring service is initiated and ends with attainment of targeted treatment goals'' (CPT Codebook, p. 52).

Other stakeholder inquiries about CPT codes 99453 and 99454 focused upon the kinds of medical devices that can be used to collect a patient's physiologic data. Prefatory language in the CPT Codebook states that ''the device must be a medical device as defined by the FDA.'' CPT simply specifies that the device must meet the FDA's definition of a medical device as described in section 201(h) of the Federal, Food, Drug and Cosmetic Act (FFDCA). As discussed in the CY 2021 PFS proposed rule (85 FR 50118), we found no language in the CPT Codebook indicating that a medical device must be FDA cleared as some stakeholders suggested, although such clearance may be appropriate. We also noted that we did not find information that suggested a medical device must be prescribed by a physician, although this could be possible depending upon the medical device. Beyond acknowledging the CPT specification that the medical device supplied for CPT code 99454 must meet the FDA definition of a medical device, we clarified in the proposed rule that the medical device should digitally (that is, automatically) upload patient physiologic data (that is, data are not patient self-recorded and/or self-reported). We also noted that use of the medical device or devices that digitally collect and transmit a patient's physiologic data must, as usual for most Medicare covered services, be reasonable and necessary for the diagnosis or treatment of the patient's illness or injury or to improve the functioning of a malformed body member. Further, we noted that the device must be used to collect and transmit reliable and valid physiologic data that allow understanding of a patient's health status in order to develop and manage a plan of treatment.

The CPT Codebook lists the RPM codes under the main heading Evaluation and Management (E/M). We clarified in the proposed rule that as E/M codes, CPT codes 99453, 99454, 99091, 99457, and 99458, can be ordered and billed only by physicians or NPPs who are eligible to bill Medicare for E/M services.

Although we initially described RPM services in the CY 2019 PFS final rule (83 FR 59574) as services furnished to patients with chronic conditions, we clarified in the CY 2021 PFS proposed rule (85 FR 50118) that practitioners may furnish these services to remotely collect and analyze physiologic data from patients with acute conditions as well as from patients with chronic conditions.

After the data collection period for CPT codes 99453 and 99454, the physiologic data that are collected and transmitted may be analyzed and interpreted as described by CPT code 99091, a code that includes only professional work (that is, there are no direct PE inputs). We finalized payment for CPT code 99091 (*Collection and interpretation of physiologic data (e.g., ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days*) in the CY 2018 PFS final rule (82 FR 53013 through 53014). The valuation for CPT code 99091 includes a total time of 40 minutes of physician or NPP work, broken down as follows: 5 minutes of preservice work (for example, chart review); 30 minutes of intra-service work (for example, data analysis and interpretation, report based upon the physiologic data, as well as a possible phone call to the patient); and 5 minutes of post-service work (that is, chart documentation). We noted that stakeholders have expressed confusion about the specification in the code descriptor for CPT code 99091 that the service is furnished by a ''physician or other qualified health care professional, qualified by education, training, licensure/regulation.'' The phrase ''physician or other qualified health care professional'' is defined by CPT as ''an individual who is qualified by education, training, licensure/regulation (when applicable) and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service. These professionals are distinct from ''clinical staff . . . [which refers to] a person who works under the supervision of a physician or other qualified health care professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service but does not individually report that professional service.'' [3] Accordingly, when referring to a particular service described by a CPT code for Medicare purposes, a physician or other qualified health care professional is an individual whose scope of practice and Medicare benefit category includes the service, and who is authorized to independently bill Medicare for the service. See our previous discussion of this in the CY 2016 PFS final rule at 80 FR 70957. Medicare also covers and makes payment for certain services performed by auxiliary personnel (which includes

[3] CPT Codebook, p. xiv.

clinical staff) ''incident to'' the professional services of the billing practitioner. Our regulation at § 410.26(a) defines auxiliary personnel and delineates the conditions for payment for ''incident to'' services.

After analyzing and interpreting a patient's remotely collected physiologic data, we noted that the next step in the process of RPM is the development of a treatment plan that is informed by the analysis and interpretation of the patient's data. It is at this point that the physician or NPP develops a treatment plan with the patient and/or caregiver (that is, develops a patient-centered plan of care) and then manages the plan until the targeted goals of the treatment plan are attained, which signals the end of the episode of care. CPT code 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/ caregiver during the month; first 20 minutes*) and its add-on code, CPT code 99458 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/ caregiver during the month; each additional 20 minutes (list separately in addition to code for primary procedure)*) describe the treatment and management services associated with RPM. Medicare stakeholders have requested that we clarify aspects of these two codes. The two most frequently asked questions include ''Who can furnish the services described by CPT codes 99457 and 99458?'' and ''What does it mean to have an 'interactive communication' with a patient?''

We addressed who can furnish CPT codes 99457 and 99458 in the CY 2020 PFS final rule (84 FR 62697 through 62698) when we designated both codes as care management services. We explained that, like other care management services, services described by CPT codes 99457 and 99458 can be furnished by clinical staff under the general supervision of the physician or NPP. We noted that RPM services are not considered to be diagnostic tests; that is, they cannot be furnished and billed by an Independent Diagnostic Testing Facility on the order of a physician or NPP.

The services described by CPT codes 99457 and 99458 are services that are typically furnished remotely using communications technologies that allow ''interactive communication,'' which we read as real-time interaction, between a patient and the physician, NPP, or clinical staff who provide the services. Stakeholders have requested that we define ''interactive communication'' as used in the code descriptors for CPT codes 99457 and 99458. We explained in the proposed rule that we saw this remote, non-face-to-face exchange as being similar to the exchange that occurs in providing services described by HCPCS code G2012, *Brief Communication Technology-Based Service,* which we finalized in the CY 2019 PFS final rule (83 FR 59483 through 59486). We clarified that ''interactive communication'' for purposes of CPT codes 99457 and 99458 involves, at a minimum, a real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission. As indicated in the code descriptor for CPT code 99457, we believed during the writing of the proposed rule that the interactive communication should total at least 20 minutes of time with the patient over the course of a calendar month for CPT code 99457 to be reported. Each additional 20 minutes of interactive communication between the patient and the physician/NPP/clinical staff would be reported using CPT code 99458. We developed our definition of time using the CPT Codebook. The CPT Codebook states that unless there are code- or code-range specific instructions, parenthetical instructions, or code descriptors to the contrary, time is considered to be ''face-to-face'' time with the patient or patient's caregiver/ medical decision-maker. See the CPT Codebook, page xvii for more information about measuring time. Although the services described by CPT codes 99457 and 99458 are not typically in-person services, we interpreted time in the code descriptor to mean the time the practitioner spent in direct, real-time interactive communication with a patient.

Lastly, we proposed to establish as permanent policy two of the changes we made on an interim basis to the requirements for furnishing RPM services in the March 31st and the May 8th COVID–19 IFCs. (See 85 FR 19264 and 85 FR 27605 through 27606 for the interim modifications and clarifications to RPM services in response to the PHE for COVID–19).

Our goals during the PHE for COVID–19 have been to reduce exposure risks to the virus for practitioners and patients while also increasing access to health care services. We eliminated as many obstacles as possible to allow timely delivery of reasonable and necessary health care. We wanted patients to be able to access services quickly and without barriers. With the goals of reducing exposure and increasing access to services, we finalized that RPM services could be furnished to new patients, as well as established patients on an interim basis for the duration of the PHE for COVID–19. We also finalized several policies on an interim basis for the duration of the PHE for COVID–19. These include: (1) Allowing consent to be obtained at the time services are furnished; (2) allowing consent to be obtained by individuals providing RPM services under contract with the billing physician or practitioner; and (3) allowing RPM codes to be billed for a minimum of 2 days of data collection over a 30-day period, rather than the required 16 days of data collection over a 30-day period as provided in the CPT code descriptors.

For CY 2021, we proposed on a permanent basis to allow consent to be obtained at the time that RPM services are furnished. Because the CPT code descriptors do not specify that clinical staff must perform RPM services, we also proposed to allow auxiliary personnel (which includes other individuals who are not clinical staff but are employees or leased or contracted employees) to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

When the PHE for COVID–19 ends, we again will require that RPM services be furnished only to an established patient. We believe that a physician or practitioner who has an established relationship with a patient would likely have had an opportunity to provide a new patient E/M service. During the new patient E/M service, the physician or practitioner would have collected relevant patient history and conducted a physical exam, as appropriate. As a result, the physician or practitioner would possess information needed to understand the current medical status and needs of the patient prior to ordering RPM services to collect and analyze the patient's physiologic data and to develop a treatment plan. Additionally, and in keeping with the CPT prefatory language for CPT codes 99453 and 99454, when the PHE for COVID–19 ends, we will once again require that 16 days of data be collected within 30 days to meet the requirements to bill CPT codes 99453 and 99454.

In response to the May 19, 2020 E.O. 13924, ''Regulatory Relief To Support Economic Recovery,'' (85 FR 31353 through 31356), we solicited comment from the medical community and other members of the public on whether

current RPM coding accurately and adequately describes the full range of clinical scenarios where RPM services may be of benefit to patients. We requested information that would help us to understand whether it would be beneficial to consider establishing coding and payment rules that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods. We expressed interest in understanding whether one or more codes that describe a shorter duration, for example, 8 or more days of remote monitoring within 30 days, might be useful. For example, CPT codes 99453 and 99454 currently require use of a medical device as defined by the FDA in section 201(h) of FFDCA that digitally collects and transmits 16 or more days of data every 30 days in order for the codes to be billed; however, some patients may not require remote monitoring for 16 or more days in a 30-day period. For some patients, continuous short-term monitoring might be more appropriate. For example, a post-surgical patient who is recovering at home might benefit from remote monitoring of his or her body temperature as a means of assessing infection and managing medications or dosage. In some clinical situations, monitoring several times throughout a day, over a period of 10 days, may be reasonable and necessary. Sixteen or more days might be unnecessary. We requested information that would help us to understand whether it would be beneficial to consider establishing coding and payment rules that would allow practitioners to bill and be paid for RPM services with shorter monitoring periods. Specifically, we were interested in understanding whether one or more codes that describe a shorter duration, for example, 8 or more days of remote monitoring within 30 days, might be useful. We welcomed comments including any additional information that the medical community and other members of the public believe might provide further clarification on how RPM services are used in clinical practice, and how they might be coded, billed, and valued under the Medicare PFS.

We received public comments on our clarifications and proposals related to digitally stored data services/remote physiologic monitoring/treatment management services. The following is a summary of comments we received and our responses.

Comment: Overall, commenters expressed appreciation and support for the clarifications proposed by CMS regarding RPM CPT codes 99453, 99454, 99091, and 99457 (and the add-on code, CPT code 99458).

Response: We thank commenters for their support, as well as for suggesting additional ways we might interpret the RPM codes. We hope to continue this dialogue as CPT creates more RPM codes.

Comment: A group of commenters disagreed with our clarification that CPT codes 99453, 99454, 99091, 99457, and 99458 can be ordered and billed only by physicians and NPPs who are eligible to bill Medicare for E/M services. Some commenters suggested that we allow the CPT Editorial Panel and the RUC to establish appropriate coding for other practitioners.

Response: We believe that as E/M codes, CPT codes 99453, 99454, 99091, 99457, and 99458, can be ordered and billed only by physicians or NPPs who are eligible to bill Medicare for E/M services. We agree with commenters that additional coding would be necessary, specifically for practitioners who cannot order and bill E/M services.

Comment: Commenters disagreed with our suggestion that CPT codes 99091 and 99457 can be billed together. Commenters reported that these two codes are incompatible and cannot be reported in the same calendar month or in conjunction with one another.

Response: We continue to believe that, if reasonable and necessary, CPT codes 99091 (*Collection & interpretation physiologic data*) and 99457 (*Remote physiologic monitoring treatment management*), given their descriptions of services in the CPT Codebook, could be reported for the same patient. We believe the two codes, as currently described, provide different types of services. We agree with commenters that the CPT Codebook states on page 53, ''Do not report 99091 in conjunction with 99457.'' However, the next section states, ''Do not report 99091 for time in a calendar month when used to meet the criteria for 99339, 99340, 99374, 99375, 99377, 99378, 99379, 99380, 99457, and 99491.'' We note that these two statements suggest that there may be instances where both codes could be billed for the same patient in the same month as long as the same time was not used to meet the criteria for both CPT codes 99091 and 99457. We remind readers that the valuation for CPT code 99091 includes a total time of 40 minutes of physician or NPP work broken down as follows: 5 minutes of pre-service work (for example, chart review); 30 minutes of intra-service work (for example, data analysis and interpretation, report based upon the physiologic data, as well as a possible phone call to the patient); and 5 minutes of post-service work (that is, chart documentation). We believe that in some instances when complex data are collected, more time devoted exclusively to data analysis and interpretation by a physician or NPP may be necessary such that the criteria could be met to bill for both CPT codes 99091 and 99457 within a 30-day period. The medically necessary services associated with all the medical devices for a single patient can be billed by only one practitioner, only once per patient per 30-day period, and only when at least 16 days of data have been collected.

Comment: Commenters suggested that other devices that do not meet the FDA's definition of medical device, but collect physiologic data, should satisfy the requirements of RPM services.

Response: We disagree with the commenters. The prefatory language and code descriptors developed by the CPT Editorial Panel indicate the device must meet the FDA definition of a medical device as found in section 201(h) of the FFDCA.

Comment: One commenter stated that a coding gap exists between physiologic and non-physiologic remote monitoring and stated that additional coding is required for non-physiologic parameters.

Response: We thank the commenter for this insight. We look forward to engaging with stakeholders on this topic to inform how we might consider a ''coding gap'' that exists for services related to remote monitoring for non-physiologic measures of health.

Comment: Several commenters suggested that CMS should allow RPM services to be furnished to new patients, as well as to established patients. Other commenters supported our decision to require that patients be known to the practitioner (established patients) prior to the start of RPM services.

Response: We continue to believe that a physician or NPP who has an established relationship with a patient would possess the information needed to understand the current medical status and needs of the patient prior to ordering RPM services to collect and analyze the patient's physiologic data and to develop a treatment plan. We note that during the PHE for COVID–19, RPM services may be furnished and billed for both new and established patients. We refer readers to the March 31st COVID–19 IFC (85 FR 19264) where we adopted the policy on an interim basis for the duration of the PHE for COVID–19 that RPM services could be furnished to new patients as well as established patients.

After considering public comments, we are not extending this interim policy beyond the end of the PHE for COVID–19. At the conclusion of the PHE, there will need to be an established patient-practitioner relationship in order to bill Medicare for CPT codes 99453, 99454, 99457, and 99458.

Comment: Some commenters suggested that we permit fewer than the required 16 days of monitoring per month that are required to bill CPT codes 99453 and 99454. One commenter indicated that patients and health care personnel are served best by a maximum data collection requirement of 6 days. Another commenter stated that the 8 days we suggested would be best. Another commenter suggested that at least 16 days of data should be required, and when 16 days of data are not collected within the 30-day period, that a modifier should be reported as a means of communicating that the service duration was reduced with an associated reduction in payment.

Response: While we agree that a full 16 days of monitoring may not always be reasonable and necessary, we requested detailed information about meaningful, clinical situations that require fewer days or shorter durations of remote monitoring. We were interested in understanding under what clinical circumstances fewer days of monitoring would be medically reasonable and necessary and allow a practitioner to establish clinically meaningful care. Although we received general support for a reduction in the number of days of data collection required to bill for CPT codes 99453 and 99454, we did not receive specific clinical examples.

After considering public comments, we are not extending the interim policy to permit billing for CPT codes 99453 and 99454 for fewer than 16 days in a 30-day period beyond the end of the PHE for COVID–19. At the conclusion of the PHE for COVID–19, we will require, in accordance with the code descriptors for CPT codes 99453 and 99454, that 16 days of data each 30 days must be collected and transmitted to meet the requirements to bill CPT codes 99453 and 99454.

Comment: A few commenters requested that Independent Diagnostic Testing Facilities (IDTFs) be allowed to bill for RPM services.

Response: As we noted in the proposed rule, RPM services are not considered to be diagnostic tests; therefore, RPM services cannot be furnished and billed by an IDTF on the order of a physician or NPP.

Comment: Commenters agreed with our clarification that practitioners should be allowed to furnish RPM services to patients with acute conditions, as well as patients with chronic conditions.

Response: We thank commenters for their support of our clarification that practitioners may furnish RPM services to patients with acute conditions, as well as patients with chronic conditions.

In the CY 2021 PFS proposed rule, we proposed to make permanent two policies that we adopted in the March 31st COVID–19 IFC (85 FR 19264). We received comments on our proposed policies. The following is a summary of the comments we received and our responses.

Comment: Commenters wrote in favor of our proposal to allow consent to be obtained at the time the services of CPT codes 99453 and 99454 are furnished.

Response: We thank our stakeholders for their comments and support of this proposal.

Comment: Commenters agreed with our proposal to allow auxiliary personnel to furnish the services of CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.

Response: We thank commenters for their support of this proposal.

After considering comments related to these two proposals, we are finalizing both as proposed.

3. Transitional Care Management (TCM)

Payment for TCM CPT codes 99495 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision-making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*) and 99496 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within seven calendar days of discharge*) was finalized in the CY 2013 PFS final rule (77 FR 68979 through 68993). At that time, we identified a list of 57 HCPCS codes (see 77 FR 68990 for the original guidance) that we stated could not be billed concurrently with TCM services because of potential duplication of services.

For CY 2020, recognizing that use of TCM services was low when compared to the number of Medicare beneficiaries with eligible discharges and that increased utilization of medically necessary TCM services could improve patient outcomes, one of our proposals included modifying our prior rule that prohibited the billing of TCM services with many other services that we had viewed as duplicative (77 FR 68990). In the CY 2020 PFS final rule (84 FR 62685 through 62687), we finalized a policy to allow concurrent billing of TCM services, when reasonable and necessary, with 16 actively priced (that is, not bundled or non-covered) codes during the 30-day period covered by TCM services. We stated at the time that we would continue to refine our billing policies for TCM through future notice and comment rulemaking.

In the CY 2021 PFS proposed rule (85 FR 50120), we proposed to remove 14 additional actively priced (not bundled or non-covered) HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM for CY 2021. We noted that we believe that no overlap exists that would warrant preventing concurrent reporting between TCM and the services of these 14 codes. We also proposed to allow the new Chronic Care Management code HCPCS code G2058 to be billed concurrently with TCM when reasonable and necessary. We stated that the minutes counted for TCM services cannot also be counted towards other services. Table 18 lists the 15 codes that we proposed could be billed concurrently with TCM services when reasonable and necessary. We welcomed comment on our proposal to allow these additional services to billed concurrently with the TCM service.

We received public comments on the TCM proposals. The following is a summary of the comments we received and our responses.

Comment: Commenters wrote in support of our proposal to allow HCPCS code G2058 to be billed concurrently with TCM when reasonable and necessary. Commenters agreed that time should not be double-counted, and that services should not overlap, but should be separately reportable.

Response: We thank the commenters for their support of our proposal to allow HCPCS code G2058 to be billed concurrently with TCM when reasonable and necessary.

Comment: Commenters stated that the services described by the 14 ESRD codes proposed for separate payment do not overlap or duplicate TCM services and should be paid separately when reasonable and necessary.

Response: We appreciate the support of commenters.

Comment: A few commenters disagreed with our proposal to allow the

ESRD codes and the chronic care management code HCPCS code G2058 to be billed concurrently with TCM. These commenters instead urged CMS to allow the RUC process and recommendations determine how these codes should be valued/revalued and reported, rather than having CMS apply a different approach.

Response: We recognize that some commenters would prefer that we follow the AMA RUC recommendations for code valuations and billing policies. We appreciate the work the AMA committees, and in particular the RUC, do to provide recommendations. We will continue to consider those recommendations along with other information when we develop values and payment policies under the PFS. We believe that allowing concurrent billing of TCM services with the proposed ESRD codes and HCPCS code G2058, when reasonable and necessary, can improve patient outcomes.

After considering the public comments, we are finalizing our proposal to remove 14 additional actively priced (not bundled or non-covered) HCPCS codes from the list of remaining HCPCS codes that cannot be billed concurrently with TCM for CY 2021. We also are finalizing our proposal to allow HCPCS code G2058 (which we are finalizing in this rule as new CPT code 99439, see the codes in section II.H. for further information) to be billed concurrently with TCM when reasonable and necessary.

TABLE 18: 15 Additional Codes That Could Be Billed Concurrently with TCM

Code Family	CPT Code	Descriptor
End Stage Renal Disease Services (for ages less than 2 months through 20+ years)	90951	ESRD related services with 4 or more face-to-face visits per month; for patients <2 years of age
	90954	ESRD related services with 4 or more face-to-face visits per month; for patients 2-11 years
	90955	ESRD related services with 2-3 face-to-face visits per month; for patients 2-11 years
	90956	ESRD related services with 1 face-to-face visit per month; for patients 2-11 years
	90957	ESRD related services with 4 or more face-to-face visits per month; for patients 12-19 years
	90958	ESRD related services with 2-3 face-to-face visits per month; for patients 12-19 years
	90959	ESRD related services with 1 face-to-face visit per month; for patients 12-19 years
	90963	ESRD related services for home dialysis per full month; for patients <2 years of age
	90964	ESRD related services for home dialysis per full month; for patients 2-11 years
	90965	ESRD related services for home dialysis per full month; for patients 12-19 years
	90966	ESRD related services for home dialysis per full month; for patients 20 years and older
	90967	ESRD related services for dialysis less than a full month of service; per day; for patients <2 years of age
	90968	ESRD related services for dialysis less than a full month of service; per day; for patients 2-11 years
	90969	ESRD related services for dialysis less than a full month of service; per day; for patients 12-19 years
Complex Chronic Care Management Services	HCPCS G2058 (Beginning CY 2021, CPT code 99439)	Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month

4. Psychiatric Collaborative Care Model (CoCM) Services (HCPCS Code G2214)

In the CY 2017 PFS final rule (81 FR 80230), we established G-codes used to bill for monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. These G-codes were replaced by CPT codes 99492–99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077).

Stakeholders have requested additional coding to capture shorter increments of time spent, for example, when a patient is seen for services, but is then hospitalized or referred for specialized care, and the number of minutes required to bill for services using the current coding is not met. To accurately account for these resources costs, in the CY 2021 PFS proposed rule (85 FR 50121), we proposed to establish a G-code to describe 30 minutes of behavioral health care manager time. Since this code would describe one half of the time described by the existing code that describes subsequent months

of CoCM services, we proposed to price this code based on one half the work and direct PE inputs for CPT code 99493 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements):*

- Tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant;
- Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health practitioners;
- Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;
- Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;
- Monitoring of patient outcomes using validated rating scales; and
- Relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.), which is assigned a work RVU of 1.53.

Therefore, as proposed, the work RVU for the new proposed code is 0.77. We proposed that this code could be used for either the initial month or subsequent months. We noted that the existing CPT time rules for the CoCM services would apply. As proposed, the code would be:

- *GCOL1:* Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional.

We proposed that the required elements listed for CPT code 99493 would also be required elements for billing HCPCS cod GCOL1. Additionally, we proposed that CPT time rules would apply, consistent with the guidance in the CPT codebook for CPT codes 99492–99494.

In the CY 2017 PFS final rule (81 FR 80235), we finalized that CCM and BHI services could be billed during the same month for the same beneficiary if all the requirements to bill each service are separately met. We also proposed that HCPCS code GCOL1 could be billed during the same month as CCM and TCM services, provided that all requirements to report each service are met and time and effort are not counted more than once. We noted that the patient consent requirement would apply to each service independently.

In the CY 2017 PFS final rule (81 FR 80235), we finalized that the psychiatric CoCM services may be furnished under general supervision because we do not believe it is clinically necessary that the professionals on the team who provide services other than the treating practitioner (namely, the behavioral health care manager and the psychiatric consultant) must have the billing practitioner immediately available to them at all times, as would be required under a higher level of supervision. Therefore, consistent with the other codes in this code family (CPT codes 99492–99494), we proposed to add HCPCS code GCOL1 to the list of designated care management services for which we allow general supervision.

We welcomed comments on the proposal to create this new code, as well as the proposed valuation.

We received public comments on the CoCM services (HCPCS code GCOL1) proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the creation of a new code to describe a shorter duration of time than is captured by the existing codes describing the psychiatric collaborative care model, noting that this will provide greater flexibility, remove barriers, and encourage further adoption of this model of care. One commenter opposed implementing this code without obtaining further evidence that it is warranted, while another commenter encouraged CMS to work with the CPT Editorial Panel to create a CPT code that would be available for billing by all payers. One commenter urged CMS to eliminate the copayment and deductible for CoCM and other care management services.

Response: We note that we do not have the statutory authority to remove application of the copayment or deductible for these services. After considering the public comments, we are finalizing the creation of HCPCS code GCOL1 as proposed. We note that HCPCS GCOL1 was a placeholder code identifier. The final code is HCPCS code G2214 (*Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional*). We welcome the opportunity to work with the CPT Editorial Panel in the event they are interested in adopting this code into the CPT code set.

F. Refinements to Values for Certain Services To Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability During the PHE for COVID–19

1. Background

a. Evaluation and Management (E/M) Visits Overview

Physicians and other practitioners who are paid under the PFS bill for common office visits for E/M visits using a relatively generic set of CPT codes (Level I HCPCS codes) that distinguish visits based on the level of complexity, site of service, and whether the patient is new or established. These CPT codes are broadly referred to as E/M visit codes and historically have included three key components within their code descriptors: History of present illness (history), physical examination (exam), and medical decision-making (MDM).[4]

Currently, there are five levels of O/O E/M visits. There are five codes representing each level for new patients (CPT codes 99201 through 99205), and five codes representing each level for established patients (CPT codes 99211 through 99215). CPT code 99211 (*Level 1 established patient*) is the only code in the O/O E/M visit code set that describes a visit that may be performed by the billing practitioner or by clinical staff under supervision, and that has no specified history, exam or MDM (see Table 19).

In total, E/M visits billed using these CPT codes comprise approximately 40 percent of allowed charges for PFS services; and O/O E/M visits, in particular, comprise approximately 20 percent of allowed charges for PFS services. Within the E/M visits represented in these percentages, there is wide variation in the volume and level of E/M visits billed by different specialties. According to Medicare claims data, E/M visits are furnished by nearly all specialties, but represent a greater share of total allowed charges for physicians and other practitioners who do not routinely furnish procedural interventions or diagnostic tests.

[4] 2019 CPT Codebook, Evaluation and Management, pages 6 through 13.

Generally, these practitioners include primary care practitioners and certain other specialists such as neurologists, endocrinologists and rheumatologists. Certain specialties, such as podiatry, tend to furnish lower level E/M visits more often than higher level E/M visits. Some specialties, such as dermatology, tend to bill more E/M visits on the same day as they bill minor procedures.

b. Overview of Policies Finalized in CY 2020 for CY 2021

In the CY 2020 PFS final rule (84 FR 62844 through 62860), for the O/O E/M visit code set (CPT codes 99201 through 99215), we finalized a policy to generally adopt the new coding, prefatory language, and interpretive guidance framework that has been issued by the AMA's CPT Editorial Panel (see *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*) and will be effective January 1, 2021. Under this new CPT coding framework, history and exam will no longer be used to select the level of code for O/O E/M visits. Instead, an O/O E/M visit will include a medically appropriate history and exam, when performed. The clinically outdated system for number of body systems/areas reviewed and examined under history and exam will no longer apply, and the history and exam components will only be performed when, and to the extent, reasonable and necessary, and clinically appropriate.

The changes will include deletion of CPT code 99201 *(Level 1 office/outpatient visit, new patient*), which the CPT Editorial Panel decided to eliminate because CPT codes 99201 and 99202 are both straightforward MDM and currently largely differentiated by history and exam elements. Table 19 provides an overview of how the level 1 and level 2 O/O E/M visits are currently structured, demonstrating this current overlap.

TABLE 19: Overview of Levels 1 and 2 Office/Outpatient E/M Visits, CY 2020

CPT Code	Service Overview
CPT code 99201 (level 1 new patient)	• Problem-focused history and exam • Straightforward medical decision-making • Typically 10 minutes face-to-face, presenting problem(s) usually self-limited or minor
CPT code 99202 (level 2 new patient)	• Expanded problem-focused history and exam • Straightforward medical decision-making • Typically 20 minutes face-to-face, presenting problem(s) usually of low to moderate severity
CPT code 99211 (level 1 established patient)	• Evaluation and management that may not require the presence of a physician or other qualified healthcare professional • Typically 5 minutes are spent performing or supervising these services, presenting problem(s) usually minimal
CPT code 99212 (level 2 established patient)	• Problem-focused history and exam • Straightforward medical decision-making • Typically 10 minutes face-to-face, presenting problem(s) usually self-limited or minor

For levels 2 through 5 O/O E/M visits, selection of the code level to report will be based on either the level of MDM (as redefined in the new AMA/CPT guidance framework, also available on the AMA website at *https://www.ama-assn.org/practice-management/cpt/cpt-evaluation-and-management*) or the total time personally spent by the reporting practitioner on the day of the visit (including face-to-face and non-face-to-face time). We continue to believe these policies will further our ongoing effort to reduce administrative burden, improve payment accuracy, and update the O/O E/M visit code set to better reflect the current practice of medicine.

Regarding prolonged visits, we finalized separate payment for a new prolonged visit add-on CPT code (CPT code 99XXX), and discontinued the use of CPT codes 99358 and 99359 (*prolonged E/M visit without direct patient contact*) to report prolonged time associated with O/O E/M visits. We refer readers to the CY 2020 PFS final rule for a detailed discussion of this policy (84 FR 62849 through 62850). We are not opposed in concept to reporting prolonged office/outpatient visit time on a date other than the visit, but we believe there should be a single prolonged code specific to O/O E/M visits that encompasses all related time.

Also, we finalized separate payment for HCPCS code GPC1X, to provide payment for visit complexity inherent to E/M associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition, or a complex condition.

The AMA RUC resurveyed and revalued the revised O/O E/M visit code set, concurrent with the CPT Editorial Panel redefining the services and associated interpretive guidance, and provided us with its recommendations. In the CY 2020 PFS final rule, we also addressed and responded to the AMA RUC recommendations. We finalized new values for CPT codes 99202 through 99215, and assigned RVUs to the new O/O E/M prolonged visit CPT code 99XXX, as well as the new HCPCS code GPC1X. These valuations were finalized with an effective date of January 1, 2021. In Table 20, we provide a summary of the codes and work RVUs finalized in the CY 2020 PFS final rule for CY 2021.

TABLE 20: Summary of Codes and Work RVUs Finalized in the CY 2020 PFS Final Rule for CY 2021

HCPCS Code	Current Total Time (mins)	Current Work RVU	CY 2021 Total Time (mins)	CY 2021 Work RVU
99201	17	0.48	N/A	N/A
99202	22	0.93	22	0.93
99203	29	1.42	40	1.6
99204	45	2.43	60	2.6
99205	67	3.17	85	3.5
99211	7	0.18	7	0.18
99212	16	0.48	18	0.7
99213	23	0.97	30	1.3
99214	40	1.5	49	1.92
99215	55	2.11	70	2.8
G2212	N/A	N/A	15	0.61
G2211	N/A	N/A	11	0.33

c. Continuing Stakeholder Feedback

Since issuing the CY 2020 PFS final rule, we have continued to engage with the stakeholder community on the issues addressed in this section of our CY 2021 PFS final rule. These include the time values for levels 2–5 O/O E/M visit codes, revaluation of services that are analogous to O/O E/M visits, the definition and utilization assumptions for the add-on code for office/outpatient visit complexity (GPC1X), and the required time to report prolonged O/O E/M visits. In the CY 2021 PFS proposed rule (85 FR 50121 through 50139), we included proposals on these topics based on continued feedback from stakeholders in the form of public comments, written requests, meetings, and other formal and informal discussions. In this section of our final rule, we summarize and respond to the public comments we received in response to our CY 2021 PFS proposals, and discuss our final polices.

2. Revisions for CY 2021

a. Time Values for Levels 2–5 Office/Outpatient E/M Visit Codes

In the CY 2020 PFS proposed rule (84 FR 40675), we sought comment on the times associated with the O/O E/M visits as recommended by the AMA RUC. When surveying these services for purposes of valuation, the AMA RUC requested that survey respondents consider the total time spent on the day of the visit, as well as any pre- and post-service time occurring within a timeframe of 3 days prior to the visit and 7 days after, respectively. In developing its recommendations to us, the AMA RUC then separately averaged the survey results for pre-service, day of service, and post-service times, and the survey results for total time, with the result that, for some of the codes, the sum of the times associated with the three service periods does not match the RUC-recommended total time. The approach used by the AMA RUC to develop recommendations sometimes resulted in two conflicting sets of times: The component times as surveyed and the total time as surveyed. In the CY 2020 PFS final rule, we finalized adoption of the RUC-recommended times as explained below, but stated that we would continue to consider whether this issue has implications for the PFS broadly. When we establish pre-, intra-, and post-service times for a service under the PFS, these times always sum to the total time. We believe it would be illogical for component times not to sum to the total, and this idea is reflected in our ratesetting system, which requires component times to sum to the total time. Commenters on the CY 2020 PFS proposed rule (84 FR 62849) stated that we should adopt the times as recommended by the RUC, and did not provide any additional details on the times they believed we should use when the total time is not the sum of the component times. Table 21 illustrates the AMA RUC surveyed times for each service period and the surveyed total time. It also shows the actual total time calculated as the sum of the component times.

TABLE 21: RUC-Recommended Pre-, Intra-, Post-Service Times, RUC-Recommended Total Times for CPT codes 99202-99215 and Actual Total Time

HCPCS	Pre-Service Time	Intra-Service Time	Immediate Post-Service Time	Actual Total Time	RUC-recommended Total Time
99202	2	15	3	20	22
99203	5	25	5	35	40
99204	10	40	10	60	60
99205	14	59	15	88	85
99211		5	2	7	7
99212	2	11	3	16	18
99213	5	20	5	30	30
99214	7	30	10	47	49
99215	10	45	15	70	70

Given the lack of clarity provided by commenters on the CY 2020 PFS proposed rule about why the sum of minutes in the components would differ from the total minutes, and our view and systems requirement that total time must equal the mathematical total of component times, we proposed beginning in CY 2021 to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215. The following is a summary of the comments we received and our responses.

Comment: Some commenters did not support our proposal to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215. These commenters further stated, if we were to use the sum of the component times instead of the RUC-recommended median total time, that we would not be appropriately capturing the physician time for the office visits, which were based on a robust survey, if we were to use the sum of the component times instead of the RUC recommended median total time.

One commenter suggested that the median survey total time for the office visits should be utilized to retain relativity. The commenter explained that, while total time is usually a sum of the pre-, intra- and immediate post-service time, for purposes of the office visit survey, the pre-service time was described as 3 calendar days prior to the office visit, the intra-service time was described as the calendar day of the office visit and the post-service time was described as within 7 days following the office visit. The commenter stated that the median survey total time will not necessarily equal the sum of the median times for each of the 3 time periods because of different practitioner workflow patterns that result in different proportions of the practitioners' times being spent in different components of the service. However, the total times as recommended by the RUC accurately capture the time associated with furnishing the service, regardless of whether that work was performed on the date of encounter or other dates surrounding the office visit. The commenter also suggested that the median of the component times was mathematically more appropriate than the median of the total times, because the function of a median is to limit the influence of outlier values.

Some commenters supported our proposal, stating that the RUC's survey methodology, which included collection of time before and after the day of the encounter, resulted in an overestimation of time and work, and that the total time in the CMS work time database should reflect the sum of the pre-, intra-, and post-times collected using the RUC survey. This methodology is consistent with the total times for all other codes in the fee schedule.

Response: We continue to believe that it would be illogical for component times not to sum to the total, and we reiterate that our ratesetting programs are constructed in a manner that assumes this. While we recognize the value of robust survey data, for purposes of consistency and relativity, we believe we should use a consistent methodology across the fee schedule. Also it is not clear why the RUC surveyed time before and after the date of service since the new CPT coding guidance instructs practitioners to report this time using CPT codes 99358 and 99359 (although CMS will no longer recognize 99358–99359 for this purpose, for reasons discussed elsewhere in this section). Having considered the public comments received, we are finalizing our proposal to adopt the actual total times (defined as the sum of the component times) rather than the total times recommended by the RUC for CPT codes 99202 through 99215.

b. Revaluing Services That Are Analogous to Office/Outpatient E/M Visits

In our proposed rule, we recognized that there are services other than the global surgical codes for which the values are closely tied to the values of the O/O E/M visit codes. We proposed to increase the valuations for these services commensurate with the valuation increases we previously finalized for the O/O E/M visit codes for 2021. Our proposals took into account input from the public (especially our 2020 comment solicitation on this topic) and our own internal review. We proposed to increase valuations for the following:

- End-Stage Renal Disease Monthly Capitation Payment (ESRD MCP) services.
- Transitional care management (TCM) services.
- Maternity services.
- Cognitive impairment assessment and care planning.
- Annual wellness visits (AWV) and initial preventive physical exam (IPPE).
- Emergency department (ED) visits.
- Therapy evaluations.
- Certain behavioral healthcare services.

Many of these services were valued via a building block methodology and have O/O E/M visits explicitly built into their definition or valuation. We noted that, unlike the global surgical codes, some of these services always include an O/O E/M visit(s) furnished by the reporting practitioner as part of the service, and therefore, it may be appropriate to adjust their valuations commensurate with any changes made to the values for O/O E/M visits. Some of these services do not actually include an E/M visit, but we valued them using a direct crosswalk to the RVUs assigned to an O/O E/M visit(s), and for this

reason they are closely tied to values for O/O E/M visits. Overall, we believed that the magnitude of the changes to the values of the O/O E/M visit codes and the associated redefinitions of the codes themselves are significant enough to warrant an assessment of the accuracy of the values of services containing, or closely analogous to, O/O E/M visits.

We received public comments in response to the CY 2020 PFS proposed rule in support of revaluing certain services commensurate with the new O/O E/M visit values. There was particular support from commenters for revaluing the ESRD (MCP) services, TCM services, cognitive impairment assessment and care planning services, and the (ED) visits. Based on input provided after publication of the CY 2020 PFS final rule by the American College of Obstetricians and Gynecologists (ACOG), we also proposed to revalue the maternity surgical packages, which, unlike other global surgery services, were valued using a methodology, described in more detail below, that allowed the valuation of the composite parts of the package to sum to the total value. Additionally, unlike the 10- and 90-day global surgical services codes (referred to in this section as 10- and 90-day globals), we had never expressed concerns as to the accuracy of the values of the maternity packages, and these services were not part of the policy we adopted to transition all 10- and 90- day globals to 0-day globals (79 FR 67591), though that policy was overridden by statutory amendments before it took effect. We also proposed to revalue certain physical therapy evaluations and behavioral healthcare services as closely analogous to the office/outpatient E/M visits. We did not propose to revalue certain ophthalmology services that the public brought to our attention.

In general, some commenters to the CY 2021 PFS proposed rule indicated that they believe CMS used inconsistent methodologies to revise the proposed RVUs to reflect the marginal increase in office/outpatient E/M visits; that other code sets should go through the same consensus process whereby CMS, CPT and the AMA RUC all agree that the services need to be redefined to better describe existing practice and then be revalued; and that CMS should increase all of the global surgical codes if any single global code is increased to reflect changes to the office/outpatient E/M visits. Other commenters agreed with our proposals and methodologies, and a few suggested additional services that should be revalued as analogous to office/outpatient E/M visits. In the following section of our final rule, we discuss the public comments we received in greater detail, respond to the comments and discuss our final policies. By way of overview, we note that we did not rely on any single factor in deciding whether to consider a given code(s) as analogous to office/outpatient E/M visits. Different factors apply to different services, and we took into consideration all of the factors relevant for the code(s) in question, considered together.

(1) End-Stage Renal Disease Monthly Capitation Payment Services

In the CY 2004 PFS final rule with comment period (68 FR 63216), we established new Level II HCPCS G codes for ESRD services and established MCP rates for them as specified under section 1881(b)(3)(A)(ii) of the Act. For ESRD center-based patients, payment for the G codes varied based on the age of the beneficiary and the number of face-to-face visits furnished each month (for example, 1 visit, 2–3 visits and 4 or more visits). We believed that many physicians would provide 4 or more visits to center-based ESRD patients, and a small proportion would provide 2 to 3 visits or only one visit per month. Under the MCP methodology, to receive the highest payment, a physician would have to furnish at least 4 ESRD-related visits per month. In contrast, payment for home dialysis MCP services only varied by the age of beneficiary. Although we did not initially specify a frequency of required visits for home dialysis MCP services, we stated that we expect physicians to provide clinically appropriate care to manage the home dialysis patient.

The CPT Editorial Panel created new CPT codes to replace the G codes for monthly ESRD-related services, and we finalized the new codes for use under the PFS in CY 2009 (73 FR 69898). The codes created were CPT codes 90951 through 90962 for monthly ESRD-related services with a specified number of visits; CPT codes 90963 through 90966 for monthly ESRD-related services for home dialysis patients; and CPT codes 90967 through 90970 for home dialysis patients with less than a full month of services. The latter set of codes is billed per encounter and valued to be 1/30 of the value of CPT codes 90965 and 90966.

In response to our comment solicitation in the CY 2020 PFS final rule and interim final rule regarding whether to adjust the values of the ESRD MCP codes to reflect the increased values of the office/outpatient E/M visit codes, we received a number of supportive comments. These commenters stated that the MCP bundled payments for all ESRD-related care for a month were constructed using a building block methodology and a number of office/outpatient E/M visits were component parts of those bundles; and that the specified number of visits in the code descriptor must be furnished in order to bill for the service. Commenters also noted that although the values of office/outpatient E/M visit codes have been increased once since the creation of the MCP G codes and once after adoption of the MCP CPT codes, the valuation of the ESRD MCP codes was never adjusted to account for increases to the office/outpatient E/M visit codes. In Table 22, we provide a summary of the visits included in the valuation of each ESRD MCP service.

TABLE 22: Number and Level of Office/Outpatient E/M Visits Bundled into the ESRD MCP Services

HCPCS	Short Descriptor	Bundled Office/Outpatient visit(s)
90951	Esrd serv 4 visits p mo <2yr	13x 99214
90954	Esrd serv 4 vsts p mo 2-11	Crosswalked to CPT code 99471
90955	Esrd srv 2-3 vsts p mo 2-11	1x 99215
		2x 99214
90956	Esrd srv 1 visit p mo 2-11	1x 99215
90957	Esrd srv 4 vsts p mo 12-19	1x 99215
		3x 99214
		3x 99213
90958	Esrd srv 2-3 vsts p mo 12-19	1x 99215
		2x 99214
90959	Esrd serv 1 vst p mo 12-19	1x 99215
90960	Esrd srv 4 visits p mo 20+	1x 99213
		3x 99214
90961	Esrd srv 2-3 vsts p mo 20+	3x 99214
90962	Esrd serv 1 visit p mo 20+	1x 99214
90963	Esrd home pt serv p mo <2yrs	1x 99215
		2x 99214
90964	Esrd home pt serv p mo 2-11	1x 99215
		1x 99214
90965	Esrd home pt serv p mo 12-19	1x 99215
		1x 99214
90966	Esrd home pt serv p mo 20+	3x 99214
90968	Esrd svc pr day pt 2-11	RVU of 90964/30
90969	Esrd svc pr day pt 12-19	RVU of 90965/30
90970	Esrd svc pr day pt 20+	RVU of 90966/30

In the past, we have not updated the valuation of this code set to reflect updates to the valuation of the office/outpatient E/M visit code set, and we do not have information on the number and level of visits actually furnished in connection with these services. So over time, the values of the ESRD MCP codes may have become out of step with valuation of their constituent visits. We believe there is sufficient reason to revalue these services to take into account the changes in valuation for the office/outpatient E/M visits. These services were initially valued using a building block methodology that summed the value of the individual service from its components, and for some of the codes in this code set, a specified number of visits must be furnished in order to bill for the respective ESRD MCP code because they are included in the code descriptor.

Therefore, we noted that we believe that the ESRD MCP codes should be updated to more accurately account for the associated office/outpatient E/M visits. We proposed to increase the work, physician time, and PE inputs in the form of clinical staff time of the ESRD MCP codes based on the marginal difference between the 2020 and 2021 office/outpatient E/M visit work, physician time, and PE inputs built into each code, as summarized in Tables 23 and 24. By improving payment accuracy for the ESRD MCP codes, we would also be supporting broader efforts at advancing kidney health.[5] We noted that we believe the majority of the visits included in the ESRD MCP bundles are being furnished, but sought comment on whether there are instances where the number and/or level of visits being furnished are not consistent with the number and level of visits built into the valuation of the code. The following is a summary of the comments we received and our responses.

Comment: One commenter noted that CMS inadvertently indicated a proposed work RVU of 8.04 for CPT code 90966 in in Table 19 in the CY 2021 PFS proposed rule (85 FR 50129). The commenter urged CMS to finalize a work RVU of 8.04 for this code to help eliminate structural barriers the commenter believes exist to home dialysis, and relieve the disparity in modality choice, as home dialysis receives a low RVU remuneration compared to in-center hemodialysis. Another commenter stated that the work RVU published in Addendum B of the proposed rule, 5.52, is the more accurate value.

Response: We regret the drafting error, and we reiterate that we did indeed propose a work RVU of 5.52 for CPT code 90966 as reflected in Addendum B. While we appreciate the concerns regarding access to care, we agree with comments stating that the proposed work RVU of 5.52 is the more accurate value.

Comment: Some commenters supported our proposal to increase the value of these services in light of previous changes to the E/M visit values. However, some commenters did not support increases to these code values absent a formal review, stating that it would be inconsistent to consider increasing values for some services and not others that are closely tied to the values of the office/outpatient E/M visit codes and/or codes that have E/M visits explicitly built into their definition or valuation, and that these codes should be subject to the same process for other potentially misvalued services. One

[5] HHS Launches President Trump's 'Advancing American Kidney Health' Initiative: *https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html.*

commenter disapproved of our proposed increasing the rates for these services, and stated that not all of the ESRD-related service CPT codes 90951–90962 were valued with a building block methodology of discrete E/M services. These commenters stated that CPT code 90951 was valued using magnitude estimation with a crosswalk to CPT code 99295, while CPT code 90954 was valued with a crosswalk to CPT code 99293. The commenters noted that both CPT code 99293 and 99295 have since been deleted. The commenters further stated that for the rest of the ESRD codes, the numbers and levels of visits were not determined based on surveys that led to use of the building block methodology; rather, they were negotiated using magnitude estimation in comparison to the two codes, CPT codes 99295 and 99293.

Response: Commenters are incorrect as to the methodology used to value CPT code 90951 in the proposed rule (as summarized in Table 22). We adopted the RUC recommended value for this service, which included the value of 13 instances of CPT code 99214 in the bundle. It was not valued using a crosswalk. However, we continue to believe it is accurate to consider these services as being among those for which values are closely tied to the values of the office/outpatient E/M visit codes. The ESRD MCP codes have numbers of visits explicitly built into their definitions, the majority of which we believe are taking place. Proportionate increases for these two codes will also maintain the relative relationships among the codes in this family.

We agree with commenters that CPT code 90954, this code was initially valued based on a crosswalk to CPT code 99293. When CPT code 99293 was deleted, it was replaced by CPT code 99471. By crosswalking CPT code 90954 to CPT code 99471, the relationship established between the two services is preserved. The public may nominate any code(s) as potentially misvalued through the usual misvalued code process or request resurvey or valuation through the AMA RUC.

We did not receive responses to our request for comments on whether there are instances where the number and level of visits actually furnished by practitioners reporting the ESRD MCP services differs from the number and level assumed in the valuation.For example, as shown in Table 22, the valuations included specified numbers and levels of office/outpatient E/M visits, but because the descriptors do not require the same level and number of visits to be furnished in order to report the services, the office/outpatient E/M visit resources assumed to be included in the ESRD services might not actually be expended. CPT code 90957 (*End-stage renal disease (ESRD) related services monthly, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month*) was valued with 1x 99215, 3x 99214, and 3x 99213. However, CPT code 90957 includes four or more visits of unspecified levels. Similar to the global surgical codes, this might suggest that we should not ''transfer'' the increase in valuation of the stand-alone office/outpatient E/M visits into these ESRD bundles. Unlike TCM, the number and level of visit included in the ESRD service valuations does not necessarily match the actual services furnished and billed. We continue to be concerned that the number and level of visits built into the valuation of these codes may not accurately reflect the number and level of visits actually being furnished, such that they may be misvalued. We may consider this issue through future rulemaking, as we have for the global surgical codes. However, we still believe the ESRD MCP codes are different from the global surgical codes in that they are valued using building block and involve largely medical care rather than procedural care. The ESRD monthly services include ongoing medical management of a chronic condition, which makes them more similar to the kind of work typically furnished and billed as office/outpatient E/M visits. Therefore, we continue to believe that the ESRD MCP services' valuation should be increased commensurate with the changes made to the values for office/outpatient E/M visits at this time as was proposed, and we are finalizing as proposed.

2. TCM Services (CPT Codes 99495 and 99496)

The goal of TCM services is to improve the health outcomes of patients recently discharged from inpatient and certain outpatient facility stays. We began making separate payment for TCM services in CY 2013. At that time, CPT code 99495 (*Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*) was valued to include one, level 4 established patient office/outpatient visit, while CPT code 99496 (*Transitional Care Management Services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver with 2 business days of discharge; medical decision making of high complexity during the service period; face-to-face visit within 7 calendar days of discharge*) was valued to include one, level 5 established patient office/outpatient visit (77 FR 68991). In the CY 2020 PFS final rule (84 FR 62687), we finalized the RUC-recommended work and direct PE inputs for the TCM codes which resulted in small RVU increases for both codes.

Because both TCM codes include a required face-to-face E/M visit (either a level 4 or 5 office/outpatient E/M visit), we proposed to increase the work RVUs associated with the TCM codes directly to the new valuations for the level 4 (CPT code 99214) and level 5 (CPT code 99215) office/outpatient E/M visits for established patients. Please see Tables 23 and 24 for long descriptors, as well as current and final work RVUs, physician time, and clinical staff time, for the TCM codes.

Comment: We received several comments specific to TCM, all in support of our proposal to revalue the TCM codes, although they did not provide specific rationale.

Response: We continue to believe that the values for services that explicitly include a single E/M visit of a given setting and level, and that were valued using a direct crosswalk to that visit, should be increased to reflect the new values for the included E/M visit. At this time, we are finalizing our proposed revised values for the two TCM codes shown in Table 23.

3. Maternity Services

In the CY 2002 PFS final rule with comment period (66 FR 55392–55393), we finalized separate global payment for maternity care services. The maternity packages are unique within the PFS in that they are the only global codes that provide a single payment for almost 12 months of services, including visits and other medical care, delivery services (that may include surgical services), and imaging; and were valued using a building-block methodology as opposed to the magnitude estimation method that is commonly used to value the 10- and 90-day global services. Seventeen CPT codes are used to bill for delivery, antepartum, and postpartum maternity care services, and these codes are all designated with a unique global period indicator ''MMM.''

For CY 2021, the AMA RUC made a recommendation to revalue these services, along with their recommendations to revalue the 10- and 90- day global surgical packages, to account for increases in the values of office/outpatient E/M visits. In the CY 2020 PFS final rule, we decided not to make changes to the valuation of 10- and 90- day global surgical packages to reflect changes made to values for the office/outpatient E/M visit codes while we continue to collect and analyze the data on the number and level of office/outpatient E/M visits that are actually being performed as part of these services.

The 10- and 90-day global surgical packages are commonly valued using a methodology known as magnitude estimation. Magnitude estimation refers to a methodology for valuing work that identifies the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS, without explicitly valuing the components of that work. Since its inception, the AMA RUC has worked under the prevailing assumption that magnitude estimation is the standard for valuation of all physicians' services, including those with global surgical packages. Consequently, the work values associated with expected typical E/M visits within a code's global period are not necessarily added to the physician work value for the code to determine the final work RVU. The postoperative visits in the 10- or 90-day global surgical code periods are often valued with reference to RVUs for separately-billed E/M visits, but the bundled post-operative visit RVUs do not directly contribute a certain number of RVUs to the valuation of the procedures.

In contrast, the MMM codes are unique in both the length of the global period and the methodology under which they were valued. When CMS established values for the maternity packages, we based them on RUC recommendations developed by the relevant specialty societies using the building block methodology. When it is used for a CPT code representing a bundle of services, the building block methodology components are the CPT codes that are considered to make up the bundled code and the inputs associated with those codes. Therefore, when the maternity packages were valued, the work (and other inputs) associated with the office/outpatient E/M visits in each package were explicitly included (along with values associated with imaging and other services in the package).

In addition, unlike the global surgical codes, we have reason to believe the visits included in the maternity codes are actually furnished given the evidence-based standards and professional guidelines for obstetrical care. For example, The *Guidelines for Perinatal Care* state that ''a woman with an uncomplicated first pregnancy is examined every 4 weeks for the first 28 weeks of gestation, every 2 weeks until 36 weeks of gestation, and weekly thereafter.''[6] For this reason, we excluded the maternity codes from our recent global surgery data collection.

Given the valuation methodology and expectations for office/outpatient E/M visits in the maternity package codes, and the revaluation recommendation developed by the AMA RUC, we believe that the maternity packages should be updated to more accurately reflect the values of the office/outpatient E/M visits included in the packages. We believe that, due to the use of the building block valuation methodology rather than magnitude estimation, and the likelihood that the bundled visits are actually being furnished, the valuations recommended to us by the AMA RUC more accurately reflect the resource costs associated with furnishing these services. In the past, the work, physician time, and PE for these services have not been revalued to reflect changes to the office/outpatient E/M visits that are included as part of the package and therefore, the valuation of the MMM surgical packages have become misaligned with the valuation of their constituent office visits.

When revaluing the maternity packages, the AMA RUC used a methodology similar to what we used when revaluing the ESRD MCP codes and TCM by adding in the marginal differences in work, physician time, and PE in the form of clinical staff time between the current and 2021 E/M values. We noted that we believe that this method accurately accounts for the increase in valuation relative to the office/outpatient E/M visits. Therefore, we proposed to increase the work RVUs, physician time, and PE inputs in the form of clinical staff time associated with the maternity packages by accepting the revaluation recommendation from the AMA RUC as detailed in Tables 23 and 24.

We also noted that, in addition to appropriately reflecting changes to values of the office and outpatient E/M visits, increases made to the valuation of the maternity package codes would be consistent with our broader focus on improving maternal health and birth outcomes. The proposed changes would account for additional resources involved with additional work that is needed on the part of practitioners to improve care for this patient population, such as risk identification and ensuring appropriate interventions and referrals.[7]

We received public comments on our proposal. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal regarding the global maternity codes. However, other commenters requested a fair and relative payment for maternity care codes and for all global codes, whether the value of the code is based on magnitude estimation, building block methodology, or a mix of both methodologies, not any subset of them using potentially disparate valuation methodologies. Some commenters stated that it is unfair to apply the RUC-recommended E/M value increases to stand-alone E/M visits, select global codes (for example, monthly end-stage renal disease (ESRD) and bundled maternity care), and select bundled services (for example, monthly psychiatric management), but not to the E/M visits that are included in the global surgical packages, and that this will disrupt the relativity of the MPFS.

Response: We continue to believe that the maternity global surgical packages are distinct from the 10- and 90-day globals for the reasons articulated above. We note that commenters did not provide any information to suggest that the number and level of visits accounted for in the valuation of these codes are not being performed. In addition, unlike the global surgical packages, the maternity packages (and the ESRD monthly services discussed above) are focused on ongoing, comprehensive medical care. This kind of care is similar to the type of care typically furnished and billed as office/outpatient E/M visits and, as such, makes the services analogous. Having considered the public comments we received, we are finalizing our proposal to revalue the maternity bundles as recommended by the AMA RUC.

[6] Kilpatrick SJ, Papile L, and Macones GA, eds. AAP Committee on Fetus and Newborn and ACOG Committee on Obstetric Practice. Guidelines for Perinatal Care. Eighth Edition. 2017. Page 150.

[7] *https://www.hhs.gov/blog/2020/01/29/achieving-better-health-mothers-and-babies.html*; *https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/21-Maternal-Health-Forum-Improving-Maternal-Health-for-Our-Communities.pdf*; *https://innovation.cms.gov/innovation-models/maternal-opioid-misuse-model*.

4. Assessment and Care Planning for Patients With Cognitive Impairment (CPT Code 99483)

In CY 2017, we established payment for HCPCS code G0505 (*Assessment and care planning for patients with cognitive impairment*) to provide payment for cognitive assessment and care planning for patients with cognitive impairments, believing that the CPT Editorial Panel was developing new coding for that service. In response to the CY 2017 PFS proposed rule, the AMA RUC submitted recommended values for this code, which we adopted in the CY 2017 PFS final rule. In CY 2018, the CPT Editorial Panel created CPT code 99483 for reporting of this service and in CY 2018, CMS adopted CPT code 99483 (deleting HCPCS code G0505) without changing the service valuation. Based upon input from commenters and the AMA RUC, the valuation of this service reflected the complexity involved in assessment and care planning for patients with cognitive impairment by including resource costs that are greater than the highest valued office/outpatient E/M visit (CPT code 99205, new patient level 5 visit) (81 FR 80352). Specifically, the service includes an evaluation of a patient's cognitive functioning and requires collecting pertinent history and current cognitive status all of which require medical decision making of moderate or high complexity.

With the forthcoming increased valuation for CPT code 99205 in CY 2021, we noted that the current work RVU for CPT code 99483 would have a lower work RVU than a new patient level 5 office/outpatient E/M visit. Given the way CPT code 99483 was valued initially, we noted that this valuation would create a rank order anomaly between the two codes. Since CPT code 99483 was valued in relation to a level 5 office/outpatient E/M new patient visit, we believed that an adjustment to the work, physician time, and PE for this service to reflect the marginal difference between the value of the level 5 new patient office/outpatient E/M visit in CY 2020 and CY 2021 would be appropriate to maintain payment accuracy. Therefore, we proposed to adjust the work, time, and PE in the form of clinical staff time for CPT code 99483 as shown in Tables 23 and 24. We used the ratio between the CY 2020 and CY 2021 values for the level 5 new patient office/outpatient visits and applied that ratio to increase the value of CPT code 99483 commensurate with the increase to CPT code 99205.

We received public comments on the Assessment and Care Planning for Patients with Cognitive Impairment (CPT code 99483). The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported our proposal to increase the valuation of CPT code 99483 in order to maintain the relationship between CPT code 99483 and the level 5 new patient office/outpatient visit, which was an important part of the initial valuation. Commenters stated that accurate payment for this service is essential for maintaining access to care for beneficiaries with cognitive impairment.

However, several commenters disagreed with our proposed revaluation of CPT code 99483. These commenters indicated that our proposed increase to CPT code 99483 would create a rank order anomaly between CPT codes 99205 and 99483. Commenters explained that the work RVU and time for code 99483 were based upon survey data and magnitude estimation. The RUC did not use any code as a crosswalk for valuation of CPT code 99483, and CPT code 99205 is not inherent to this service. Commenters suggested that in order to identify the relative valuation for the services of CPT code 99483, the code should be referred to the RUC for review.

Response: While we appreciate the additional insight into the valuation of these codes, we continue to believe that maintaining the value of CPT code 99483 at its current rate would create a rank order anomaly. This service comprises a stand-alone E/M visit that is always furnished; has most of the same components as CPT code 99205, including identical interpretive guidance for level of medical decision making; and was (and continues to appropriately be) valued in direct relation to CPT code 99205. While the cognitive assessment and care planning code was valued using magnitude estimation, these other factors provide additional support for continuing to reflect its exact relationship with the level 5 new patient office/outpatient visit. Therefore, we believe these services are sufficiently analogous to warrant preserving the same relationship. Members of the public can request that the RUC review certain code sets at any time. After consideration of the public comments, we are finalizing this proposal to revalue CPT code 99483 as proposed.

5. Initial Preventive Physical Examination (IPPE) and Initial and Subsequent Annual Wellness Visits (AWV)

In the CY 2011 PFS final rule with comment period, we finalized separate payment for HCPCS codes G0438 (*Annual wellness visit; includes a personalized prevention plan of service (pps), initial visit*) and G0439 (*Annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit*). These services were valued via a direct crosswalk to the work, time, and direct PE inputs associated with CPT codes 99204 and 99214, respectively. In that same rule, we stated that the HCPCS code G0402 (*Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment*) was also valued based on a direct crosswalk to the work, time, and direct PE inputs for CPT code 99204 (75 FR 73408 through 73411).

Because these codes are valued using direct crosswalks to office/outpatient E/M visits, we believed that to maintain payment accuracy for the IPPE and the AWV, their values should be adjusted to reflect the changes in value for CPT codes 99204 and 99214. Therefore, we proposed to revise the work, physician time, and direct PE inputs for these codes as shown in Tables 23 and 24. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with our proposal to revalue the IPPE and AWV HCPCS codes. These commenters agreed that because these services were valued using direct crosswalks to CPT codes 99204 and 99214, their values should be updated to reflect the increases to those visits finalized for CY 2021.

Response: We thank the commenters for their support.

Comment: Several commenters disagreed with our proposal to revalue the IPPE and AWV HCPCS codes. A commenter indicated that because the AMA RUC has never reviewed these codes, it is unclear that the work associated with the services represents work described by a level 4 office/outpatient E/M visit.

Response: We continue to believe that because the IPPE and AWV were valued using direct crosswalks to CPT codes 99204 and 99214, respectively, changes to the work associated with CPT codes 99204 and 99214 should be applied to the valuation of the IPPE and AWV codes. Regarding the point that these codes have not been reviewed by the RUC, we note that the IPPE and AWV are services that are unique to the Medicare program. These services are reported using Medicare-specific HCPCS G codes that are not applicable for other payers. As such, we do not see a need for these codes to be reviewed by

the RUC. If the RUC did review them, however, we would consider any RUC recommendations through our usual rulemaking process. As discussed above, our decision to consider a given code(s) as analogous to the office/outpatient E/M visits is not based on any single factor, but rather, takes into account various applicable factors. The public may nominate any code(s) as potentially misvalued through the usual misvalued code process, or request that codes reviewed by the AMA RUC.

We received comments primarily in support of our proposal to revalue the IPPE and AWV codes. Our proposed revaluations reflect changes in value to the two office and outpatient E/M codes (that is, CPT codes 99204 and 99214) upon which the IPPE and AWV code values were originally crosswalked. We continue to believe that to maintain payment accuracy, the values for the IPPE and AWV codes should be adjusted accordingly. After considering the comments, we are finalizing as proposed.

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TABLE 23: CY 2020 Work RVUs and CY 2021 Final Work RVUs

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Final CY 2021 Work RVUs
59400	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care	32.16	36.58
59410	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	18.01	18.34
59425	Antepartum care only; 4-6 visits	6.31	7.80
59426	Antepartum care only; 7 or more visits	11.16	14.3
59430	Postpartum care only (separate procedure)	2.47	3.22
59510	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	35.64	40.39
59515	Cesarean delivery only; including postpartum care	21.47	22.13
59610	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	33.87	38.29
59614	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	19.73	20.06
59618	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	36.16	40.91
59622	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	22.00	22.66
90951	End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	18.46	23.92
90954	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	15.98	15.98
90955	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	8.79	10.32
90956	End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month	5.95	6.64
90957	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	12.52	15.46
90958	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	8.34	9.87
90959	End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of	5.50	6.19

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Final CY 2021 Work RVUs
	parents; with 1 face-to-face visit by a physician or other qualified health care professional per month		
90960	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month	5.18	6.77
90961	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month	4.26	5.52
90962	End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month	3.15	3.57
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	10.56	12.09
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	9.14	10.25
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents	8.69	9.80
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older	4.26	5.52
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age	0.30	0.34
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age	0.29	0.33
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older	0.14	0.18
99483	Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (eg, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.	3.44	3.80

HCPCS Code	Long Descriptor	CY 2020 Work RVUs	Final CY 2021 Work RVUs
99492	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.	1.70	1.88
99493	Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.	1.53	2.05
99495	Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge	2.36	2.78
99496	Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within 2 business days of discharge; medical decision making of high complexity during the service period; face-to-face visit within 7 calendar days of discharge	3.10	3.79
G0402	Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment	2.43	2.60
G0438	Annual wellness visit; includes a personalized prevention plan of service (pps), initial visit	2.43	2.60
G0439	Annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit	1.50	1.92

TABLE 24: Comparison of Physician Time, and Clinical Staff Time (Non-facility and Facility) for HCPCS Codes, CY 2020 Values vs. CY 2021 Final Values

HCPCS	Phys. Time (Minutes) – CY 2020	Phys. Time (Minutes) – CY 2021 Final	NF Clinical Staff Time (Minutes) - CY2020	NF Clinical Staff Time (Minutes) – CY 2021 Final	Fac. Clinical Staff Time (Minutes) – CY 2020	Fac. Clinical Staff Time (Minutes) – CY 2021 Final
59400	739.5	753.5	N/A	N/A	551.0	551.0
59410	398.5	327.5	N/A	N/A	42.0	42.0
59425	137.0	180.0	206.0	198.0	-	-
59426	252.0	330.0	386.0	378.0	-	-
59430	63.0	77.0	89.0	87.0	-	-
59510	817.5	818.5	N/A	N/A	587.0	587.0
59515	476.5	392.5	N/A	N/A	78.0	78.0
59610	739.5	753.5	N/A	N/A	551.0	551.0
59614	398.5	327.5	N/A	N/A	42.0	42.0
59618	792.5	793.5	N/A	N/A	587.0	587.0
59622	451.5	367.5	N/A	N/A	78.0	78.0
90791	90.0	90.0	-	-	-	-
90792	90.0	90.0	-	-	-	-
90832	45.0	45.0	-	-	-	-
90834	60.0	60.0	-	-	-	-
90837	75.0	75.0	-	-	-	-
90951	274.0	365.0	60.0	34.0	60.0	60.0
90954	240.0	240.0	60.0	-	60.0	60.0
90955	198.0	227.0	60.0	55.0	60.0	60.0
90956	148.0	163.0	60.0	59.0	60.0	60.0
90957	253.0	310.0	60.0	53.0	60.0	60.0
90958	183.0	212.0	60.0	55.0	60.0	60.0
90959	133.0	148.0	60.0	59.0	60.0	60.0
90960	128.0	156.0	60.0	54.0	60.0	60.0
90961	113.0	134.0	60.0	54.0	60.0	60.0
90962	63.0	70.0	60.0	58.0	60.0	60.0
90963	258.0	287.0	60.0	55.0	60.0	60.0
90964	233.0	255.0	60.0	57.0	60.0	60.0
90965	218.0	240.0	60.0	57.0	60.0	60.0
90966	75.0	96.0	60.0	54.0	60.0	60.0
90968	7.8	8.5	2.0	1.9	2.0	2.0
90969	7.3	8.0	2.0	1.9	2.0	2.0
90970	2.5	3.2	2.0	1.8	2.0	2.0
92521	110.0	110.0	-	-	N/A	N/A
92522	85.0	85.0	-	-	N/A	N/A
92523	157.0	157.0	-	-	N/A	N/A
92524	75.0	75.0	-	-	N/A	N/A
97161	55.0	55.0	41.0	41.0	N/A	N/A
97162	55.0	55.0	41.0	41.0	N/A	N/A
97163	55.0	55.0	41.0	41.0	N/A	N/A
97164	35.0	35.0	34.0	34.0	N/A	N/A
97165	65.0	65.0	32.0	32.0	N/A	N/A
97166	65.0	65.0	32.0	32.0	N/A	N/A
97167	65.0	65.0	32.0	32.0	N/A	N/A
97168	45.0	45.0	26.0	26.0	N/A	N/A
99201	17.0	N/A	26.0	N/A	-	-
99202	22.0	20.0	39.0	34.0	-	-
99203	29.0	35.0	51.0	43.0	-	-
99204	45.0	60.0	62.0	54.0	-	-
99205	67.0	88.0	71.0	67.0	-	-

HCPCS	Phys. Time (Minutes) – CY 2020	Phys. Time (Minutes) – CY 2021 Final	NF Clinical Staff Time (Minutes) - CY2020	NF Clinical Staff Time (Minutes) – CY 2021 Final	Fac. Clinical Staff Time (Minutes) – CY 2020	Fac. Clinical Staff Time (Minutes) – CY 2021 Final
99211	7.0	7.0	19.0	17.0	-	-
99212	16.0	16.0	28.0	28.0	-	-
99213	23.0	30.0	36.0	36.0	-	-
99214	40.0	47.0	53.0	51.0	-	-
99215	55.0	70.0	63.0	62.0	-	-
99283	30.0	30.0	N/A	N/A	-	-
99284	40.0	40.0	N/A	N/A	-	-
99285	55.0	55.0	N/A	N/A	-	-
99483	85.0	85.0	92.0	92.0	-	-
99492	40.0	40.0	85.0	85.0	-	-
99493	36.0	36.0	60.0	60.0	-	-
99495	47.0	54.0	107.0	105.0	-	-
99496	60.0	75.0	145.0	144.0	-	-
G0402	0.2	45.0	62.0	54.0	-	-
G0438	0.2	45.0	62.0	54.0	-	-
G0439	0.4	1.9	40.0	0.4	51.0	40.0

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6. Emergency Department Visits

We have revalued the ED visit codes (CPT codes 99281–99285, see Table 25 for long descriptors) under the PFS three times: In 1997, 2007, and most recently in 2020 as part of the misvalued code initiative. In the past, consistent with AMA RUC recommendations, we revalued these services such that the values of levels 1 through 3 of the ED visits were equal to levels 1 through 3 new patient office/outpatient E/M visits, and the levels 4 and 5 ED visits were valued higher than the levels 4 and 5 new patient office/outpatient E/M visits to reflect higher typical intensity. Also in the CY 2018 PFS final rule, we finalized a proposal to nominate all five ED visit codes as potentially misvalued, based on information suggesting that the work RVUs for ED visits may not appropriately reflect the full resources involved in furnishing these services. Specifically, some stakeholders expressed concerns that the work RVUs for these services have been undervalued given the increased acuity of the patient population and the heterogeneity of the sites, such as freestanding and off-campus EDs, where ED visits are furnished (82 FR 53018). Accordingly, the AMA RUC resurveyed and reviewed these five codes for the April 2018 RUC meeting, and provided a recommendation to CMS for consideration in CY 2020 rulemaking. In the CY 2020 PFS final rule (84 FR 62796), we finalized the RUC-recommended increases to the work RVUs of 0.48 for CPT code 99281, a work RVU of 0.93 for CPT code 99282, a work RVU of 1.42 for 99283, a work RVU of 2.60 for 99284, and a work RVU of 3.80 for CPT code 99285. The RUC did not recommend, and we did not finalize, any change in direct PE inputs for the codes in this family. We note that the AMA RUC submitted these recommended values to CMS prior to the submission of the RUC-recommended revaluation of the office/outpatient E/M visit code family.

In response to our proposal to accept the RUC-recommended values for the ED visits, and to our comment solicitation in CY 2020 PFS proposed rule regarding whether we should revalue certain services commensurate with increases to the office/outpatient E/M visits (84 FR 62859 through 62860), a commenter submitted a public comment stating that relativity between the ED visits and office/outpatient E/M visits should be maintained, and submitting a specific recommendation for CPT codes 99283–99285 that was higher than the RUC-recommended values. The commenter stated we should preserve the relationship between the ED and office/outpatient E/M visit code sets that was established in prior years and that they believe would have likely been maintained had the office/outpatient E/M visits been reviewed prior to the ED visits. In order to avoid the rank order anomaly whereby an ED visit would be valued lower than the analogous office/outpatient E/M visit in CY 2021, we proposed in this current rulemaking cycle to adopt the values recommended by this commenter, and as shown in Table 25. The following is a summary of the comments we received and our responses.

Comment: One commenter supported our proposal. This commenter stated that levels 1–3 ED visits should remain the same as the levels 1–3 new patient office visits, and that levels 4–5 ED visits should have a higher value than the corresponding office visits due to the complexity of the patients requiring that level of emergency care.

Response: We are finalizing as proposed, as shown in Table 25, in order to avoid a rank order anomaly. We understand that the AMA workgroup on E/M services is continuing to consider further changes in coding and interpretive guidance for visit level selection for all of the E/M visit code sets other than the office/outpatient E/M visits, in light of the recent changes for office/outpatient visits. We will continue to stay abreast of this important work and continue considering the appropriate valuation of ED and other E/M visit code sets in light of any future changes in this arena by the CPT Editorial Panel and the AMA RUC.

Comment: Several commenters requested that we consider the nursing facility visits (CPT codes 99304–99318), domiciliary visits (CPT codes 99324–99337), and home visits (CPT codes 99341–99350) to be analogous to the office/outpatient E/M visits, noting that they are identical in every way except the setting of care and vulnerability of

the patient population. These commenters indicated that the CPT Editorial Panel and the AMA RUC will be reviewing these code sets in the near future, and their primary concern was to maintain access to care until this review is complete. Accordingly, these commenters recommended that we increase the work RVUs for these services to the extent necessary to maintain the payment rate for these codes at 2020 levels. These commenters provided an estimate of the revised work RVUs necessary to achieve this as a temporary measure, stating that due to relatively low service volume, these changes would not negatively impact the conversion factor.

Response: We did not propose to treat and revalue nursing facility visits, domiciliary visits and home visits as analogous to office/outpatient E/M visits. We do not agree with the commenters' assertions that these visits are identical to the office/outpatient E/M visit codes. The setting of care means that these visits involve different resources. In particular, skilled nursing facility (SNF) visits are reported using the nursing facility visit codes, rendering them substantially different from office/outpatient visits. For these reasons, we do not believe the commenters' requested changes to values for nursing facility visits, domiciliary visits, and home visits would be appropriate at this time. Additionally, we understand that the AMA workgroup on E/M services is continuing to consider further changes in coding and interpretive guidance for visit level selection for all of the E/M visit code sets other than the office/outpatient E/M visits, in light of the forthcoming changes for office/outpatient visits. We will continue to stay abreast of this important work and consider the appropriate valuation of home, domiciliary, nursing facility and other E/M visit code sets in light of any future changes in this arena by the CPT Editorial Panel and the AMA RUC.

7. Therapy Evaluations

There are a number of services paid under the PFS that are similar in many respects to the office/outpatient E/M visit code set, but do not specifically include, were not valued to include, and were not necessarily valued relative to, office/outpatient E/M visits. Some codes inherently include work associated with assessment and work associated with management, similar to the work included in the office/outpatient E/M visits, which involve time spent face-to-face assessing and treating the patient. These services include therapy evaluation services and psychiatric diagnostic evaluation services. The practitioners who furnish these services are prohibited by CMS from billing E/M services due to the limitations of their Medicare benefit categories. As such, the CPT Editorial Panel has created specific coding to describe the services furnished by these practitioners. Although these services are billed using specific, distinct codes relating to therapy evaluations and psychiatric diagnostic evaluations, we believe that a significant portion of the overall work in the codes is for assessment and management of patients, as it is for the office/outpatient E/M visit codes.

Therefore, we proposed to adjust the work RVUs for these services based on a broad-based estimate of the overall change in the work associated with assessment and management to mirror the overall increase in the work of the office/outpatient E/M visits. We calculated this adjustment based on a volume-weighted average of the increases to the office/outpatient E/M visit work RVUs from CY 2020 to CY 2021. Details on this calculation are available as a public use file on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices*. We proposed to apply that percentage increase, which we estimated to be approximately 28 percent, to the work RVUs for the therapy evaluation and psychiatric diagnostic evaluation services codes. We noted that we believe that it is important to the relativity of the PFS to revalue these services to reflect the overall increase in value associated with spending time assessing and managing patients, as reflected in the changes to work values for the office/outpatient E/M visits, particularly in recognition of the value of the clinicians' time which is spent treating a growing number of patients with greater needs and multiple medical conditions. We recognized that this is not the methodology typically used to value services under the PFS and solicited comment on potential alternative methodologies or specific values for these services, particularly about whether commenters believe it would be better to develop values using comparator codes from the office/outpatient E/M visit code set, and if so, why.

We received public comments on these proposals. The following is a summary of the comments we received and our responses.

Comment: Some commenters supported our proposal to adjust the work RVUs for outpatient therapy evaluations and to consider alternative approaches submitted by stakeholders in future rulemaking that may better reflect the true values. Many commenters urged us to implement similar increases to the work RVUs of additional therapy services, including CPT codes 97140 (*Manual therapy techniques (eg, mobilization/manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes*), 97537 (*Community/work reintegration training (eg, shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis, use of assistive technology device/adaptive equipment), direct one-on-one contact, each 15 minutes*), 97542 (*Wheelchair management (eg, assessment, fitting, training), each 15 minutes*), 97760 (*Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes*), 97761 (*Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes*), 97763 (*Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), lower extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes*), 97597 (*Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less*), 97598 (*Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; each additional 20 sq cm, or part thereof (List separately in addition to code for primary procedure)*), 97750 (*Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes*), and 97755 (*Assistive technology assessment (eg, to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility),*

direct one-on-one contact, with written report, each 15 minutes). These commenters stated that these services also involve assessment and management, and thus, are analogous to office/outpatient E/M visit codes.

Response: In the proposed rule, we discussed that these evaluations contained types of work, specifically time spent assessing and managing patients, that is similar to the work described by the office/outpatient E/M visit code set. We stated that the increase in value associated with the office/outpatient E/M visits reflected the changes to work values, particularly in recognition of the value of the clinicians' time spent treating a growing number of patients with greater needs and multiple medical conditions, that could also apply to physical therapy, occupational therapy, and speech language pathology evaluations. The CPT codes identified by commenters involve work that is not similar to that captured by the office/outpatient E/M codes, such as various types of therapeutic treatment. Therefore, we do not believe it would be appropriate to adjust the values of these codes to reflect the changes in valuation for the office/outpatient E/M codes.

Comment: Some commenters did not support our proposal to implement the proposed increases to these therapy codes, stating that it will amplify a previous misvaluation by CMS for codes that do not specifically include, were not valued to include, and were not necessarily valued relative to, office/outpatient E/M visits. According to the commenters, these therapy codes were originally misvalued when CMS finalized a single RVU of 1.20 for all three codes rather than the RUC-recommended work RVUs, which created an overvaluation in aggregate for these services.

Response: In the proposed rule, we discussed our rationale for proposing to increase the values of these services relative to the increased values for the office/outpatient E/M visit code set. If the commenters believe the therapy codes are not appropriately valued, we note the public may nominate any code(s) as potentially misvalued through the usual misvalued code process or request that it be surveyed or valued through the AMA RUC.

After considering the public comments, we are finalizing the changes in values for the therapy codes as proposed.

8. Behavioral Healthcare Services

The psychotherapy code set is divided into psychotherapy that can be furnished as a standalone service and psychotherapy furnished in conjunction with an office/outpatient E/M visit. The standalone psychotherapy services are CPT codes 90832, 90834, and 90837 (See Table 25 for long descriptors). The CPT codes describing psychotherapy furnished in conjunction with an office/outpatient E/M visit are CPT codes 90833 (*Psychotherapy, 30 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*), 90836 (*Psychotherapy, 45 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*) and 90838 (*Psychotherapy, 60 minutes with patient when performed with an evaluation and management service (List separately in addition to the code for primary procedure)*). As the values for the office/outpatient E/M visits are increasing, there will necessarily be an increase in the overall value for psychotherapy furnished in conjunction with office/outpatient E/M visits. We believe that it is important, both in terms of supporting access to behavioral health services through appropriate payment and maintaining relativity within this code family, to increase the values for the standalone psychotherapy services to reflect changes to the value of the office/outpatient E/M visits which are most commonly furnished with the add-on psychotherapy services with equivalent times. For example, under the finalized revaluation of the office/outpatient E/M visits, the proportional work value of the standalone psychotherapy CPT code 90834 (*Psytx w pt 45 minutes*) would decrease relative to the combined work RVUs for CPT code 99214 (*Level 4 Office/outpatient visit est*) when billed with CPT code 90836 (*Psytx w pt w e/m 45 min*). The current combined work RVU for CPT code 99214 when reported with CPT code 90836 is 3.40 (1.90 + 1.50) and the current work RVU for CPT code 90834 is 2.0. With the revaluation of the office/outpatient E/M visits beginning for CY 2021, the combined work RVU for CPT codes 99214 and 90836 would be 3.82 (1.90 + 1.92), while the current work RVU for 90834 would remain at 2.0, resulting in a change to relativity between these services.

To maintain the current relativity, which we believe to be appropriate based on the proportionate difference between these services, we are proposing to increase the work RVU for CPT code 90834 from 2.00 to 2.25 based on the marginal increase in work value for CPT code 99214 from CY 2020 to CY 2021. Similarly, for CPT code 90832, which describes 30 minutes of psychotherapy, we proposed to increase its work RVU based on the increase to CPT code 99213, which is most commonly billed with the 30 minutes of psychotherapy add-on, CPT code 90833. For CPT code 90837, which describes 60 minutes of psychotherapy, we propose to increase the work RVU based on the proportional increase to CPT codes 99214 and 90838, which is the office/outpatient E/M visit code most frequently billed with the 60 minutes of psychotherapy add-on. Table 25 provides a summary of the current and final RVUs for these services.

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TABLE 25: Current and Final Work RVUS for ED Visits, Therapy, and Psychotherapy Services

HCPCS Code	Long Descriptor	CY 2020 Work RVU	CY 2021 Final Work RVU
99283	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.	1.42	1.60
99284	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.	2.60	2.74
99285	Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.	3.80	4.00
90791	Psychiatric diagnostic evaluation	3.00	3.84
90792	Psychiatric diagnostic evaluation with medical services	3.25	4.16
90832	Psychotherapy, 30 minutes with patient	1.50	1.70
90834	Psychotherapy, 45 minutes with patient	2.00	2.24
90837	Psychotherapy, 60 minutes with patient	3.00	3.31
97161	Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97162	Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97163	Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity	1.2	1.54

HCPCS Code	Long Descriptor	CY 2020 Work RVU	CY 2021 Final Work RVU
	limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.		
97164	Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.	0.75	0.96
97165	Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97166	Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97167	Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.	1.2	1.54
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed	0.75	0.96

HCPCS Code	Long Descriptor	CY 2020 Work RVU	CY 2021 Final Work RVU
	when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.		
92521	Evaluation of speech fluency (eg, stuttering, cluttering)	1.75	2.24
92522	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria);	1.5	1.92
92523	Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)	3	3.84
92524	Behavioral and qualitative analysis of voice and resonance	1.5	1.92

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We received public comments on the Behavioral Healthcare services. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support this proposal, stating it relies on a flawed methodology; specifically, the stand-alone codes, which were established for NPPs to report psychotherapy services, were not valued based on a comparison to the psychotherapy codes delivered in conjunction with an E/M (codes 90833, 90836 and 90838). These commenters noted that these are two distinct codes sets: one for NPPs and one for physicians/QHPs representing different levels of similar work. CMS should compare psychotherapy to psychotherapy, not psychotherapy to psychotherapy plus E/M. Accordingly, these commenters did not support CMS's proposal to increase the values of 90832, 90834, and 90837 to reflect changes to the value of the office/outpatient E/M visits which are most commonly furnished with the add-on psychotherapy services with equivalent times.

Other commenters were concerned that the increases to some of the psychotherapy services will skew the relativity not only to the psychotherapy services provided along with an E/M service but to other services within the psychiatry section.

Some commenters supported increases for these services, but stated that commensurate relativity adjustments are needed for all Psychotherapy, Psychological and Neuropsychological Testing, and HBAI codes. Specifically, these commenters recommended proportionate increases to CPT codes 90791 (*Psychiatric diagnostic evaluation*), 90839 (*Psychotherapy for crisis; first 60 minutes*), 90845 (*Psychoanalysis*), 90847 (*Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes*), and 90853 (*Group psychotherapy (other than of a multiple-family group)*), as well as to the HBAI code set (CPT codes 96156 (*Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)*), 96158 (*Health behavior intervention, individual, face-to-face; initial 30 minutes*), 96159 (*Health behavior intervention, individual, face-to-face; each additional 15 minutes (List separately in addition to code for primary service)*), and 97170 (*Athletic training evaluation, moderate complexity, requiring these components: A medical history and physical activity profile with 1–2 comorbidities that affect physical activity; An examination of affected body area and other symptomatic or related systems addressing a total of 3 or more elements from any of the following: body structures, physical activity, and/or participation deficiencies; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.*); and to the Psychological and Neuropsychological Testing code set (CPT codes 96116 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; first hour*), 96121 (*Neurobehavioral status exam (clinical assessment of thinking, reasoning and judgment, [eg, acquired knowledge, attention, language, memory, planning and problem solving, and visual spatial abilities]), by physician or other qualified health care professional, both face-to-face time with the patient and time interpreting test results and preparing the report; each additional hour (List separately in addition to code for primary procedure)*), 96130 (*Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*), 96131 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*), 96132 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*), 96133 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for*

primary procedure)), 96136 (*Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes*), 96137 (*Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)*), 96138 (*Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes*), 96139 (*Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)*), and 96146 (*Psychological or neuropsychological test administration, with single automated, standardized instrument via electronic platform, with automated result only)*), all of which were valued relative to the family of psychotherapy services through the AMA RUC process.

Response: We identified standalone psychotherapy services for adjustment to preserve the relative value of these services to psychotherapy services performed in conjunction with an office/outpatient E/M. We disagree with commenters who stated that, as the standalone psychotherapy codes were purposefully and appropriately valued without reference to the values of E/M services, we should not consider updating these values to retain relativity between standalone psychotherapy and psychotherapy billed in conjunction with an office/outpatient E/M. With regard to requests from commenters to adjust values of additional services, we continue to believe that our rationale for proposing proportionate adjustments to the stand-alone psychotherapy services does not apply to the wider psychotherapy code set. We believe that the value of stand-alone psychotherapy is analogous to the values of the office/outpatient E/M visit codes due to the nature of the work performed. These services describe E/M-type services furnished in some circumstances by practitioners who would not bill E/M services. Health and Behavior Assessment and Intervention and Psychological and Neuropsychological Testing are fundamentally different in that they describe testing services.

Having considered the public comments we received, we are finalizing our proposed increases to the values of CPT codes 90832, 90834, and 90837.

9. Ophthalmological Services

Prior to the CY 2021 PFS proposed rule, we had received a request to revalue the following ophthalmological services that we did not propose to revalue:

- CPT code 92002: *Ophthalmological services: Medical examination and evaluation with initiation of diagnostic and treatment program; intermediate, new patient.*
- CPT code 92004: *Ophthalmological services: Medical examination and evaluation with initiation of diagnostic and treatment program; comprehensive, new patient, 1 or more visits.*
- CPT code 92012: *Ophthalmological services: Medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient.*
- CPT code 92014: *Ophthalmological services: Medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits.*

We did not propose to revalue these services because they are not sufficiently analogous to the office/outpatient E/M visit codes. While these ophthalmological services have historically been valued relative to office/outpatient E/M visits, the AMA RUC has not reviewed them since 2007. Two of these ophthalmological services can include more than one visit, and the number of visits included in the package is uncertain and therefore not so closely tied to office and outpatient E/M services, which describe a single visit. In addition, starting in 2021, the office/outpatient E/M visit codes will be substantially redefined to allow time or medical decision-making for code level selection—concepts that do not apply to the ophthalmological visits which rely on criteria specific to evaluation, examination, specified technical procedures, and treatment of ocular conditions for purposes of level selection.[8] The number of levels is different within the two code sets, and the number of levels has changed for office/outpatient E/M visits. Given the revised code set and framework for level selection for office/outpatient E/M visits, the level of office/outpatient E/M visits to which the ophthalmological visits might be analogous is unclear. We also noted that we are aware that ophthalmologists report office/outpatient E/M visits as well these ophthalmologic-specific evaluation codes. The relationship between the two separate code sets and the reason for maintaining and using both of them is unclear.

In the proposed rule, we also noted that the four ophthalmological evaluation codes are frequently reported with modifier -25 (significant, separately identifiable E/M service by the same physician on the same day of the procedure or other service), as are ED visits. For the ophthalmological evaluations and ED visits, approximately one-third of the time, the same-day E/M service is a zero-day global surgical code, whereas for the office/outpatient E/M visits, approximately one-fifth of the same-day claims are for zero-day global services. We noted that we believe that visit/evaluation codes furnished the same day as a minor procedure are not closely analogous to stand-alone office/outpatient E/M visits. As we discussed in prior rulemaking, we continue to believe that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing office/outpatient E/M visits to warrant different payment (see, for example, the CY 2019 PFS final rule, 83 FR 59639). As we were still in process of analyzing these data, we solicited public comment on whether visits/evaluations that are furnished frequently with same-day procedures should be revalued commensurate with increases to the office/outpatient E/M visits, or whether they are substantially different enough to warrant independent valuation. We noted further that the stand-alone psychotherapy services would be revalued to maintain relativity with the psychotherapy services that can be performed in conjunction with an E/M visit. Stand-alone psychotherapy services cannot be billed with office/outpatient E/M visits while ophthalmological visits can, as well as with a separate procedure.

We received public comments on our decision not to propose new valuations for these ophthalmological services. The following is a summary of the comments we received and our responses.

Comment: One commenter stated that concurrent billing with same-day, zero-day global procedures should not be factor in whether or not we increase the ophthalmology evaluation codes commensurate with office/outpatient E/M visits. The commenter stated that the intravitreal injection code accounting for much of the volume of these zero-day global procedures (CPT code 67028) does not include an office examination. The commenter also stated that resource

[8] CPT Codebook pp. 656–7.

duplication between the same-day services is accounted for in the RUC valuation that reduces the pre- and post-times for the procedure if it is furnished more than 50 percent of the time with an E/M visit or eye evaluation. Another commenter noted that the AWV can be reported the same day as an office/outpatient E/M visit, and urged CMS not to treat primary care and surgical specialties differentially.

Response: We continue to believe that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone office/outpatient E/M visits to warrant different payment. However, we understand that such a policy would apply to ophthalmology evaluations, ED visits and other services. We believe the better way to account for duplicative resources across the fee schedule would be a payment reduction along the lines of a multiple procedure payment reduction for services reported using modifier −25.We will continue to consider implementing a policy to address this issue. We note that the policy that we proposed and declined to finalize for CY 2019 would have applied a multiple ''procedure'' payment adjustment to two visits reported the same day, as well as a visit with a minor procedure. We are also considering whether the office/outpatient visit complexity HCPCS add-on code GPC1X should be reported when the visit is reported with modifier −25 (see section II.F.2.c. of this final rule).

Comment: One commenter stated that while the ophthalmological evaluations have not been recently revalued by the AMA RUC, the AWV has never been reviewed by the RUC.

Response: We discuss above our rationale for considering the AWV as an analogous service to the office/outpatient E/M services. Regarding consideration of the AWV by the RUC, we note that the AWV is a service described by a code that is unique to Medicare and not applicable for other payers. As such, we do not see a need for the RUC to review this service, but if it did, we would consider its recommendations through our usual rulemaking process. As discussed above, our decision to consider a given code(s) as analogous to the office/outpatient E/M visits is not based on any single factor, but rather takes into account various applicable factors. The public may nominate any code(s) as potentially misvalued through the usual misvalued code process or request that it be surveyed or valued through the AMA RUC.

Comment: The same commenter stated that all four of the ophthalmology codes are valued based on a single visit on the date of encounter, and the level of that visit is directly compared to levels of office E/M codes. The commenter also stated that while the ophthalmological codes do not rely on time to select visit level, both code sets will be able to use MDM to select visit level, and that MDM was a basis for prior comparison to office/outpatient E/M visit codes.

Response: We continue to note that two of these ophthalmological services can include more than one visit, and therefore, the resource costs are not as closely tied to office and outpatient E/M visits (that describe a single visit) as the AWV/IPPE, TCM, cognitive impairment and other codes we are considering to be analogous to office/outpatient E/M visits. We disagree that reliance on time and differences in MDM interpretive guidance are not substantial differences between the 2021 office/outpatient E/M visit codes and the ophthalmology evaluation codes. Also, we continue to believe that the corresponding visit levels for the two code sets are not clear, such that the level of office/outpatient E/M visits to which the ophthalmological visits might be analogous is not apparent. We continue to note that ophthalmologists report office/outpatient E/M visits as well these ophthalmologic-specific evaluation codes. The relationship between the two separate code sets and the reason for maintaining and using both of them remains unclear. Having considered the public comments we received, we are finalizing our decision not to revalue the ophthalmological evaluations commensurate with the changes to the office/outpatient EM visit valuations for 2021. Stakeholders may still request review of these services by the RUC or through our misvalued code initiative.

c. Comment Solicitation on the Definition of HCPCS Add-On Code G2211

Although we believe that the RUC-recommended values for the revised office/outpatient E/M visit codes will more accurately reflect the resources involved in furnishing a typical office/outpatient E/M visit, we continue to believe that the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits. Therefore, in the CY 2020 PFS final rule (84 FR 62856), we finalized the HCPCS add-on code G2211 (which replaces temporary HCPCS add-on code GPC1X) and which describes the ''visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition.'' We stated that we were not restricting billing based on specialty, but that we did assume that certain specialties furnished these types of visits more than others.

Since the publication of the CY 2020 PFS final rule, some specialty societies have stated that our definition of this service, as articulated in the code descriptor and the associated preamble discussion, is unclear. For example, some stakeholders have suggested that HCPCS add-on code G2211, as currently described, could be applicable for every office/outpatient E/M visit. They have also expressed concerns regarding our utilization assumptions, since we assumed that specialties that predominantly furnish the kind of care described by the code would bill it with every visit. Therefore, we solicited public comments providing additional, more specific information regarding what aspects of the definition of HCPCS add-on code G2211 are unclear, how we might address those concerns, and how we might refine our utilization assumptions for the code.

We continue to believe that the time, intensity, and PE involved in furnishing services to patients on an ongoing basis that result in a comprehensive, longitudinal, and continuous relationship with the patient and involves delivery of team-based care that is accessible, coordinated with other practitioners and providers, and integrated with the broader health care landscape, are not adequately described by the revised office/outpatient E/M visit code set. We believe the inclusion of HCPCS add-on code G2211 appropriately recognizes the resources involved when practitioners furnish services that are best-suited to patients' ongoing care needs and potentially evolving illness. We also believe the work reflected in HCPCS add-on code G2211 is inherently distinct from existing coding that describes preventive and care management services. For example, the AWV describes and pays for a static annual health assessment rather than the time, intensity, and PE involved in furnishing services to patients on an ongoing basis. Similarly, TCM service codes are focused on care management for 30 days

following a discharge rather than the time, intensity, and PE involved in furnishing services to patients on an ongoing basis. Chronic care management and principal care management service codes are limited to patients with chronic condition(s). Under chronic care management codes, patients have two or more chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, whereas principal care management services are for patients who have a single high-risk disease of sufficient severity to place the patient at risk of hospitalization or have been the cause of recent hospitalization. In contrast, we believe HCPCS add-on code G2211 reflects the time, intensity, and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single-high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time. For example, in the context of primary care, HCPCS add-on code G2211 could recognize the resources inherent in holistic, patient-centered care that integrates the treatment of illness or injury, management of acute and chronic health conditions, and coordination of specialty care in a collaborative relationship with the clinical care team. In the context of specialty care, HCPCS add-on code G2211 could recognize the resources inherent in engaging the patient in a continuous and active collaborative plan of care related to an identified health condition the management of which requires the direction of a clinician with specialized clinical knowledge, skill and experience. Such collaborative care includes patient education, expectations and responsibilities, shared decision-making around therapeutic goals, and shared commitments to achieve those goals. In both examples, HCPCS add-on code G2211 reflects the time, intensity, and PE associated with providing services that result in care that is personalized to the patient. Finally, we believe that the HCPCS add-on code G2211 could bolster the efforts of practitioners in rural communities, including NPPs, to deliver the comprehensive and longitudinal care that HCPCS add-on code G2211 describes.

We received public comments on our comment solicitation related to HCPCS add-on code G2211. The following is a summary of the comments we received and our responses.

Comment: Many commenters who rely upon office/outpatient E/M visits to report the majority of their services continued to be supportive of HCPCS add-on code G2211. These commenters agreed with CMS that the revised office/outpatient E/M visit codes do not adequately describe or reflect the resources associated with primary care and certain types of specialty visits and agreed that the code descriptor fits its intended purpose, is well-defined, and did not allude to specific specialties. Other commenters disagreed, maintaining that the definition of HCPCS add-on code G2211 is unclear. Some commenters stated that it appeared that HCPCS add-on code G2211 could be reported with most office/outpatient E/M visits and questioned whether widespread use accurately captured genuine longitudinal care relationships. These commenters requested that CMS provide clinical examples for appropriate reporting. Other commenters provided CMS with suggested clinical examples for when HCPCS add-on code G2211 could be reported. For example, some commenters stated that HCPCS add-on code G2211 would capture additional work by the reporting practitioner to treat patients with disease processes that require active monitoring outside of office/outpatient E/M visits and are not captured in current coding. This work could include oversight of medication refills; evaluating appropriateness of current and new medications, including those initially prescribed by other practitioners; and conducting medication-related monitoring and safety activities when these activities are not part of a visit. It could also include review of lab and imaging reports, including those requested by another practitioner, that fall outside the timeframe of an office/outpatient E/M visit, and do not necessitate a new visit. Finally, some commenters suggested that CMS describe circumstances when HCPCS add-on code G2211 would not be reported with an office/outpatient E/M visit.

Response: We appreciate all of the feedback from the commenters. We believe that HCPCS add-on code G2211 captures the work by the reporting practitioner for many office/outpatient E/M visits that is not accounted for in the valuation of the primary office/outpatient E/M visit code. In the context of primary care, a clinical example for the use of HCPCS add-on code G2211 could be: a 68 year-old woman with progressive congestive heart failure (CHF), diabetes, and gout, on multiple medications, who presents to her physician for an established patient visit. The clinician discusses the patient's current health issues, which includes confirmation that her CHF symptoms have remained stable over the past 3 months. She also denies symptoms to suggest hyper- or hypoglycemia, but does note ongoing pain in her right wrist and knee. The clinician adjusts the dosage of some of the patient's medications, instructs the patient to take acetaminophen for her joint pain, and orders laboratory tests to assess glycemic control, metabolic status, and kidney function. The practitioner also discusses age appropriate prevention with the patient and orders a pneumonia vaccination and screening colonoscopy. In this clinical example, the practitioner is serving as a focal point for the patient's care, addressing the broad scope of the patient's health care needs, by furnishing care for some or all of the patient's conditions across a spectrum of diagnoses and organ systems with consistency and continuity over time.

Moreover, we believe that similar visits might be furnished by other specialists when management of a particular disease condition(s) is ongoing or serves as a focal point of care for a patient's overall health needs over a period of time. In other words, when care by specialists for a particular disease condition(s) is consistent and continuous over long periods of time, the work associated with those visits is similar to the kind of work described above.

In contrast, there are many visits with new or established patients where HCPCS add-on code G2211 would not be appropriately reported, such as when the care furnished during the office/outpatient E/M visit is provided by a professional whose relationship with the patient is of a discrete, routine, or time-limited nature, such as a mole removal or referral to a physician for removal of a mole; for treatment of a simple virus; for counseling related to seasonal allergies, initial onset gastroesophageal reflux disease; treatment for a fracture; and where comorbidities are either not present or not addressed, and/or and when the billing practitioner has not taken responsibility for ongoing medical care for that particular patient with consistency and continuity over time, or does not plan to take responsibility for subsequent, ongoing medical care for that particular patient with consistency and continuity over time. Reporting the add-on code with these types of visits would be inconsistent with the code

descriptor, which describes care that is a continuing focal point and/or part of ongoing care. We also would not expect that HCPCS add-on code G2211 would be reported when the office/outpatient E/M is reported with a payment modifier, such as the modifier -25 described in the ophthalmological services section above. It seems likely that visits reported with payment modifiers have resources that are sufficiently distinct from stand-alone office/outpatient E/M visits. We will be considering this issue to inform potential future rulemaking.

Comment: Some commenters suggested that a lack of clarity in the definition of HCPCS add-on code G2211 poses program integrity challenges for CMS. They pointed out that CMS has offered no information about how appropriate use will be determined or what documentation will be expected. Some commenters requested guidance on what documentation would need to be included when HCPCS add-on code G2211 is reported.

Response: We appreciate the concerns raised by the commenters. Since HCPCS add-on code G2211 is a new service paid under the PFS, we plan to monitor utilization for appropriate use of the add-on code, which could inform additional efforts to refine the code descriptor, or provide further guidance, as appropriate. With respect to documentation, we are considering an approach to minimize burden similar to what we finalized in the CY 2019 PFS final rule (83 FR 59560) for HCPCS add-on codes GPC1X and GCG0X. In that rule, we discussed that we would expect that information included in the medical record or in the claims history for a patient/practitioner combination, such as diagnoses, the practitioner's assessment and plan for the visit, and/or other service codes billed could serve as supporting documentation. We believe Medicare claims data could be a useful gauge of appropriate use of the code. For example, when billing practitioners are separately reporting care management services for particular beneficiaries, the G2211 add-on service would be appropriately reported with their visits, as claims for these care management services could indicate an ongoing, continuous relationship with the patient. Likewise, patients returning to the same practitioner for routine preventive services would indicate that the practitioner has taken responsibility for ongoing medical needs for that patient with consistency and continuity over time. In contrast, an annual visit for ophthalmologic care, or a single episode of dermatologic care—even when several services are billed over a few months—would not suggest ongoing care provided with consistency and continuity over time and would suggest an inappropriate use of the code, were it to be billed with such visits. Additionally, to provide evidence of the ongoing relationship between the patient and practitioner, it is possible that use of patient relationship codes that were established under MACRA and finalized in the CY 2018 PFS (82 FR 53234) could be further example of evidence in the claims record to support the use of HCPCS add-on code G2211. These codes are Level II HCPCS modifiers that help define and distinguish the relationship and responsibility of a clinician with a patient at the time of furnishing an item or service, facilitate the attribution of patients and episodes to one or more clinicians, and to allow clinicians to self-identify their patient relationships.

Comment: Some commenters recommended that HCPCS add-on code G2211 should be available for both new and established patients. A few other commenters noted that the code descriptor for HCPCS add-on code G2211 had one version of the long descriptor in this section of the proposed rule and another version of the long descriptor in section II.D. Another commenter recommended an edit to the code descriptor to eliminate the comma between ''single'' and ''serious.''

Response: We are confirming that HCPCS add-on code G2211 can be reported for both new and established patients. With respect to the version of the long descriptor, the version used in section II.D of the proposed rule was a drafting error. We regret the error and have corrected the description in section II.D of this final rule. While we appreciate the suggested edit to the code descriptor, we did not believe it offered additional clarification. To improve the clarity of the code descriptor, we are finalizing a refinement for the code description to clarify that the code applies to a single condition that is serious, rather than any single condition. We are inserting the word ''condition'' after ''single, serious''. The revised descriptor reads as follows, ''*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established).*''

Comment: A few commenters recommended that CMS allow HCPCS add-on code G2211 to be reported with E/M services furnished in domiciliary care settings.

Response: We reiterate that we are implementing HCPCS add-on code G2211 because we believe the that the typical visit described by the revised and revalued office/outpatient E/M visit code set still does not adequately describe or reflect the resources associated with primary care and certain types of specialty visits and as such, does not include other types of E/M visits. As the CPT Editorial Panel, the AMA RUC and CMS consider future changes to other E/M visit code sets, we will consider this issue in that context.

Comment: Other commenters expressed continued concern regarding the necessity of HCPCS add-on code G2211 entirely and recommended that CMS withdraw the code. A few stated that HCPCS add-on code G2211 is not a separately identifiable service given the changes to the office/outpatient E/M visit code set and that it may be duplicative to care management services, such as TCM or CCM.

Response: As we stated in the proposed rule, we continue to believe that the time, intensity, and PE involved in furnishing services to patients on an ongoing basis that result in a comprehensive, longitudinal, and continuous relationship with the patient and involves delivery of team-based care that is accessible, coordinated with other practitioners and providers, and integrated with the broader health care landscape, are not adequately described by the revised office/outpatient E/M visit code set. We also reiterate what we stated in the proposed rule that HCPCS add-on code G2211 is inherently distinct from coding that describes care management services. For example, TCM service codes are focused on care management for 30 days following a discharge rather than the time, intensity, and PE involved in furnishing services to patients on an ongoing basis. Chronic care management and principal care management service codes are limited to patients with chronic condition(s). Under chronic care management codes, patients have two or more chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, whereas principal care management services are for patients who have a single high-risk disease of sufficient severity to place the patient at risk of hospitalization or have been the cause of recent hospitalization. In contrast, we believe HCPCS add-on code G2211 reflects the time, intensity,

and PE when practitioners furnish services that enable them to build longitudinal relationships with all patients (that is, not only those patients who have a chronic condition or single-high risk disease) and to address the majority of patients' health care needs with consistency and continuity over longer periods of time.

Comment: Many commenters expressed concerns about the utilization assumptions for HCPCS add-on code G2211. Commenters stated that, in the CY 2020 PFS rulemaking cycle, CMS appeared to assume that HCPCS add-on code G2211 would be reported with 50 percent of all office/outpatient E/M visits; and in the CY 2021 PFS proposed rule, CMS appeared to assume that HCPCS add-on code G2211 would be reported with 75 percent of all office/outpatient E/M visits. Commenters noted that this additional utilization further contributed to the redistributive effect of the budget neutrality adjustment related to revaluing the office/outpatient visit codes. The AMA RUC requested that CMS publish the methodology used for the utilization assumptions in the CY 2021 PFS proposed rule prior to HCPCS add-on code G2211's implementation.

Response: In the CY 2020 PFS rulemaking cycle, we proposed and finalized that HCPCS add-on code G2211 would be billed with every level of an office/outpatient E/M visit. We assumed that specialties that rely on office/outpatient E/M visit coding to report the majority of their services would be most likely to report HCPCS add-on code G2211 with every office/outpatient E/M visit they reported and we did not restrict billing to any particular specialty or group of specialties. We published the utilization estimates for HCPCS add-on code G2211 in the CY 2020 PFS final rule in this public use file: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-EM-Add-on-Code.zip*.

In the CY 2021 PFS proposed rule, we continued to assume that the specialties listed in the aforementioned public use file would report HCPCS add-on code G2211 with all of their office/outpatient E/M visits. As part of updating our data sources from CY 2018 to CY 2019 claims data for setting rates for the CY 2021 PFS proposed rule, we included modifier −25 utilization, meaning that we assumed that HCPCS add-on code G2211 would also be reported with office/outpatient E/M visits that were reported with a modifier −25. While this additional utilization was included in the budget neutrality calculations, we note that other proposals for CY 2021 also factor into the budget neutrality adjustment.

As we noted above, while we would not expect that HCPCS add-on code G2211 would be reported when the office/outpatient E/M visits is reported with a payment modifier, such as a modifier −25, we are not establishing any policies that prohibit reporting the add-on code under those circumstances. Thus, we will continue to include office/outpatient visits reported with a modifier −25 in our utilization assumptions for HCPCS code G2211 as part of calculating the budget neutrality adjustment for the policies we are finalizing in this rule. As we noted above, we would not expect HCPCS add-on code G2211 to be reported when the visit is reported with a modifier 2−5, and will consider whether to establish an explicit prohibition in future rulemaking. We continue to believe that separately identifiable visits occurring on the same day as minor procedures (such as zero-day global procedures) have resources that are sufficiently distinct from the costs associated with furnishing stand-alone office/outpatient E/M visits to warrant different payment. We are also analyzing our data to determine if separately identifiable visits occurring on the same day as another visit have resources that are sufficiently distinct from the costs associated with furnishing stand-alone office/outpatient E/M visits to warrant different payment. We will consider these analyses to inform potential future rulemaking.

Comment: Many commenters recommended that CMS reexamine and lower utilization assumptions for HCPCS add-on code G2211. These commenters stated that utilization tends to be lower than expected in the first year of implementation and cited the initial low utilization of the TCM and CCM codes These commenters also stated that they expected adoption to be slow given the necessity for medical societies to educate their members about appropriate use, ongoing implementation of the revisions to the office/outpatient E/M visit code set, electronic health records integration, and the persistence of the COVID–19 pandemic in many parts of the country. They recommended that utilization in the initial year could be as low as 10 percent of reported office/outpatient E/M visits and could range as high as 25 percent of reported office/outpatient E/M visits. Other commenters recommended that CMS delay the implementation of HCPCS add-on code G2211, citing the expected budget neutrality offset.

Response: We acknowledge commenters' concerns that, given the necessity of medical societies to educate their members about appropriate use, ongoing implementation of the revisions to the office/outpatient E/M visit code set, electronic health records integration, and the persistence of the COVID–19 pandemic, practitioners that rely on office/outpatient E/M visits to report the majority of their services are not likely to report HCPCS add-on code G2211 with every office visit. However, we disagree the utilization will be as low as the 10 percent to 25 percent range as recommended by these commenters. We have not implemented any additional policies that restrict the billing of this code, and so we are assuming that utilization will be 90 percent of office/outpatient E/M visits instead of the 100 percent that we assumed in the proposed rule.

d. Prolonged Office/Outpatient E/M Visits (CPT Code 99417/HCPSC Code G2212)

We reviewed our final policy for 2021 regarding the reporting of prolonged office/outpatient E/M visits finalized in the CY 2020 PFS final rule (84 FR 62848 through 62850). To report these visits beginning in 2021, we finalized CPT code 99417 (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)*), which was referred to in our previous rules as temporary CPT code 99XXX. Under CPT prefatory language, CPT code 99417 should only be reported when time is used to select the visit level, and only time of the physician or qualified healthcare professional is counted. In the CY 2020 PFS final rule, we stated that our interpretation of revised CPT prefatory language and reporting instructions would mean that CPT code 99417 could be reported when the physician's (or NPP's) time is used for code level selection and the time for a level 5 office/outpatient E/M visit (the floor of the level 5 time range) is exceeded by 15 minutes or more on the date of service (84 FR 62848 through 62849). The intent of the CPT Editorial Panel was unclear because of the use of the terms ''total time'' and ''usual service'' in the CPT code descriptor (''*requiring total time with or without direct patient contact beyond the usual*

service.'') The term ''total time'' is unclear because office/outpatient E/M visits now represent a range of time, and ''total'' time could be interpreted as including prolonged time. Further, the term, ''usual service'' is undefined. There is no longer a typical time in the code descriptor that could be used as point of reference for when the ''usual time'' is exceeded for all practitioners, and there would be variation (as well as potential double counting of time) if applied at the individual practitioner level.

Having reviewed the policy we finalized last year, we believe that allowing reporting of CPT code 99417 after the minimum time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time. As a specific example, the time range for CPT code 99215 is 40–54 minutes. If the reporting practitioner spent 55 minutes of time, 14 of those minutes are included in the services described by CPT code 99215. Therefore, only 1 minute should be counted towards the additional 15 minutes needed to report CPT code 99417 and prolonged services should not be reportable as we finalized last year (see Table 33 of the CY 2020 PFS final rule (84 FR 62849)). Therefore, we proposed that when the time of the reporting physician or NPP is used to select office/outpatient E/M visit level, CPT code 99417 could be reported when the maximum time for the level 5 office/outpatient E/M visit is exceeded by at least 15 minutes on the date of service. In Tables 26 and 27, we provided examples.

TABLE 26: Proposed Prolonged Office/Outpatient E/M Visit Reporting - New Patient

CPT Code(s)	Total Time Required for Reporting*
99205	60-74 minutes
99205 x 1 and 99417 x 1	89-103 minutes
99205 x 1 and 99417 x 2	104-118 minutes
99205 x 1 and 99417 x 3 or more for each additional 15 minutes.	119 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

TABLE 27: Proposed Prolonged Office/Outpatient E/M Visit Reporting – Established Patient

CPT Code(s)	Total Time Required for Reporting*
99215	40-54 minutes
99215 x 1 and 99417 x 1	69-83 minutes
99215 x 1 and 99417 x 2	84- 98 minutes
99215 x 1 and 99417 x 3 or more for each additional 15 minutes.	99 or more

*Total time is the sum of all time, including prolonged time, spent by the reporting practitioner on the date of service of the visit.

We received public comments on our proposal for use of CPT code 99417. The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with our concerns about the lack of clarity in the code descriptor and the potential for double-counting time. Several other commenters disagreed with our proposal and recommended that CMS adopt the CPT code descriptors. These commenters stated that a change in policy by CMS could be confusing to practitioners and disruptive to the ongoing work of medical societies to educate practitioners about the use of these codes. Some commenters also stated the CPT Editorial Panel intended to apply the general CPT rule where practitioners can report a timed code once the midpoint is reached.

Response: In the CPT 2021 Professional Edition, CPT code 99417 is described as, ''*Prolonged office or other outpatient evaluation and management service(s) beyond the minimum required time of the primary procedure which has been selected using total time, requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)).*'' The terms ''total time'' and ''usual service'' continue to be unclear.

While we prefer to align with CPT coding to reduce potential confusion to practitioners, we continue to believe that CPT code 99417 as written is unclear and that allowing reporting of CPT code 99417 when the minimum required time for the level 5 visit is exceeded by at least 15 minutes would result in double counting time. It has not been our understanding that CPT intended for the midpoint time to suffice for reporting this code, and regardless, we did not previously finalize or intend to apply such a policy.

We continue to believe it is important for CMS and other stakeholders to know with certainty how much time practitioners spend furnishing office/outpatient E/M visits, in order to assess whether resources are accurately accounted for in their valuation. This is especially true once time can be used to select visit level, with new times established for this code set. To resolve the lack of clarity, we are finalizing our proposal regarding the time that may be counted for prolonged office/outpatient E/M visits; and to resolve the potential inconsistency of our policy with CPT code 99417, we are creating a new HCPCS code G2212 to be used when billing Medicare for this service instead of CPT code 99417, starting in 2021. HCPCS code G2212 is as follows,

''*Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services*) ''*(Do not report G2212 on the same date of service as 99354, 99355, 99358, 99359, 99415, 99416). (Do not report G2212 for any time unit less than 15 minutes)*)''.''

We believe the creation of HCPCS code G2212 will serve to resolve the potential differences between Medicare and other interpretations of CPT rules, and better address questions we frequently receive about the required times and what time may be counted toward the required time to report prolonged office/outpatient E/M visits. We also note that we are not opposed in concept to reporting prolonged office/outpatient visit time on a date other than the visit. However, we continue to believe there should be a single prolonged code specific to office/outpatient E/M visits that encompasses all related time (see the CY 2020 PFS final rule for a more detailed discussion of this issue, (84 FR 62849 through 62850)). We will continue to stay abreast of any changes in CPT coding. The valuation for HCPCS code G2212 will be the same as for CPT code 99417.

G. Scope of Practice and Related Issues

We proposed several policies consistent with the President's E.O. 13890 on ''Protecting and Improving Medicare for Our Nation's Seniors'' to modify supervision and other requirements of the Medicare program that limit healthcare professionals from practicing at the top of their license (84 FR 53573, October 8, 2019, E.O. 13890). In December 2019, we requested feedback in response to part of this E.O. seeking the public's help in identifying additional Medicare regulations which contain more restrictive supervision requirements than existing state scope of practice laws, or which limit health professionals from practicing at the top of their license (the request for feedback is available at *https://www.cms.gov/files/document/request-information-reducing-scope-practice-burden.pdf*). Through review of the feedback we received, we identified the proposed policies in section II.G. of the CY 2021 PFS proposed rule (85 FR 50139). We noted that we believe that physicians, NPPs, and other professionals should be able to furnish services to Medicare beneficiaries in accordance with their scope of practice and state licensure, including education and training, to the extent permitted under the Medicare statute, as long as it is not likely to result in fraud, waste or abuse or create potential risks to beneficiary safety. The proposed policies may also help ensure an adequate number of clinicians, in addition to physicians, are able to furnish critical services including primary care services in areas where there is a shortage of physicians.[9] We noted that some of the proposals may also help alleviate the opioid crisis.

We solicited information about the number and names of states that have licensure or scope of practice laws in place, as well as any facility-specific policies, that would impact the ability of clinicians to exercise the flexibilities we proposed, to help us assess the potential impact of, or challenges for, the proposed changes. We noted that information about specific services (service-level information) would be especially helpful. We solicited public comment on whether applicable state laws, scope of practice, and facility policies would permit practitioners to exercise the proposed flexibilities if we were to adopt the proposed policies, and to what extent practitioners would be permitted to exercise the proposed flexibilities, such as for all diagnostic tests or only a subset.

We solicited information on these topics because the responses to our request for feedback issued in 2019 did not indicate the number of states that have more flexible scope of practice rules than our federal regulations, or whether facilities (such as hospitals or nursing facilities) have relevant policies that limit the ability of the impacted professionals to perform certain services. For example, if Medicare payment policy provided for payment of diagnostic tests supervised by NPPs, there may still be facility- or state-specific policies in place that limit NPPs' ability to supervise some or all diagnostic tests, and those limitations would inform the potential impact of changing our policy. While our proposed flexibility may increase the capacity and availability of practitioners who can supervise diagnostic tests, which would alleviate some of the demand on physicians as the only source to perform this particular function, we noted that we have not located information indicating the degree to which NPP scope of practice includes supervision of auxiliary staff, especially for the subset of services that are diagnostic tests. There is a wide range of diagnostic tests, from a simple strep throat swab to more sophisticated and/or invasive tests such as x-rays and cardiology procedures. We would need to understand the scope of practice for many types of auxiliary staff (some of whom are not licensed) who could potentially provide these tests under the supervision of an NPP, including RNs, LPNs, medical assistants, radiologic technicians, and many others. To the extent practice patterns change, there could be induced utilization that would increase costs, but this might be offset by reduced payment rates because direct payment to NPPs is at a lower rate than payment to physicians.

[9] Zhang et al. Physician workforce in the United States of America: forecasting nationwide shortages. *Human Resources for Health* (2020); 18:8. Published online February 6, 2020 and available online at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7006215/*.

1. Teaching Physician and Resident Moonlighting Policies

a. Background

In the March 31st COVID–19 IFC (85 FR 19258 through 19261) and the May 8th COVID–19 IFC (85 FR 27587 through 27589), we implemented several policies on an interim final basis related to PFS payment for the services of teaching physicians involving residents and resident moonlighting during the PHE for COVID–19. In the proposed rule, we noted that we planned to address comments received on the IFCs for those policies that we made proposals or solicited comment on in the proposed rule when we published the PFS final rule.

b. Finalization of Interim Final Rule With Comment Period Provisions Related to Application of Teaching Physician and Moonlighting Regulations During the PHE for the COVID–19 Pandemic

We received public comments on the policies that we adopted on an interim basis in the Interim Final Rule with Comment Period provisions related to the Application of Teaching Physician and Moonlighting Regulations During the PHE for the COVID–19 Pandemic (85 FR 19258 through 19261). The following is a summary of the comments we received and our responses.

i. Virtual Presence of a Teaching Physician Using Audio/Video Real-Time Communications Technology

Comment: Commenters were generally supportive of the virtual presence policies in §§ 415.172, 415.174, 415.180, and 415.184 that we implemented on an interim basis during the PHE for COVID–19. Several commenters supported extending the flexibilities permanently, while several

other commenters recommended continuing the policy temporarily through the end of the PHE for COVID–19, or for a period of time following the end of the PHE for COVID–19.

Response: We appreciate commenters' support for the virtual presence policies adopted on an interim basis during the PHE for COVID–19. After considering the comments, we are finalizing these policies for the duration of the PHE for COVID–19.

Comment: One commenter, in support of the virtual presence policies adopted on an interim basis during the PHE for COVID–19, recommended that CMS encourage residency programs, residency review committees, and ACGME to increase monitoring of clinical and educational work hour standards, acknowledge the impact of the changes to the teaching physician presence requirements on the residents and their optimal learning environment, and share additional information regarding how to best meet the need for reporting of information related to workload and growing service demands, patient safety, medical error, continuity of care, resident well-being and burnout, development of professionalism, resident learning outcomes, and preparation for independent practice as they relate to the use of teaching physician presence through real-time interactive audio and video technology.

Response: We do not believe it is CMS' role to regulate or monitor training outcomes or advocate on behalf of the residents themselves. Organizations representing the interests of residents and overseeing the actual operation of residency programs are in a better position to establish rules regarding the impact of virtual presence and involvement of teaching physicians on residency training outcomes.

Comment: One commenter noted that the GME community has learned many lessons during the pandemic, related to resident education and supervision. Consequently, the commenter believed that the GME community should be provided the flexibility to test new and better modalities of treatment and learning.

Response: We appreciate the commenter's support of our policies. As described previously, we are finalizing these policies for the duration of the PHE for COVID–19.

Comment: One commenter requested clarification of the definition of ''telecommunications,'' and asked whether supervision, in the context of a teaching institution, can be performed by telephone as opposed to a tablet or smartphone.

Response: The policy to allow a teaching physician to use audio/video real-time communications technology for purposes of furnishing care with a resident, and in the case of the primary care exception, directing, managing, and reviewing the care furnished by the resident, generally requires real-time direct observation (not mere availability) by the teaching physician through interactive, real-time audio and video technology, and does not include audio-only technology (for example, telephone without video).

Comment: Several commenters expressed support for the exclusion of surgical, high risk, interventional, endoscopic, or other complex procedures identified under § 415.172(a)(1), and anesthesia services under § 415.178 from the policy to allow the teaching physician to be present using audio/video real-time communications technology. One commenter recommended that the teaching physician virtual presence policy be permitted for CPT codes 31231 (*Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)*), 31575 (*Laryngoscopy, flexible; diagnostic*), and 31579 (*Laryngoscopy, flexible or rigid telescopic, with stroboscopy*) performed through an endoscope.

Response: We continue to believe the requirement for the physical, in-person presence of the teaching physician during all key or critical portions of the procedure and immediately availability to furnish services during the entire service or procedure is necessary for patient safety given the risks associated with these services. In complex, high-risk procedures, including the endoscopic procedures associated with CPT codes 31231, 31575 and 31579, a patient's clinical status can quickly change. To permit payment under the PFS for such teaching physician services, we believe the services must be furnished with a certain level of personal oversight and involvement of the teaching physician who has the experience and judgment that is necessary for rapid on-site decision-making during these procedures. With respect to the procedures associated with CPT codes 31231, 31575 and 31579, we do not believe that virtual presence by a teaching physician would provide sufficient personal involvement and control over the service to warrant billing of the services under the PFS or allow for the rapid on-site decision-making that could be necessary during the procedures, which could pose an increased risk to patients.

ii. Virtual Presence of a Teaching Physician During Medicare Telehealth Services

Comment: Commenters were generally supportive of the policy adopted on an interim basis to allow payment under the PFS when residents furnish telehealth services to beneficiaries with the teaching physician present using audio/video real-time communications technology. In addition, several commenters supported extending the flexibility permanently.

Response: We appreciate commenters' support for the policy, adopted on an interim basis during the PHE for COVID–19, to allow payment under the PFS when residents furnish telehealth services to beneficiaries with the teaching physician present using interactive, audio/video real-time communications technology (excluding audio-only). After considering the comments, we are finalizing this policy for the duration of the PHE for COVID–19.

iii. Resident Moonlighting in the Inpatient Setting

Comment: Commenters were generally supportive of the policy under § 415.208 that we adopted on an interim basis during the PHE for COVID–19 to allow PFS payment for services provided by fully licensed residents that are not related to their approved GME program in the inpatient setting of a hospital in which they are training, provided that the conditions specified in § 415.208(b)(2)(i) through (iii) are met. Several commenters recommended that this policy be implemented permanently, and some other commenters recommended that the policy be implemented for the duration of the PHE only.

Response: We appreciate commenters' support for the moonlighting policy we adopted on an interim basis during the PHE for COVID–19. After considering the comments, we are finalizing this policy for the duration of the PHE for COVID–19.

iv. Primary Care Exception Policies

Comment: Commenters were generally supportive of the policy adopted on an interim basis under § 415.174 to expand the primary care exception to include all levels of office and outpatient E/M codes. Some commenters recommended that this policy be implemented permanently, and some other commenters recommended that the policy be implemented for the duration of the PHE for COVID–19 only.

Response: We appreciate commenters' support of the expansion of the primary care exception policy adopted on an interim basis during the PHE for COVID–19. After considering the comments, we are finalizing this policy for the duration of the PHE for COVID–19.

Comment: One commenter interpreted the policy described in § 415.174 to mean that the ''immediately available supervision'' requirement described in this section could be met by the teaching physician being ''immediately available'' via real-time audio/video technology.

Response: Subsequent to the publication of the March 31st COVID–19 IFC, the May 8th COVID–19 IFC amended § 415.174 to add a new paragraph (c) to allow that, on an interim basis for the duration of the PHE for COVID–19, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through virtual means via interactive, audio/video real-time communications technology (excluding audio-only).

v. Payment Under the PFS for Teaching Physician Services When Resident Under Quarantine

Comment: A commenter supported the interim policy for the duration of the PHE for COVID–19 to permit PFS payment for teaching physician services that do not require face-to-face patient care when the resident is furnishing such services while in quarantine when the teaching physician is present through audio/video real-time communications technology.

Response: We thank the commenter for their support. After considering the comments, we are finalizing this policy for the duration of the PHE for COVID–19.

c. Finalization of Interim Final Rule Provisions Related to Additional Flexibility Under the Teaching Physician Regulations

We received public comments on the policies that we adopted on an interim basis in the Interim Final Rule provisions related to Additional Flexibility Under the Teaching Physician Regulations (85 FR 27587 through 27589). The following is a summary of the comments we received and our responses.

i. Primary Care Exception Policies

*Comment: S*everal commenters supported the policy adopted on an interim basis to allow, under the primary care exception described in § 415.174(c), the teaching physician to direct the care furnished by the resident, and to review the services furnished by the resident during or immediately after the visit, remotely using audio/video real-time communications technology. Several commenters supported a temporary extension of the policy through the end of the PHE for COVID–19 or through 2021, while other commenters suggested a permanent extension of this flexibility.

Response: We appreciate the commenters' support of this policy during the PHE for COVID–19. After considering the comments and for the reasons discussed above, we are finalizing this policy for the duration of the PHE for COVID–19.

Comment: Some commenters requested clarification of the phrase ''interactive audio/visual real-time communication technology'' because CMS has used various terms when expressing technology requirements for remote supervision and in the context of teaching physician services, and because the presence of the slash mark in the phrase makes it unclear whether both audio and visual communication must be utilized to meet the requirement, or if one or the other is sufficient. One commenter also recommended that the phrase be revised to explicitly state that a real-time audio-only communication is sufficient in order to meet the regulations set forth in § 415.174(a)(3) for use of the primary care exception.

Response: While we believe our statements have been clear on this point, we clarify here that this virtual presence policy requires real-time observation (not mere availability) by the teaching physician through a contemporaneous, interactive combination of both audio and video communications technology, and does not include audio-only technology (for example, telephone without video). We note that we have used the ''audio/video'' formulation in our regulations, and that the ''slash'' should be read consistently to mean a synchronous, interactive, real-time combination of both audio and video technology, which would not include audio-only communications for any portion of the time of the furnished service.

Comment: Commenters were generally supportive of the policy adopted on an interim basis to allow Medicare to make payment to the teaching physician for additional services under the primary care exception, including all levels of office and outpatient E/M codes, audio-only telephone E/M services, transitional care management, and communication technology-based services. Several commenters supported a temporary extension of the policy through the end of the PHE for COVID–19 or through 2021, while other commenters suggested a permanent expansion of the services that residents could furnish under the primary care exception.

Response: We appreciate commenters' support of this policy during the PHE for COVID–19. After considering the comments, we are finalizing the policy for the duration of the PHE for COVID–19.

Comment: Several commenters thanked CMS for the clarification that Medicare may make payment under the PFS for teaching physician services when a resident furnishes services permitted under the primary care exception, including via telehealth, and the teaching physician can provide the necessary direction, management and review of the resident's services using interactive audio/video real-time communications technology.

Response: We appreciate the commenters' support for this policy during the PHE.

Comment: Several commenters supported the interim policy during the PHE for COVID–19 that the office/outpatient E/M level selection for services under the primary care exception when furnished via telehealth can be based on medical decision-making or time.

Response: We thank the commenters for their support of this policy during the PHE. This policy is similar to the policy that will apply to all office/outpatient E/M services beginning in 2021 under policies finalized in the CY 2020 PFS final rule and thus, we are not finalizing it.

d. Summary of Proposed Rule Provisions and Public Comments

i. Background

In the proposed rule, we considered whether the policies implemented on an interim basis in the March 31st COVID–19 IFC or the May 8th COVID–19 IFC should be extended on a temporary basis (that is, if the PHE for COVID–19 ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comment. We noted that the public comments would assist us in identifying appropriate policies that we would consider in drafting the CY 2021 PFS final rule.

For teaching physicians, section 1842(b)(7)(A)(i)(I) of the Act specifies

that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought.

Regulations regarding PFS payment for teaching physician services and services of moonlighting residents are codified in 42 CFR part 415. In general, under § 415.170, payment is made under the PFS for services furnished in a teaching hospital setting if the services are personally furnished by a physician who is not a resident, or the services are furnished by a resident in the presence of a teaching physician, with exceptions as specified in subsequent regulatory provisions in part 415. Under § 415.172, if a resident participates in a service furnished in a teaching setting, PFS payment is made only if the teaching physician is present during the key portion of any service or procedure for which payment is sought. The regulation at § 415.180 states that, for the interpretation of diagnostic radiology and other diagnostic tests, PFS payment is made if the interpretation is performed or reviewed by a physician other than a resident. Under § 415.184, PFS payment is made for psychiatric services furnished under an approved graduate medical education (GME) program if the requirements of §§ 415.170 and 415.172 are met, except that the requirement for the presence of the teaching physician during psychiatric services in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

ii. Supervision of Residents in Teaching Settings Through Audio/Video Real-Time Communications Technology

In both the March 31st COVID–19 IFC (85 FR 19258 through 19261) and the May 8th COVID–19 IFC (85 FR 27587 through 27589), we adopted a policy on an interim basis during the PHE for COVID–19 that, under § 415.172, the requirement for the presence of a teaching physician during the key portion of the service furnished with the involvement of a resident can be met using audio/video real-time communications technology. In other words, the teaching physician must be present, either in person or virtually through audio/video real-time communications technology, during the key portion of the service. This policy generally requires real-time observation (not mere availability) by the teaching physician through audio and video technology, and does not include audio-only technology (for example, telephone without video). For the primary care exception under § 415.174(c), we adopted a policy on an interim final basis for the duration of the PHE for COVID–19 to allow the teaching physician to direct the care furnished by the resident, and to review the services furnished by the resident during or immediately after the visit, remotely using audio/video real-time communications technology.

Under § 415.180, we adopted a policy on an interim basis for the duration of the PHE for COVID–19 to allow PFS payment for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. A physician other than the resident must still review the resident's interpretation. Under § 415.184, we adopted a policy on an interim basis during the PHE for COVID–19 that the requirement for the presence of the teaching physician during the psychiatric service in which a resident is involved may be met by the teaching physician's direct supervision using audio/video real-time communications technology. We considered whether the flexibilities described above that we implemented on an interim basis during the PHE for COVID–19 under §§ 415.172, 415.174, 415.180, and 415.184 should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comments on whether these policies should continue once the PHE for COVID–19 ends. We noted that the public comments would assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. In addition, we proposed to make a technical edit to the regulation text at § 415.184 to eliminate the term ''direct supervision'' to conform with the language in sections §§ 415.172, 415.174, and 415.180 regarding the presence of the teaching physician via audio/video real-time communications technology.

While we believe it was appropriate to permit teaching physicians to be involved in services furnished with residents through audio/video real-time communications technology to respond to critical needs during the PHE to reduce exposure risk and to increase the capacity of teaching settings to respond to COVID–19, we expressed concern that continuing to permit teaching physicians to be involved through their virtual presence may not be sufficient to warrant PFS payment to the teaching physician on a temporary or permanent basis. Absent the circumstances of the PHE for COVID–19, the physical, in-person presence of the teaching physician may be necessary to provide oversight to ensure that care furnished to Medicare beneficiaries is medically reasonable and necessary, and to ensure that the teaching physician renders sufficient personal services to exercise full, personal control of the key portion of the case.

We also noted concerns about patient safety when the teaching physician is only virtually present. For example, in the March 31st COVID–19 IFC, we excluded the surgical, high risk, interventional, endoscopic, or other complex procedures identified under § 415.172(a)(1), and anesthesia services under § 415.178 from the policy to allow the teaching physician to be present using audio-video real-time communications technology because we believed the requirement for the physical, in-person presence of the teaching physician for either the entire procedure or the key portion of the service with immediate availability throughout the procedure, as applicable, is necessary for patient safety given the risks associated with these services. In complex, high-risk, surgical, interventional, or endoscopic procedures, or anesthesia procedures, a patient's clinical status can quickly change. To permit payment under the PFS for these teaching physician services, we believed the services must be furnished with a certain level of personal oversight and involvement of the teaching physician who has the experience and judgment that is necessary for rapid on-site decision-making during these procedures.

We also noted that there may be circumstances in which virtual presence of the teaching physician, considered in light of the potential risks to patient safety and absent exposure risk concerns due to COVID–19, does not demonstrate sufficient personal involvement in the service to the patient to warrant payment to the teaching physician under the PFS. For example, a resident could evaluate a patient for change in mental status following surgery for hip fracture, perform a physical exam and report it as unrevealing, and note that the patient is uncooperative with a full exam. If a full exam had been performed by the

teaching physician or with the physical presence of the teaching physician (or with the teaching physician immediately available in the clinic to provide the necessary direction, under the primary care exception) to render personal and identifiable physicians' services to the patient, the exam would likely have revealed crystal-mediated acute arthritis, and that the patient's lack of cooperation was due to hypoactive delirium. However, the teaching physician may not have been able to identify this concern through the use of audio/video interactive communications technology. In this case, the presence of the teaching physician through audio/video interactive communications technology might have been insufficient to allow the teaching physician to render personal and identifiable physicians' services to exercise full, personal control over the key portion of the encounter.

We stated that there also may be certain patient populations that require greater clinical attentiveness and skill than the teaching physician could provide via audio/video interactive communications technology. For example, patients with cognitive impairment or dementia may require the experience and skill to recognize a need for specialized testing, and patients with communication disabilities may require more experience and skill to recognize specialized needs. It may not be possible for the teaching physician to meet these clinical needs and exercise full, personal control while being present for the key portion of the service through audio/video interactive communications technology. Moreover, the virtual connection between the teaching physician and the resident who is with the patient could be disrupted (as with any virtual supervision scenario), rendering it impossible for the teaching physician to provide necessary direction for the resident to furnish appropriate care to the patient, thus foreclosing the ability of the teaching physician to exercise full, personal control over the key portion of the services, and potentially putting the patient's safety at risk.

While we expressed significant concerns about extending our interim policy to permit virtual presence of the teaching physician, whether on a temporary or permanent basis, we noted that we believe public comments would be helpful as we further consider the status of this policy. For example, because COVID–19 may continue to persist in some communities after the expiration of the PHE for COVID–19, we considered extending our policy to permit the teaching physician to be present through audio/video interactive communications technology on a temporary basis until the end of the calendar year in which the PHE for COVID–19 ends. The presence of COVID–19 may result in a need for some teaching settings to continue to limit exposure risks, especially for high risk patients isolated for their own protection or in cases where the teaching physician has been exposed to the virus and must be under quarantine. If the teaching physician is under quarantine, termination of the policy to permit virtual presence of the teaching physician could unintentionally limit the number of licensed practitioners available to furnish services to Medicare patients in some communities, and could have the unintended consequence of limiting access to services for Medicare patients. Some communities may experience a resurgence of COVID–19, and extending our policy until the end of the calendar year in which the PHE for COVID–19 ends to permit PFS payment when the teaching physician is present through audio/video real-time communications technology could temporarily help teaching settings remain prepared with surge capacity.

Based on the clinical experience gained during the PHE for COVID–19, we noted that we might identify circumstances or procedures for which the teaching physician can routinely render sufficient personal and identifiable services to the patient to exercise full, personal control over the management of the key portion of the case when the services are furnished by a resident with the teaching physician present through audio/video real-time communications technology. For example, under ordinary circumstances for the primary care exception at § 415.174, we permit PFS payment to the teaching physician when a resident furnishes office/outpatient evaluation and management (E/M) visit codes of lower and mid-level complexity and annual wellness visits without the presence of a teaching physician (these codes are discussed in section II.F. of this final rule (85 FR XXXXX)). Additionally, the teaching physician may be able to provide sufficient involvement for simple procedures such as CPT code 36410 (*Venipuncture, age 3 years or older, necessitating the skill of a physician or other qualified health care professional (separate procedure), for diagnostic or therapeutic purposes (not to be used for routine venipuncture*) or CPT code 51701 (*Insertion of non-indwelling bladder catheter (e.g., straight catheterization for residual urine)*). For such circumstances and procedures, we stated that it may be appropriate to continue the virtual presence policy on a temporary or permanent basis.

We noted that having the virtual presence policy in place temporarily or permanently would not preclude teaching physicians from providing a greater degree of involvement in services furnished with residents, and teaching physicians would still have discretion to determine whether, and if so, when it is appropriate to be present virtually rather than in person depending on the services being furnished and the experience of the particular residents involved. We solicited comments to help us understand how the option to provide for teaching physician presence using audio/video real-time communications technology would support patient safety for all patients and particularly for at-risk patients (for example, patients who are aged and/or who have a disability); ensure burden reduction without creating risks to patient care or increasing fraud; avoid duplicative payment between the PFS and the IPPS for GME programs; and support emergency preparedness. We also solicited comments to provide data and other information on experiences implementing this policy during the PHE for COVID–19.

We received public comments on our proposal to make a technical edit to the regulation text at § 415.184 to eliminate the term ''direct supervision'' to conform with the language in sections §§ 415.172, 415.174, and 415.180 regarding the presence of the teaching physician via audio/video real-time communications technology. The following is a summary of the comments we received and our responses.

Comment: Multiple commenters supported striking the term ''direct supervision'' from § 415.184 to conform to related sections describing the requirements for supervision of residents in teaching settings.

Response: We appreciate the commenters' support and are finalizing the technical edit to the regulation text at § 415.184 as proposed.

We also received public comments in response to the CY 2021 PFS proposed rule on whether the policies we adopted on an interim basis during the PHE for COVID–19 under §§ 415.172, 415.174, 415.180, and 415.184 should continue once the PHE ends. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of the virtual presence policies in §§ 415.172,

415.174, 415.180, and 415.184 that we implemented on an interim basis during the PHE for COVID–19. Several commenters supported extending the flexibilities permanently and asserted that a permanent expansion would promote patient access to physicians' services, particularly in rural areas, as well as continuity, convenience, flexibility, choice, and a decrease in the spread of COVID–19. Another commenter stated that in rural settings, it was not always possible for the teaching physician to accompany a resident while also being present with other residents. This commenter stated that the ability for the resident to be physically with a patient while the teaching physician is virtually present has increased patient access to physicians' services in rural areas. Similarly, other commenters stated that the permanent ability for teaching physicians to be virtually present when not physically present could open up additional training opportunities to care for underserved populations or increase specialty training opportunities for rural training programs.

Commenters broadly supported the exclusion of surgical, high risk, interventional, endoscopic, or other complex procedures, including anesthesia, from the virtual presence policy. While supportive of the flexibilities that we implemented on an interim basis, some commenters recommended temporarily extending the policies through the end of the PHE for COVID–19 to provide flexibility for communities that may experience resurgences in COVID–19 infections. These commenters cited a need to gather data regarding patient safety and potential impacts on resident training outside the context of the PHE before considering permanent implementation of the policies. For example, one commenter noted that CMS could use data from procedures furnished by residents during the PHE under virtual presence of the teaching physician to determine which procedures may be appropriate for virtual supervision on an ongoing basis.

Response: We appreciate commenters' support of the virtual presence policies that we implemented on an interim basis during the PHE for COVID–19. We remain concerned that, absent the circumstances of the PHE, virtual presence may not allow the teaching physician to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought, in accordance with section 1842(b)(7)(A)(i)(I) of the Act in most settings. For rural areas, however, we found compelling the commenters' statements that our virtual presence policy has increased access to Medicare-covered services. Accordingly, we believe that permitting the teaching physician to meet the requirements to bill under the PFS for their services through virtual presence when furnishing services involving residents in rural training settings could increase access to Medicare-covered services by preventing the beneficiary from potentially having to travel long distances to obtain care, particularly as rural areas have stretched and diminishing clinical workforces.[10]

Increasing beneficiary access to care in rural areas is also consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas.[11] Further, permitting the virtual presence of the teaching physician could facilitate expanded training opportunities for residents in rural settings, which have historically been in limited supply.[12] As such, the need to improve rural access to care for patients and training for residents overshadows our concerns about the ability for the teaching physician to render sufficient personal and identifiable physicians' services through virtual presence. Accordingly, we believe it would be appropriate to continue our policy to permit teaching physicians to meet the requirements to bill under the PFS for their services through virtual presence when furnishing services involving residents in rural settings after the conclusion of the PHE for COVID–19. This policy not only furthers our goals to increase beneficiary access to Medicare-covered services, it also facilitates needed training opportunities in a similar way to the longstanding primary care exception under § 415.174. The primary care exception permits the teaching physician to bill for certain types of physicians' services furnished by residents in certain settings even when the teaching physician is not present with the resident. Like the policy we are finalizing in this rule, the primary care exception facilitates access to Medicare-covered services and expanded residency training opportunities in primary care settings.

Therefore, we are finalizing a permanent policy to permit teaching physicians to meet the requirements to bill for their services involving residents through virtual presence, but only for services furnished in residency training sites that are located outside of an OMB-defined metropolitan statistical area (MSA).[13] In order to ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought in accordance with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying our existing documentation requirements to specify that, when a teaching physician, through virtual presence, furnishes services involving residents in a residency training site located outside of a MSA, the patient's medical record must clearly reflect how and when the teaching physician was present for the service in accordance with our regulations. For example, in the medical record, the teaching physician could document their physical or virtual presence at the training site during the key portion of a service, along with a notation describing the specific portion(s) of the service for which the teaching physician was virtually present, and/or that the teaching physician reviewed the service with the resident during or immediately after the service in accordance with the primary care exception under § 415.174. We also expect that, if the teaching physician is virtually present and bills for services during which there is a disruption to the virtual connection between the teaching physician and the resident who is with the patient, the encounter would be paused until the connection resumes, or the appointment would be rescheduled.

For all other settings, we are not permanently finalizing our teaching physician virtual presence policies; however, they will remain in place for the duration of the PHE to provide flexibility for communities that may experience resurgences in COVID–19 infections. While we do not anticipate any program integrity concerns to arise from this expanded flexibility in rural areas, we agree with commenters that it is necessary for use to consider

[10] Supply and Distribution of the Primary Care Workforce in Rural America: 2019: *https://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2020/06/RHRC_PB167_Larson.pdf. https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/reports/HRSA-Rural-Collaboration-Guide.pdf.*

[11] CMS Rural Health Strategy: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.*

[12] HHS awards $20 million to 27 organizations to increase the rural workforce through the creation of new rural residency programs: *https://www.hhs.gov/about/news/2019/07/18/hhs-awards-20-million-to-27-organizations-to-increase-rural-workforce.html.*

[13] Revised Delineations of Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and Guidance on Uses of the Delineations of These Areas: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf.*

additional data prior to proposing additional policies in this area, which could range from expanding this flexibility to include non-rural settings to terminating this flexibility in all settings. Specifically, we anticipate considering to what degree the permanent establishment of the policy to permit teaching physician virtual presence in residency training sites that are located outside of a MSA increased patient access to Medicare-covered services and provided additional training opportunities for residents while enabling the teaching physician to render sufficient personal and identifiable physicians' services. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data or another assessment mechanism, to further study the impacts of this limited permanent expansion of the virtual presence policy to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

We are amending our regulations to reflect this final policy. In § 415.172(a), to conform with the regulation text we are finalizing to describe direct supervision in § 410.32(b)(3)(ii), we are adding language to state that, as a general rule, the required presence of a teaching physician in order to bill under the PFS for their services at a residency training site that is located outside of a MSA can be met through interactive, audio/video real-time communications technology, which, as noted above, means synchronous, interactive, audio and video communications technology, and does not include audio-only communications. We are also adding language to provide that, for the duration of the PHE for COVID–19, in all teaching settings, the required presence of a teaching physician can be met through interactive, audio/video real-time communications technology (excluding audio-only).

In § 415.172(a)(2), we are adding language to note the exceptions under which virtual presence is permitted in the case of E/M services.

In § 415.172(b), which discusses existing documentation requirements, we are adding language to clarify that, for residency training sites that are located outside of a MSA, the medical record must clearly reflect whether the teaching physician was physically or virtually present at the training site during the key portion of the service. We are also adding language to clarify that, for all teaching settings and for the duration of the PHE for COVID–19, the patient's medical record must clearly reflect whether the teaching physician was physically or virtually present during the key portion of the service. Finally, we are adding language to clarify that the medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through interactive, audio/video real-time communications technology (excluding audio-only).

In § 415.174(c), we are adding language to state that, for all teaching settings and for the duration of the PHE for COVID–19, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through interactive, audio/video real-time communications technology (excluding audio-only).

In § 415.174(d), we are adding language to state that, for residency training sites that are located outside of a MSA, the teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through interactive, audio/video real-time communications technology (excluding audio-only).

In § 415.180(a), we are adding language to state that, for residency training sites that are located outside of an MSA, PFS payment may be made for the interpretation of diagnostic radiology and other diagnostic tests when the interpretation is performed by a resident and when the teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only). We are also adding language to state that, for all teaching settings and for the duration of the PHE for COVID–19, PFS payment may be made for the interpretation of diagnostic radiology and other diagnostic tests when the interpretation is performed by a resident and when the teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only). Finally, we are adding language to clarify that the medical records must document the extent of the teaching physician's participation in the interpretation or review of the diagnostic radiology or diagnostic test.

In § 415.184, we are adding language to state that, for residency training sites that are located outside of a MSA, the requirement for the presence of the teaching physician during the psychiatric service in which a resident is involved may be met using interactive, audio/video real-time communications technology (excluding audio-only). We are also adding language to state that, for all teaching settings and for the duration of the PHE for COVID–19, the requirement for the presence of the teaching physician during the psychiatric service in which a resident is involved may be met using interactive, audio/video real-time communications technology (excluding audio-only). Finally, we are adding language to clarify that the medical records must document the extent of the teaching physician's participation in the service.

While difficult to quantify, we believe that permanently extending the policy to permit virtual presence of teaching physicians in residency training sites that are located outside of an MSA will improve patient access to Medicare-covered physicians' services in rural areas. In addition, the ability of a teaching physician to meet the requirements to bill for services furnished involving residents through their virtual presence in these settings will improve teaching capabilities and potentially allow for additional resident education opportunities in rural areas. Settings that have traditionally been inaccessible as training sites for residents due to the limited ability of teaching physicians to be physically present will be more readily available, thereby affording increased access to physicians' services to patients in these areas. However, in order to ensure that this limited extension of the virtual presence policy is also consistent with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying our existing documentation requirements to specify that the medical record must clearly reflect how and when the teaching physician was present for the service. We believe this documentation clarification will ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought. Further, in order to minimize potential risks to patients, we remind physicians and other practitioners that the adoption of these virtual presence policies in residency training sites that are located outside a MSA does not preclude teaching physicians from being physically present when providing services furnished with residents. We therefore urge teaching physicians to continue to use their professional judgment to determine the circumstances under which it is appropriate to be present virtually rather than in person depending on the services being furnished and the experience of the

particular resident(s) and/or teaching physician involved.

Comment: In response to our comment solicitation for information regarding how the virtual presence of a teaching physician would support patient safety, several commenters stated that guardrails exist through the Accreditation Council for Graduate Medical Education (ACGME) and other accrediting organizations that have standards and systems to ensure patient safety and oversight of residents when virtual supervision of residents occurs.

Response: We appreciate commenters' suggestions that the policies of the ACGME and other accrediting organizations could serve as guardrails in the context of virtual supervision; however, the commenters provided no specific description of any such policies or any other evidence to further identify those guardrails. Without further information, CMS cannot opine on the sufficiency of ACGME or other accrediting organization policies. Therefore, we continue to rely on the clinical judgment of teaching physicians and the residents they involve in their care to ensure appropriate patient safety.

iii. Virtual Teaching Physician Presence During Medicare Telehealth Services

In the March 31st COVID–19 IFC (85 FR 19230), we adopted a policy on an interim basis to allow Medicare to make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/video real-time communications technology. We also noted that we were considering whether this policy should be extended on a temporary basis (that is, if the PHE for COVID–19 ends in 2021, this policy could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comments on whether this policy should continue once the PHE for COVID–19 ends. We noted that the public comments would assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. Outside the circumstances of the PHE for COVID–19, under the requirements at section 1834(m) of the Act that discuss payment for telehealth services, the patient would be located at a telehealth originating site, and the teaching physician would be furnishing the service as the distant site practitioner with the involvement of the resident.

While teaching physician presence through audio/video real-time communications technology when a resident furnishes Medicare telehealth services was responsive to critical needs during the PHE for COVID–19 to reduce exposure risk and to increase the capacity of teaching settings to respond to COVID–19, we expressed concern that the policy to permit virtual presence of the teaching physician may not allow for sufficient personal and identifiable physicians' services to exercise full, personal control over the services such that PFS payment to the teaching physician would be appropriate outside the circumstances of the PHE for COVID–19 on a temporary or permanent basis. We also noted concern that if the resident was furnishing the service at the distant site and the teaching physician was at a third site and present with the resident through audio/video real-time communications technology, the teaching physician may not be able to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the service to warrant separate payment on the PFS.

Absent the need to reduce exposure risk to COVID–19 during the PHE, we also expressed some concerns about patient safety when the teaching physician is present only virtually during a telehealth service furnished by a resident. For example, the virtual connection between the teaching physician and the resident who is with the patient could be disrupted (as with any virtual supervision scenario), rendering it impossible for the teaching physician to provide necessary direction for the resident to furnish appropriate care to the patient, thus foreclosing the ability of the teaching physician to exercise full, personal control over the key portion of the service, and potentially putting the patient's safety at risk.

However, because COVID–19 may continue to persist in some communities and some communities may experience a resurgence of COVID–19 after the expiration of the PHE for COVID–19, we solicited comments about whether it would be appropriate to extend this policy on a temporary basis until the end of the calendar year in which the PHE for COVID–19 ends. The presence of COVID–19 may result in a need to continue to limit exposure risks. In cases where the teaching physician has been exposed to the virus and is under quarantine, termination of the policy to permit virtual presence of the teaching physician could unintentionally limit the number of licensed practitioners available to furnish services to Medicare patients in some communities, and could have the unintended consequence of limiting access for Medicare patients. Finally, based on experience gained during the PHE for COVID–19, we noted that we might identify circumstances for which the teaching physician can routinely render sufficient personal and identifiable services to the patient to exercise full, personal control over the management of the key portion of the case while providing virtual presence during Medicare telehealth services furnished by a resident on a permanent basis. For example, under ordinary circumstances for the primary care exception at § 415.174, we permit PFS payment to the teaching physician when a resident furnishes office/outpatient E/M visit codes of lower and mid-level complexity and annual wellness visits without the presence of a teaching physician (these codes were discussed in section II.F. of the proposed rule (85 FR 50121)). For such services, we noted that it may be appropriate to continue the virtual presence policy on a temporary or permanent basis. We solicited comments to help us understand how the option to allow teaching physician presence using audio/video real-time communications technology could support patient safety for all patients and particularly for at-risk patients (for example, patients who are aged and/or who have a disability), ensure burden reduction without creating risks to patient care or increasing fraud, avoid duplicative payment between the PFS and the IPPS for GME programs, and support emergency preparedness. We also solicited comments to provide data and other information on experiences implementing this policy during the PHE for COVID–19.

We received public comments on whether the policy we adopted on an interim final basis during the PHE for COVID–19 to allow Medicare to make payment under the PFS to the teaching physician when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using audio/video real-time communications technology should continue once the PHE for COVID–19 ends. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of our interim policy to allow Medicare to make payment under the PFS to the teaching physician when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician

is present using audio/video real-time communications technology. Several commenters supported extending the flexibility permanently, while others recommended temporarily extending the policy through the end of the PHE for COVID–19, and cited a need to gather data regarding patient safety and potential impacts on resident training outside the context of the PHE for COVID–19. One commenter stated that in rural settings, it was not always possible for the teaching physician to accompany a resident while also being present to other residents. This commenter stated that the ability for the teaching physician is virtually present has increased patient access to physicians' services in rural areas. Similarly, other commenters stated that the permanent ability for teaching physicians to be virtually present when not physically present could increase training opportunities for rural training programs, and better prepare residents for the nuances and differences of providing care over video instead of in person.

Response: We appreciate commenters' support of our interim policy to allow Medicare to make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present using interactive, audio/video real-time communications technology (excluding audio-only). We remain concerned that, absent the circumstances of the PHE, a teaching physician's presence via interactive, audio/video real-time communications technology (excluding audio-only) when a resident is furnishing Medicare telehealth services may not allow the teaching physician to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought, in accordance with section 1842(b)(7)(A)(i)(I) of the Act, in most settings. For rural areas, however, we found compelling the commenters' statements that our virtual presence policy has increased access to Medicare-covered services. Accordingly, we believe that a policy to permit Medicare to make PFS payment for teaching physician services when a resident located within a rural training setting furnishes Medicare telehealth services to beneficiaries while a teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only) could increase access to Medicare-covered services in rural areas by preventing the beneficiary from potentially having to travel long distances to obtain care, particularly as rural areas have stretched and diminishing clinical workforces.[14] Increasing beneficiary access to care in rural areas is also consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas; therefore, in order to allow for more widespread access to care for beneficiaries in rural areas, we believe it would be appropriate for a resident located within a rural training setting to furnish telehealth services to a beneficiary who is in a separate location within the same rural area as the resident or within a different rural area, while a teaching physician is present, through interactive, audio/video real-time communications technology (excluding audio-only), in a third location, either within the same rural training setting as the resident or outside of that rural training setting.[15] Further, allowing Medicare to make PFS payment for teaching services when a resident furnishes Medicare telehealth services to a beneficiary while a teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only) could facilitate additional training opportunities for residents in rural settings, which have historically been in limited supply.[16] As such, the need to improve rural access to care for patients and training for residents overshadows our concerns about the ability for the teaching physician to render sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. Accordingly, in rural areas, we believe it would be appropriate to continue our policy to permit teaching physicians to meet the requirements to bill under the PFS for their services when a resident furnishes Medicare telehealth services to beneficiaries while a teaching physician is present through interactive, audio/video real-time communications technology (excluding audio-only) after the conclusion of the PHE for COVID–19. This policy not only furthers our goals to increase beneficiary access to Medicare-covered services, it also facilitates needed training opportunities in a similar way to the longstanding primary care exception under § 415.174. The primary care exception permits the teaching physician to bill for certain types of physicians' services furnished by residents in certain settings even when the teaching physician is not present with the resident. Like the policy we are finalizing in this rule, the primary care exception facilitates access to Medicare-covered services and expanded residency training opportunities in primary care settings. Therefore, we are permanently finalizing our policy that Medicare may make payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services in a residency training site located outside of a MSA to a beneficiary who is in a separate location outside the same MSA (that is, in the same rural area) as the residency training site or is within a rural area outside of a different MSA, while a teaching physician is present, through interactive, audio/video real-time communications technology (excluding audio-only), in a third location, either within the same rural training site as the resident or outside of that rural training site. In order to ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought, in accordance with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying our existing documentation requirements to specify that, when a resident furnishes Medicare telehealth services in a residency training site located outside of a MSA and the teaching physician is present using interactive, audio/video real-time communications technology (excluding audio-only), the patient's medical record must clearly reflect how and when the teaching physician was present during the key portion of the service, in accordance with our regulations. For example, in the medical record, the teaching physician could document their physical or virtual presence at the training site during the key portion of the service, along with a notation describing the specific portion(s) of the service for which the teaching physician was virtually present, and/or that the teaching physician reviewed the service with the resident during or immediately after the service in accordance with the primary

[14] A Guide for Rural Health Care Collaboration and Coordination: *https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/reports/HRSA-Rural-Collaboration-Guide.pdf.*

[15] CMS Rural Health Strategy: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.*

[16] HHS awards $20 million to 27 organizations to increase the rural workforce through the creation of new rural residency programs: *https://www.hhs.gov/about/news/2019/07/18/hhs-awards-20-million-to-27-organizations-to-increase-rural-workforce.html.*

care exception under § 415.174. We also expect that, if the teaching physician is virtually present and bills for services during which there is a disruption to the virtual connection between the teaching physician and the resident who is with the patient, the encounter would be paused until the connection resumes, or the appointment would be rescheduled.

For all other settings, we are not permanently finalizing this policy; however, the policy will remain in place for the duration of the PHE for COVID–19 to provide flexibility for communities that may experience resurgences in COVID–19 infections. While we do not anticipate any program integrity concerns from this expanded flexibility, we agree with commenters that it is necessary for us to consider additional data prior to proposing additional policies in this area, which could range from expanding this flexibility to include non-rural settings to terminating this flexibility in all settings. Specifically, we anticipate considering to what degree the permanent implementation of the policy to allow PFS payment for teaching services when a teaching physician is virtually present while a resident furnishes Medicare telehealth services in a residency training site located outside of an MSA increased patient access to Medicare-covered services and provided more training opportunities for residents while enabling the teaching physician to render sufficient personal and identifiable physicians' services. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data or another assessment mechanism, to further study the impacts of this limited permanent expansion of the policy to allow PFS payment for teaching services when a teaching physician is virtually present while a resident furnishes Medicare telehealth services to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

We are amending our regulations to reflect this final policy. In § 415.172(a), we are adding language to state that, in a residency training site located outside of an MSA, a teaching physician may bill under the PFS for services furnished when they are present with the resident during the key portion of the service through interactive, audio/video real-time communications technology (excluding audio-only), including when the resident provides Medicare telehealth services. We are also adding language to state that, for all teaching settings and for the duration of the PHE for COVID–19, payment under the PFS is permitted if a teaching physician is present during the key portion of the service, including Medicare telehealth services, through interactive, audio/video real-time communications technology (excluding audio-only). In § 415.172(b), which discusses existing documentation requirements, we are adding language to clarify that, for residency training sites that are located outside of a MSA, the patient's medical record must clearly reflect whether the teaching physician was physically or virtually present at the training site during the key portion of the service, including for Medicare telehealth services. We are also adding language to clarify that, for all teaching settings and for the duration of the PHE for COVID–19, the patient's medical record must clearly reflect whether the teaching physician was physically or virtually present during the key portion of the service, including for Medicare telehealth services. Finally, we are adding language to clarify that the medical records must contain a notation describing the specific portion(s) of the service, including Medicare telehealth services, for which the teaching physician was present through interactive, audio/video real-time communications technology (excluding audio-only).

While difficult to quantify, we believe that permanently extending our policy to allow payment under the PFS for teaching physician services when a resident furnishes Medicare telehealth services in a residency training site located outside of an MSA and the teaching physician is present through interactive audio/video real-time communications technology (excluding audio-only) will promote enhanced patient access to Medicare-covered physicians' services in rural areas. In addition, allowing PFS payment for teaching physician services when a resident furnishes Medicare telehealth services in a residency training site located outside of an MSA and the teaching physician is present through interactive audio/video real-time communications technology (excluding audio-only) will improve teaching capabilities and potentially allow for additional resident education opportunities in rural areas. Settings that have traditionally been inaccessible as training sites for residents due to the limited ability of teaching physicians to be physically present will be more readily available, thereby affording increased access to physicians' services to patients in these areas. However, in order to ensure that the limited extension of this policy is also consistent with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying the existint documentation requirements to specify that the medical record must clearly reflect how and when the teaching physician was present for the Medicare telehealth service. We believe this documentation clarification will ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. Further, in order to minimize potential risks to patients, we remind physicians and other practitioners that the adoption of this policy in residency training sites that are located outside of an MSA does not preclude teaching physicians from being physically present when a resident is furnishing Medicare telehealth services. We therefore urge teaching physicians to continue to use their professional judgment to determine the circumstances under which it is appropriate to be present virtually rather than in person, depending on the Medicare telehealth services being furnished and the experience of the particular residents involved.

Comment: One commenter, who favored a permanent policy to allow PFS payment for teaching physician services when a resident furnishes Medicare telehealth services in a residency training site located outside of a MSA and the teaching physician is present using interactive audio/video real-time communications technology, advocated for the permanent extension of the policy by noting that ACGME recognizes and endorses an expansion of telemedicine as well as the use of audio/visual communications devices by residents and their teaching physicians. Further, the commenter stated that, as long as the virtual presence of teaching physicians during Medicare telehealth services continues to adhere to ACGME standards, an optimal learning environment, with appropriate education and supervision, would be maintained.

Response: We appreciate the commenter's feedback regarding ACGME standards in the context of the expansion of telemedicine and the use of audio/visual communication devices by residents and teaching physicians; however, the commenter provided no specific description of ACGME's standards or any evidence to support a permanent implementation of the policy to allow PFS payment for teaching services when a resident furnishes Medicare telehealth services in all settings when a teaching physician is present through interactive, audio/video

real-time communications technology (excluding audio-only). Without further information, CMS cannot opine on whether or not ACGME's standards would support a wider permanent implementation of this policy. Therefore, we continue to rely on the clinical judgment of teaching physicians and the residents they involve in their care to ensure appropriate patient safety.

iv. Resident Moonlighting in the Inpatient Setting

Under certain conditions, the services of a licensed resident physician who is ''moonlighting'' are considered to be furnished by the individual in their capacity as a physician, rather than as a resident in an approved GME program. As specified in the regulation at § 415.208, except during the PHE for COVID–19, as defined in the regulation at § 400.200, the services of residents to inpatients of hospitals in which the residents have their approved GME program are not considered separately billable as physicians' services and instead are payable under §§ 413.75 through 413.83 regarding direct GME payments, whether or not the services are related to the approved GME training program. When a resident furnishes services that are not related to their approved GME programs in an outpatient department or emergency department of a hospital in which they have their training program, those services can be billed separately as physicians' services and payable under the PFS if they meet the criteria described in our regulation at § 415.208(b)(2)(i) through (iii). In addition, under § 415.208(c), services of a licensed resident furnished outside the scope of an approved GME program when moonlighting in a hospital or other setting that does not participate in the approved GME program are payable under the PFS when the resident is fully licensed to practice in the state where the services are furnished, and the resident's time spent in patient care activities in that setting is not counted for the purpose of Medicare direct GME payments.

In the March 31st COVID–19 IFC, we amended our regulation at § 415.208 to state that, during the PHE for COVID–19, the services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program are separately billable physicians' services for which payment can be made under the PFS provided that the services are identifiable physicians' services and meet the conditions for payment of physicians' services to beneficiaries by providers in § 415.102(a), the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the state in which the services are performed, and the services can be separately identified from those services that are required as part of the approved GME program. We considered whether this flexibility that we implemented on an interim basis should be extended on a temporary basis (that is, if the PHE for COVID–19 ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comments on whether this policy should continue once the PHE ends. We expressed concerns that there may be risks to program integrity in allowing residents to furnish separately billable physicians' services to inpatients in the teaching hospitals where they are training when the services are outside the scope of their approved GME program. For example, there could be a risk of duplicate Medicare payment for the resident's services under the IPPS for GME and the PFS if the physicians' services furnished by residents were not adequately separately identified from those services that are required as part of the GME program. However, because COVID–19 may continue to persist in some communities or some communities may experience a resurgence of COVID–19 after the expiration of the PHE, we noted that it may be appropriate for us to extend this policy on a temporary basis to meet the needs of teaching hospitals to ensure that there are as many qualified practitioners available as possible. We noted that the public comments would assist us in identifying appropriate policy continuation decisions that we would consider finalizing in this CY 2021 PFS final rule. We also solicited comments to provide data and other information on experiences implementing this policy during the PHE for COVID–19.

We received public comments from our comment solicitation in the proposed rule regarding whether our resident moonlighting policy under § 415.208 that we implemented on an interim basis for the PHE for COVID–19 should continue once the PHE ends. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of the policy under § 415.208 that we adopted on an interim basis during the PHE for COVID–19. Several commenters supported extending the flexibility permanently, while others recommended temporarily extending the policy through the end of the PHE for COVID–19, and cited a need to maintain surge capacity and to allow more data to be gathered regarding patient safety and potential impacts on resident training outside the context of the PHE. A few commenters suggested that to prevent duplicate billing, CMS should educate practitioners about the need for sufficient documentation to demonstrate that services furnished while residents are moonlighting are separate from those services that are required as part of approved GME programs.

Response: We appreciate commenters' support for our interim policy. After considering the comments, we are finalizing our interim policy for the services of moonlighting residents on a permanent basis. Consequently, we are amending our regulation at § 415.208(b)(2) to state that the services of residents that are not related to their approved GME programs and are performed in the outpatient department, emergency department, or inpatient setting of a hospital in which they have their training program are separately billable physicians' services for which payment can be made under the PFS provided that the services are identifiable physicians' services and meet the conditions of payment for physicians' services to beneficiaries in providers in § 415.102(a), the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and the services are not performed as part of the approved GME program.

We agree with commenters about the need for sufficient documentation to allay concerns about potential duplication of payment with the IPPS for GME. Thus, we are also amending § 415.208(b)(2) to clarify that, regardless of whether the resident's services are performed in the outpatient department, emergency department or inpatient setting of a hospital in which they have their training program, the patient's medical record must clearly reflect that the resident furnished identifiable physician services that meet the conditions of payment of physician services to beneficiaries in providers in § 415.102(a), that the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and that the services are not performed as part of the approved GME program. For example, in the medical record, the resident could state that they are licensed to practice medicine, osteopathy, dentistry or podiatry by the

state in which the service was performed, document that the service was performed outside of their approved GME program, and include a notation describing the specific physician service that was furnished,

v. Primary Care Exception Policies

The regulation at § 415.174 sets forth an exception to the conditions for PFS payment for services furnished in teaching settings in the case of certain E/M services furnished in certain centers. Under the so-called ''primary care exception,'' Medicare makes PFS payment in certain teaching hospital primary care centers for certain services of lower and mid-level complexity furnished by a resident without the physical presence of a teaching physician. Section 415.174(a)(3) requires that the teaching physician must not direct the care of more than four residents at a time, and must direct the care from such proximity as to constitute immediate availability (that is, provide direct supervision) and must review with each resident during or immediately after each visit, the beneficiary's medical history, physical examination, diagnosis, and record of tests and therapies. Section 415.174(a)(3) also requires that the teaching physician must have no other responsibilities at the time, assume management responsibility for the beneficiaries seen by the residents, and ensure that the services furnished are appropriate.

As provided in the regulation at § 415.174(a), the codes of lower and mid-level complexity that can be furnished under the primary care exception are specified in section 100 of chapter 12 of the Medicare Claims Processing Manual (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf*). They are the following:

- CPT code 99201 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99202 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 20 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99211 (*Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal. Typically, 5 minutes are spent performing or supervising these services*);
- CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*);
- CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 15 minutes are spent face-to-face with the patient and/or family*);
- HCPCS code G0402 (*Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of Medicare enrollment*);
- HCPCS code G0438 (*Annual wellness visit; includes a personalized prevention plan of service (PPS), initial visit*); and
- HCPCS code G0439 (*Annual wellness visit, includes a personalized prevention plan of service (PPS), subsequent visit*).

In the March 31st COVID–19 IFC, we amended § 415.174 of our regulations to allow, during the PHE for COVID–19, all levels of office/outpatient E/M visits to be furnished by the resident and billed by the teaching physician under the primary care exception. In the May 8th COVID–19 IFC), we further expanded the list of services included in the primary care exception during the PHE for COVID–19. We also allowed PFS payment to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services were also on the list of Medicare telehealth services.

We noted that we were considering whether these policies should be extended on a temporary basis (that is, if the PHE for COVID–19 ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent, and solicited public comments on whether these policies should continue once the PHE for COVID–19 ends. We also noted that the public comments would assist us in identifying appropriate policy continuation decisions that we would consider finalizing in the CY 2021 PFS final rule. We also considered whether specific services added under the primary care exception should be extended temporarily or made permanent and solicited public comments on whether these services should continue as part of the primary care exception once the PHE for COVID–19 ends. These services are the following:

- CPT code 99204 *(Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of moderate complexity. Counseling and/or*

coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family);

- CPT code 99205 *(Office or other outpatient visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family);*
- CPT code 99214 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 25 minutes are spent face-to-face with the patient and/or family);*
- CPT code 99215 *(Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family);*
- CPT code 99495 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least moderate complexity during the service period; face-to-face visit within 14 calendar days of discharge*);
- CPT code 99496 (*Transitional Care Management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge; medical decision making of at least high complexity during the service period; face-to-face visit within 7 calendar days of discharge*);
- CPT code 99421 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes*);
- CPT code 99422 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11–20 minutes*);
- CPT code 99423 (*Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes*);
- CPT code 99452 (*Interprofessional telephone/internet/electronic health record referral service(s) provided by a treating/requesting physician or qualified health care professional, 30 minutes*);
- HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion*); and
- HCPCS code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*).

We noted that expanding the array of services for which Medicare may make PFS payment to the teaching physician when furnished by a resident under the primary care exception was responsive to critical needs during the PHE for COVID–19 for patients who may be quarantined at home or who may need to be isolated for purposes of minimizing exposure risk based on presumed or confirmed COVID–19 infection. Because COVID–19 may continue to persist in some communities or some communities may experience a resurgence of COVID–19 after the expiration of the PHE for COVID–19, we also noted that it may be appropriate for us to extend all of these services on a temporary basis (that is, until the end of the calendar year in which the PHE for COVID–19 ends).

However, we expressed concern that it may be inappropriate to extend all of these services on a temporary basis or add them to the primary care exception permanently. The intent of the primary care exception as described in § 415.174 is that E/M visits of lower and mid-level complexity furnished by residents are simple enough to permit a teaching physician to be able to direct and manage the care of up to four residents at any given time and direct the care from such proximity as to constitute immediate availability. While CPT code 99421 and HCPCS code G2012 may be simple services, others such as levels 4 and 5 office/outpatient E/M visits (CPT codes 99204 through 99205 and CPT codes 99214 through 99215) and transitional care management codes (CPT codes 99495 through 99496) require medical decision-making that is of at least moderate complexity. We also noted concern that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. We noted that when the teaching physician is directing the care of a patient that requires moderate or higher medical decision-making, the ability to be immediately available to other residents could be compromised, potentially putting patients at risk. Thus, we considered whether, upon expiration of the PHE for COVID–19, we should extend on a temporary basis some or all of the services we added to the primary care exception list during the PHE and solicited public comments on whether these services should continue as part of the primary care exception after the PHE ends. We also solicited comments to provide data and other information on experiences implementing this policy during the PHE for COVID–19.

We also considered whether our interim policy that PFS payment could be made to the teaching physician when residents furnish telehealth services under the primary care exception should be extended on a temporary basis or be made permanent, and solicited public comments on whether this policy should continue once the

PHE for COVID–19 ends. In these cases, outside the circumstances of the PHE for COVID–19, the patient would be at the originating site and the resident furnishing the care, along with the teaching physician billing for it, would be located at the primary care center as the distant site practitioner. If we were to temporarily extend or add permanently to the primary care exception services such as e-visits or communication technology-based services, we noted that it may also make sense to permit PFS payment to the teaching physician when the resident furnishes an office/outpatient E/M visit via telehealth, on the basis that the patient is not physically in the clinic and that these services all involve the use of virtual technology (for example, patient portals for e-visits, telecommunications technology for the office/outpatient E/M visit) to facilitate care delivery. Further, we noted that, if we were to remove the services that we added to the primary care exception on an interim basis, we could separately consider continuing to permit PFS payment to the teaching physician when the resident furnishes an office/outpatient E/M visit via telehealth because the teaching physician would be immediately available in the distant site clinic with the resident to direct and manage the care.

We received public comments on the primary care exception policies. The following is a summary of the comments we received and our responses.

Comment: Commenters were generally supportive of the policy adopted on an interim basis under § 415.174 to allow Medicare to make payment to the teaching physician for additional services under the primary care exception, including all levels of office and outpatient E/M, audio-only telephone E/M services, transitional care management, and communication technology-based services. Commenters were also generally supportive of our interim policy to allow Medicare to make payment under the PFS to the teaching physician for services furnished by residents via telehealth under the primary care exception if the services are on the list of Medicare telehealth services. These commenters stated that in general, the expansion of the primary care exception increases beneficiary access to Medicare-covered services and provides additional training opportunities for residents, particularly in rural areas.

Several commenters supported making permanent all the services that we implemented on an interim basis during the PHE for COVID–19. Several other commenters supported making certain services permanent, stating that services such as communication technology-based services (for example, CPT codes 99421–99423 and HCPCS codes G2010 and G2012) were simple, require low to moderate complexity medical decision-making, and do not involve a diagnostic complexity that is beyond a resident's skill. In addition, some commenters supported the permanent inclusion of CPT code 99452 and stated that in some models of care, these inter-professional consults are typically initiated by a primary care practitioner to a specialist for a low acuity, condition-specific question that can be answered without an in-person visit.

Some commenters supported the permanent inclusion of CPT codes 99204 and 99214, while other commenters did not. Commenters in support of including these codes stated that office/outpatient level 4 visits are typical visit for the Medicare population and that these visits do not involve a level of diagnostic complexity that is beyond a resident's skill. Other commenters stated that office/outpatient level 4 visits should be furnished with the teaching physician present, either physically or through interactive audio/video real-time communications technology. These commenters were concerned that allowing office/outpatient level 4 visits to be furnished without the presence of the teaching physician could pose risks to patient safety and potential for abuse.

Some commenters did not support the permanent inclusion of high-complexity services, including office/outpatient level 5 visits (CPT codes 99205 and 99215) and transitional care management (CPT code 99496), due to the high level of medical complexity, patient safety concerns, and potential for abuse.

Several commenters recommended temporarily extending the primary care exception policies through the end of the PHE for COVID–19 and cited a need to gather data regarding patient safety and potential impacts on resident training outside the context of the PHE. Other commenters stated that the expansion of the primary care exception has allowed residents to be trained based on ''real life,'' which will leave them better prepared to furnish additional services upon completion of their residency programs.

Response: We appreciate commenters' support of our interim policy to allow Medicare to make payment to the teaching physician when the resident furnishes an expanded array of services under the primary care exception. We remain concerned that permanently adding all of the proposed services to the primary care exception may be inappropriate because some of the services require at least a moderate level of medical decision-making, whereas the intent of the primary care exception as described in § 415.174 is that E/M visits of lower and mid-level complexity furnished by residents are simple enough for a teaching physician to be able to direct and manage the care of up to four residents at any given time and direct the care from such proximity as to constitute immediate availability. We also remain concerned that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. However, we found the comments regarding the advantages of an expansion of services under the primary care exception in rural areas particularly compelling. Specifically, allowing PFS payment for additional primary care services furnished by residents without the physical presence of a teaching physician in rural areas could increase the availability of Medicare-covered services, which is consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas[17]. For example, permitting PFS payment to the teaching physician when the resident furnishes communication-technology based services, an inter-professional consultation, or an office/outpatient visit via telehealth without a teaching physician present could prevent the beneficiary from potentially having to travel long distances to obtain care. Accordingly, we believe that permitting Medicare to make PFS payment to the teaching physician when the resident furnishes an expanded array of services under the primary care exception in rural settings could increase access to Medicare-covered services. Further, this policy could also provide the benefit of additional training opportunities for residents in rural settings, which have historically been in limited supply. As such, the need to improve rural access to care for patients and training for resident overshadows our concerns that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when

[17] CMS Rural Health Strategy: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.*

some or all of the residents might be furnishing services that are more than lower and mid-level complexity. Accordingly, we are finalizing, for residency training sites that are located outside of a MSA, a policy to allow Medicare to make payment to the teaching physician when the resident furnishes an expanded array of services under the primary care exception. However, in accordance with the original intent of the primary care exception to limit the scope of services to those of lower and mid-level complexity, we are limiting the permanent expanded array of services under the primary care exception to include communication-technology based services and inter-professional consults. These services are described by CPT codes 99421–99423, and 99452, and HCPCS codes G2010 and G2012. We are also adding to the primary care exception, for residency training sites that are located outside of an MSA, Medicare telehealth services that furnished by residents. Based on the descriptors, these codes all represent E/M services of a low-to-mid-level complexity, which is consistent with our regulations in § 415.174.

As noted above, some commenters supported adding office/outpatient E/M level 4 visits (CPT codes 99204 and 99214) to the primary care exception. While we included these services in the exception during the PHE to meet the needs of all teaching settings to ensure that there are as many qualified practitioners available as possible, we agree with the commenters who stated that it is inappropriate to allow these services to be billed by the teaching physician when furnished by residents without the presence of a teaching physician on a permanent basis because these services involve medical decision-making of at least a moderate level of complexity, so the ability for the teaching physician to be immediately available to other residents could be compromised. Thus, we agree with the commenters who stated that adding office/outpatient E/M level 4 visits to the primary care exception could pose risks to patient safety. We also believe that, because the transitional care management codes require medical decision-making of at least moderate complexity, the ability for the teaching physician to be immediately available to other residents could be compromised.

This policy to limit the expanded array of services permitted to be furnished under the primary exception only to those services furnished in residency training sites that are located outside of a MSA is consistent with other teaching physician payment policies regarding virtual presence and telehealth that we are finalizing as described earlier in this final rule, and which were also similarly limited to residency training sites that are located outside of a MSA. However, practitioners are reminded that the permanent extension of the expanded primary care exception in residency training sites that are located outside of a MSA does not preclude teaching physicians from being physically present when a resident is furnishing these primary care services. We therefore urge teaching physicians to continue to use their professional judgment to determine the circumstances under which it is appropriate for residents to perform these services without the presence of the teaching physician, depending on the Medicare service being furnished and the experience of the particular resident involved.

For all other settings, we are not finalizing a policy to allow Medicare to make payment to the teaching physician when the resident furnishes an expanded array of services under the primary care exception, including when those services are furnished under Medicare telehealth; however, the interim policy to include an expanded set of services under the primary care exception will remain in place for the duration of the PHE for COVID–19 to provide flexibility for communities that may experience resurgences in COVID–19 infections. Accordingly, at the end of the PHE, we will be terminating the inclusion of CPT codes 99204, 99214, 99205, 99215, 99495 and 99496 from the primary care exception for all settings.

While we do not anticipate any program integrity concerns to arise from the final policy to expand the services that may be furnished under the primary care exception in rural settings, we also agree with commenters that it is necessary for us to consider additional data prior to proposing additional policies in this area, which could range from expanding this flexibility to include non-rural settings to terminating this flexibility in all settings. Specifically, anticipate considering to what degree the permanent establishment of the policy to allow PFS payment to teaching physicians when the resident furnishes an expanded array of services under the primary care exception in residency training sites that are located outside of an MSA increased patient access to care and provided more training opportunities for residents while enabling the teaching physician to remain immediately available. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data or another assessment mechanism, to further study the impacts of this limited permanent expansion of the policy to allow PFS payment to teaching physicians when the resident furnishes an expanded array of services under the primary care exception in residency training sites of a teaching setting that are outside of an MSA to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

Comment: One commenter requested clarification that when teaching physicians meet all of the requirements of the primary care exception, they are also able to provide direction and immediate availability thru virtual presence for moderate to high complexity encounters, such CPT codes 99204, 99205, 99214, and 99215.

Response: Through the end of the PHE for COVID–19, a teaching physician that meets the requirements of the primary care exception described in § 415.174(c) to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met through interactive, audio/video real-time communications technology (excluding audio-only). This policy applies for moderate to high complexity encounters, including all levels of office/outpatient services. Once the PHE for COVID–19 ends, in accordance with the final policy to allow PFS payment to teaching physicians when the resident furnishes an expanded array of services under the primary care exception in residency training sites that are located outside of an MSA, a teaching physician may meet the requirements of the primary care exception described in § 415.174 to direct the care and then to review the services furnished by each resident during or immediately after each visit through interactive, audio/video real-time communications technology (excluding audio-only) when residents furnish services that we are including under the primary care exception, as described above. We believe that establishing this policy for residency training sites that are located outside of an MSA is consistent with the expansion of services that are permitted under the primary care exception in residency training sites that are located outside of an MSA, and that similarly, this policy will also increase beneficiary access to Medicare-covered primary care services and provide additional training opportunities for residents in settings to which there has previously been limited access. However, as noted above, the

services we are permanently including under the primary care exception in residency training sites that are located outside of an MSA do not include codes 99204, 99214, 99205, 99215, 99495 and 99496 because these services are of moderate to high complexity, and we believe it is inappropriate to allow these services to be furnished by residents without the presence of a teaching physician.

We are amending our regulations to reflect this final policy. In § 415.174, we are adding a new paragraph (d) to state that, in residency training sites that are located outside of an MSA, a teaching physician that meets the requirements of the primary care exception described in § 415.174 may meet the requirement to direct the care and then to review the services furnished by each resident during or immediately after each visit through interactive, audio/video real-time communications technology (excluding audio-only) when residents furnish services that are included under the primary care exception associated with these sites.

Comment: One commenter requested clarification that office/outpatient E/M services furnished by residents under the primary care exception described in § 415.174 may be billed on the basis of time, and also requested confirmation that, under the primary care exception, the teaching physician need not be present with the resident for the period of time billed.

Response: In the May 8th COVID–19 IFC, we stated that, consistent with policy that we established in the March 31st COVID–19 IFC for selecting the level of office/outpatient E/M visits when furnished as Medicare telehealth services, (85 FR 19268 through 19269), the office/outpatient E/M level selection for services under the primary care exception when furnished via telehealth can be based on medical decision-making or time, with time defined as all of the time associated with the E/M on the day of the encounter; and the requirements regarding documentation of history and/or physical exam in the medical record do not apply. As described in section II.Z. of the May 8th COVID–19 IFC, the typical times for purposes of level selection for an office/outpatient E/M are the times listed in the CPT code descriptor.

vi. Conclusion

In summary, we reminded stakeholders that during the PHE for COVID–19 we implemented these policies on an interim basis to support our goals of ensuring beneficiary access to necessary services and maintenance of sufficient workforce capacity by offering flexibility to practitioners. While we anticipated reverting to our previous teaching physician policy that was in place prior to the PHE for COVID–19 for the reasons discussed above, we considered whether the teaching physician and resident moonlighting policies that we implemented on an interim basis during the PHE for COVID–19 should be extended on a temporary basis (that is, if the PHE ends in 2021, these policies could be extended to December 31, 2021, to allow for a transition period before reverting to status quo policy) or be made permanent policy for CY 2021. As discussed above, we noted concern that the teaching physician may not be able to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower or mid-level complexity. We also noted concern that when the teaching physician is directing the care of a patient that requires moderate or higher medical decision-making, their ability to be immediately available to other residents could be compromised, which can potentially put patients at risk. We noted that we would consider under which scenarios our policies for moonlighting or virtual presence as discussed above, should apply, if any. As discussed for our moonlighting policy, we expressed concern that there may be risks to program integrity in allowing residents to furnish separately billable physicians' services to inpatients in the teaching hospitals where they are training when the services are outside the scope of their approved GME program. For example, there could be a risk of duplicate Medicare payment for the resident's services under the IPPS for GME and the PFS if the physicians' services furnished by residents were not adequately separately identified from those services that are required as part of the GME program. Under our discussion of virtual presence, we highlighted concerns about how continuing to permit teaching physicians to be involved through their virtual presence may not be sufficient to warrant PFS payment to the teaching physician on a temporary or permanent basis. Absent the circumstances of the PHE for COVID–19, the physical, in-person presence of the teaching physician may be necessary to provide oversight to ensure that care furnished to Medicare beneficiaries is medically reasonable and necessary, and to ensure that the teaching physician renders sufficient personal services to exercise full, personal control of the key portion of the case. We also discussed concerns about patient safety when the teaching physician is only virtually present.

We noted that public comments, especially those that focused on the variables we identified regarding the specific services included on the primary care exception list, and clinical scenarios under which residents could moonlight or furnish certain types of services under the supervision of a teaching physician via virtual presence, would assist us in identifying the appropriate policy continuation decisions after the end of the PHE for COVID–19, which we would consider while drafting this CY 2021 PFS final rule. As part of our review of public comments, we would weigh and make decisions based on the potential benefits and risks associated with the potential temporary or permanent continuation, in whole or in part, of these policies. We noted that the benefits of continuation may include limiting COVID–19 exposure risk for practitioners and patients, increasing workforce capacity of teaching settings to respond to continuing effects following the PHE for COVID–19 as practitioners may be asked to assist with the response, and increasing access so that we do not unintentionally limit the number of licensed practitioners available to furnish services to Medicare beneficiaries. We noted that the risks may include the potential for duplicative payment with Medicare Part A reimbursement for GME training programs, the potential for increases to cost-sharing for Medicare beneficiaries that could result from additional Part B claims for services furnished by the teaching physician with the involvement of residents, and potential threats to patient safety.

Comment: Commenters were generally supportive of the teaching physician and resident moonlighting policies that we implemented on an interim basis during the PHE for COVID–19. Several commenters recommended that we finalize our policies and asserted that making these policies permanent would promote patient access to physicians' services, particularly in rural and underserved areas and could provide additional training opportunities for rural training programs. Other commenters recommended that we extend the policies on a temporary basis, to provide flexibility for communities that may experience resurgences in COVID–19 infections. In addition, these commenters cited a need to gather data regarding patient safety and potential

impacts on resident training outside the context of the PHE before considering permanent implementation of the polices.

Response: We appreciate commenters' support of the teaching physician and resident moonlighting policies that we implemented on an interim basis during the PHE for COVID–19. As we reviewed these comments, we considered the benefits and risks of finalizing the proposals. After considering the comments, we are finalizing our virtual presence and primary care exception policies for residency training sites that are located outside of an MSA. We are finalizing our resident moonlighting policies for all inpatient teaching settings.

We found compelling the comments regarding the benefits of the virtual presence and primary care exception policies in rural settings. Accordingly, we believe that permitting the teaching physician to meet the requirements to bill under the PFS for their services through virtual presence when furnishing services involving residents in rural training settings, and allowing PFS payment for additional primary care services furnished by residents without the physical presence of a teaching physician in rural areas could increase access to Medicare-covered services by preventing the beneficiary from potentially having to travel long distances to obtain care, particularly as rural areas have stretched and diminishing clinical workforces.[18] Increasing beneficiary access to care in rural areas is also consistent with our longstanding interest in increasing beneficiary access to Medicare-covered services in rural areas.[19] Further, these policies could provide the benefit of additional training opportunities for residents in rural settings, which have historically been in limited supply.[20] As such, the need to improve rural access to care for patients and training for residents overshadows our aforementioned concerns about the teaching physician's ability to render sufficient personal and identifiable physicians' services through virtual presence, or to maintain sufficient personal involvement in all of the care to warrant PFS payment for the services being furnished by up to four residents when some or all of the residents might be furnishing services that are more than lower and mid-level complexity. Accordingly, we believe it would be appropriate to continue these policies in rural settings after the conclusion of the PHE for COVID–19. These policies not only further our goal to increase beneficiary access to Medicare-covered services, they also facilitate needed training opportunities is similar to the rationale for the existing primary care exception under § 415.174. The primary care exception permits the teaching physician to bill for certain types of physicians' services furnished by residents in certain settings even when the teaching physician is not present with the resident. Like the policies we are finalizing in this rule, the primary care exception facilitates access to Medicare-covered services and expanded residency training opportunities in primary care settings. Therefore, we are finalizing our virtual presence and primary care exception policies for residency training sites that are located outside of an OMB-defined MSA. In addition, in order to ensure that the teaching physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought in accordance with section 1842(b)(7)(A)(i)(I) of the Act, we are clarifying existing documentation requirements to specify that the patient's medical record must clearly reflect how and when the teaching physician was present during the key portion of the service, in accordance with our regulations.

For our resident moonlighting policies, we believe that complete documentation in the medical record would guard against the risk of potential duplicative payment with the IPPS. Consequently, we are clarifying that, regardless of whether the resident's services are performed in the outpatient department, emergency department or inpatient setting of a hospital in which they have their training program, the patient's medical record must clearly reflect that the resident furnished identifiable physician services that meet the conditions of payment of physician services to beneficiaries in providers in § 415.102(a), that the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and that the services are not performed as part of the approved GME program.

For the virtual presence, primary care exception and resident moonlighting policies, while we do not anticipate any program integrity concerns, we agree with commenters that it is necessary for us to consider additional data prior to proposing additional policies in this area, which could range from expanding these flexibilities to include non-rural settings to terminating these flexibilities in all settings. Specifically, we anticipate considering to what degree the permanent establishment of these policies increased patient access to Medicare-covered services and provided additional training opportunities for residents while enabling the teaching physician to render sufficient personal and identifiable physicians' services. We may use such information, obtained through, for example, a commissioned study, analysis of Medicare claims data, or another assessment mechanism, to further study the impacts of these policies to inform potential future rulemaking, and in an effort to prevent possible fraud, waste and abuse.

2. Supervision of Diagnostic Tests by Certain NPPs

In response to E.O. 13890 discussed above, we sought assistance from stakeholders in identifying Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license. In response to our request for feedback discussed above, physician assistants (PAs) and nurse practitioners (NPs) recommended regulatory changes that would allow them to supervise the performance of diagnostic tests because they are currently authorized to do so under their state scope of practice rules in many states. In the May 8th COVID–19 IFC (85 FR 27550 through 27629), we established on an interim basis during the PHE for COVID–19, a policy to permit these and certain other NPPs to supervise diagnostic tests. In the CY 2021 PFS proposed rule, we proposed to make those changes permanent by making modifications to the regulations at § 410.32. We noted that we planned to address comments we received on the proposals from the CY 2021 PFS proposed rule and comments received on the May 8th COVID–19 IFC (85 FR 27550 through 27629) simultaneously in this final rule.

Prior to the PHE for COVID–19, under § 410.32(a)(2), physicians, NPs, CNSs, PAs, certified nurse-midwives (CNMs), clinical psychologists (CPs), and clinical social workers (CSWs) who are treating

[18] A Guide for Rural Health Care Collaboration and Coordination: *https://www.hrsa.gov/sites/default/files/hrsa/ruralhealth/reports/HRSA-Rural-Collaboration-Guide.pdf.*

[19] CMS Rural Health Strategy. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Rural-Strategy-2018.pdf.*

[20] HHS awards $20 million to 27 organizations to increase the rural workforce through the creation of new rural residency programs: *https://www.hhs.gov/about/news/2019/07/18/hhs-awards-20-million-to-27-organizations-to-increase-rural-workforce.html.*

a beneficiary for a specific medical problem may order diagnostic tests when they use the results of the tests in the management of the beneficiary's specific medical problem. However, generally only physicians were permitted to supervise diagnostic tests. The regulation at § 410.32(b)(1) provided as a basic general rule that all diagnostic tests paid under the PFS must be furnished under an appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Section 410.32(b)(2) then provided for certain exceptions to which this basic rule did not apply. For instance, under § 410.32(b)(2)(v), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician did not apply for tests performed by an NP or CNS authorized under applicable state law to furnish the test. (We noted that, as for all services furnished by a NP or CNS, they would have to be furnished working in collaboration with a physician as provided in regulations at §§ 410.75 and 410.76, respectively). Similarly, under the regulation at § 410.32(b)(2)(vii), the requirement that diagnostic tests must be furnished under the appropriate level of supervision by a physician did not apply for tests performed by a CNM authorized under applicable state law to furnish the test. This exception is in place because the Medicare statute does not include any physician supervision requirement for CNM services. Thus, while NPs, CNSs, PAs, and CNMs were permitted to furnish diagnostic tests to the extent they were authorized under state law and their scope of practice to do so, the regulations at § 410.32 did not address whether these practitioners could supervise others who furnished diagnostic tests.

In light of stakeholder feedback to CMS on identifying additional Medicare regulations that contain more restrictive supervision requirements than existing state scope of practice laws, or that limit health professionals from practicing at the top of their license, effective January 1, 2021, we proposed to amend the basic rule under the regulation at § 410.32(b)(1) to allow NPs, CNSs, PAs or CNMs to supervise diagnostic tests on a permanent basis as allowed by state law and scope of practice. These NPPs have separately enumerated benefit categories under Medicare law that permit them to furnish services that would be physician's services if furnished by a physician, and are authorized to receive payment under Medicare Part B for the professional services they furnish either directly or ''incident to'' their own professional services, to the extent authorized under state law and scope of practice.

We proposed to amend the regulation at § 410.32(b)(2)(iii)(B) on a permanent basis to specify that supervision of diagnostic psychological and neuropsychological testing services can be done by NPs, CNS's, PAs or CNMs to the extent that they are authorized to perform the tests under applicable State law and scope of practice, in addition to physicians and CPs who are currently authorized to supervise these tests. We also proposed to amend on a permanent basis, the regulation at § 410.32 to add paragraph (b)(2)(ix) to specify that diagnostic tests performed by a PA in accordance with their scope of practice and State law do not require the specified level of supervision assigned to individual tests, because the relationship of PAs with physicians as defined under § 410.74 would continue to apply. We also proposed to make permanent the removal of the parenthetical, previously made as part of the May 8th COVID–19 IFC (85 FR 27550 through 27629), at § 410.32(b)(3) that required a general level of physician supervision for diagnostic tests performed by a PA.

We received public comments on whether the policies we adopted on an interim basis during the PHE for COVID–19 under § 410.32 should continue once the PHE ends. The following is a summary of the comments we received and our responses.

Comment: We received many comments expressing appreciation for the flexibilities that we put in place for purposes of the PHE for COVID–19, allowing NPPs to supervise the performance of diagnostic tests and treat patients at the top of their scope of practice. Additionally, they encouraged CMS to make this flexibility permanent, beyond the COVID–19 pandemic.

Response: We appreciate the feedback from these commenters and plan to finalize these provisions as proposed, with modifications described below.

Comment: We received a comment that certified registered nurse anesthetists (CRNAs) should be listed among the delineated NPPs, explaining the value of their services within the health care system. The commenter noted that in the CY 2013 PFS final rule (77 FR 69006), CMS indicated Medicare coverage of CRNA services within their state scope of practice. The commenter stated that CRNAs have continuously practiced autonomously, and provide every aspect of anesthesia delivery as well as acute and chronic pain management services.

Response: We appreciate the information provided and are adding CRNAs to the previously enumerated list of NPPs.

Comment: Some commenters opposed our proposed change to allow NPPs to supervise the performance of psychological and neuropsychological tests. These commenters provided information indicating that these tests are not within the scope of practice of the proposed NPPs, and require special training only available to psychologists and physicians.

Response: We appreciate the information provided by these commenters stating that the specified NPPs are not qualified or authorized by their scope of practice and State law to supervise the performance of this specific category of diagnostic tests. As directed under the E.O. to allow NPPs to practice at the top of their license, our intent regarding this supervision flexibility is to allow NPPs with separate benefit categories under Medicare law to supervise the performance of diagnostic tests, regardless of the specific category of diagnostic tests, only to the extent their scope of practice and State laws authorize them to do so. Accordingly, we believe that the scope of practice and State laws for the State in which the specified NPPs furnish diagnostic psychological and neuropsychological tests will determine whether these NPPs are qualified to supervise the performance of diagnostic psychological and neuropsychological tests in addition to physicians and clinical psychologists who are already authorized to supervise such tests.

Comment: Some commenters expressed concern about the ability of NPPs to supervise diagnostic tests beyond the PHE for COVID–19. They opined that such supervision should not extend beyond the PHE for COVID–19. These commenters expressed that while NPPs are critical team members, it is vital to maintain physician-led teams for quality and cost of care. They cited information indicating that NPPs order more tests and prescribe opioids more than physicians, that patients prefer physicians, and that increasing the supply of NPPs does not increase access to care.

Response: We appreciate the commenters' feedback; however, we did not find sufficient evidence to support altering our proposal. Accordingly, we are finalizing our policy as proposed on a permanent basis and amending regulations text at § 410.32(b) to include CRNAs in the group of specified NPPs with a separately enumerated Medicare benefit category to who are allowed to supervise the performance of diagnostic tests, as permitted within their scope of

practice and State law for the State in which the test is furnished.

3. Pharmacists Providing Services Incident to Physicians' Services

Stakeholders have asked us to clarify that pharmacists can provide services incident to the professional services of a physician or other NPP just as other clinical staff may do. These stakeholders have asked us, in particular, about pharmacists who provide medication management services. Medication management is covered under both Medicare Part B and Part D. We are reiterating the clarification we provided in the May 8th COVID–19 IFC (85 FR 27550 through 27629), that pharmacists fall within the regulatory definition of auxiliary personnel under our regulations at § 410.26. As such, pharmacists may provide services incident to the services, and under the appropriate level of supervision, of the billing physician or NPP, if payment for the services is not made under the Medicare Part D benefit. This includes providing the services incident to the services of the billing physician or NPP and in accordance with the pharmacist's state scope of practice and applicable state law.

We noted that when a pharmacist provides services that are paid under the Part D benefit, the services are not also reportable or paid for under Part B. In addition to circumstances where medication management is offered as part of the Part D benefit, Part B payment is also not available for services included in the Medicare Part D dispensing fees, such as a pharmacist's time in checking the computer for information about an individual's coverage, measurement or mixing of the covered Part D drug, filling the container, physically providing or delivering the completed prescription to the Part D enrollee. Similarly, performing required quality assurance activities consistent with § 423.153(c)(2), such as screening for potential drug therapy problems due to therapeutic duplication, age/gender-related contraindications, potential over-utilization and under-utilization, drug-drug interactions, incorrect drug dosage or duration of drug therapy, drug-allergy contraindications, and clinical abuse/misuse are considered part of dispensing fees under Part D and are not separately reportable services under Part B. Additionally, services and supplies paid under the incident to benefit must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness (§ 410.26). We also noted that our manual provisions specify that ''incident to'' services must be of a type that are medically appropriate to provide in the office setting; and that where a physician supervises auxiliary personnel to assist him or her in rendering services to patients and includes the charges for their services in his or her own bills, the services of such personnel are considered incident to the physicians' service if there is a physicians' service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician (section 60.1 of chapter 15 of the Medicare Benefit Policy Manual (Pub. 100–02) available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*).

Although it is fully consistent with current CMS policy for pharmacists to provide services incident to the services of the billing physician or NPP, we believe this clarification may encourage pharmacists to work with physicians and NPPs in new ways where pharmacists are working at the top of their training, licensure and scope of practice. It may free up the time of physicians and NPPs for other work and increase access to medication management services, for individuals with chronic conditions and other conditions. As an example, we found that this clarification was helpful in recently addressing in the May 8th COVID–19 IFC (85 FR 27550 through 27629), the ability of pharmacies to enroll as laboratories and work with physicians in the assessment of clinical information, specimen collection and reporting results of COVID–19 clinical diagnostic laboratory tests.

We received a few public comments on this clarification made in our IFC and proposed rule. The following is a summary of the comments we received and our responses.

Comment: We received several comments asking us to allow pharmacists to directly bill office/outpatient E/M visit codes (CPT codes 99202–99215), or if this is not possible, allow physicians to bill these codes for time spent by pharmacists providing services incident to a physician's service. One commenter questioned why we referred to pharmacists as auxiliary staff or auxiliary personnel, and whether the AMA CPT Editorial Panel would agree with this classification.

Response: As mentioned above, the Medicare Part B benefit category of services furnished ''incident to'' the professional services of a physician, describe services furnished by the staff (or contracted staff) of a physician under his or her supervision. Specifically, section 1861(s)(2)(A) of the Act describes, services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills.'' Our regulation that implements section 1861(s)(2)(A) of the Act similarly describes these services in § 410.26(b) where we specify, among other things, that ''incident to'' services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness. In the regulation at § 410.26(a), we have long used the term ''auxiliary personnel'' to describe the individuals who may provide services incident to the professional services of a physician or practitioner who is authorized by law to bill Medicare for their services. The regulation defines the term as any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner) and meets other stated rules, including licensure rules imposed by the State in which the services are being furnished. This Medicare Part B framework applies to any individual working with the billing physician or other practitioner to provide services on an ''incident to'' basis, for example, a physician assistant, medical assistant, nurse, pharmacist, administrative assistant or others, whether they have a clinical role or not. The Medicare term ''auxiliary personnel'' could include staff that have clinical roles and staff that do not.

The CPT codebook that delineates a common system of codes for use by all payers, describes individuals who perform or report a given service using different terms, ''physician or qualified health care professional'' (QHP) and ''clinical staff.'' The CPT codebook defines these terms as follows, ''A 'physician or other qualified health care professional' as an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his or her scope of practice and independently reports that

professional service. These professionals are distinct from 'clinical staff.' A clinical staff member is a person who works under the supervision of physician or other qualified healthcare professional, and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a professional service, but does not individually report that professional service. Other policies may also affect who may report specific services.'' [21] Under the PFS, we sometimes use the term ''clinical staff'' to describe specially qualified auxiliary personnel who perform services specifically comprised of ''clinical staff'' time (such as chronic care management services by clinical staff), even though our regulations refers to them as ''auxiliary personnel.'' Under the PFS, ''clinical staff'' is a subset of ''auxiliary personnel.''

As commenters noted, pharmacists could be considered QHPs by some other payers who provide for their direct payment. We do not consider them such because there is no Medicare statutory benefit allowing them to enroll, bill and receive direct payment for PFS services. As such, pharmacists are not among the physicians and QHPs that can furnish and bill for the 2021 office/outpatient E/M visit codes, because levels two through five are by definition only performed and directly reported by physicians or QHPs.[22] For example, when time is used to select visit level, only the time of the physician or QHP is counted. By definition, these codes cannot be furnished and billed as ''incident to'' services; therefore, they cannot be used to report services consisting of time spent solely by a pharmacist working ''incident to'' the services of a billing physician. We also note that services furnished directly by pharmacists are listed in a separate section of the CPT Codebook that includes codes describing Medication Therapy Management Services.[23]

In summary, we agree with certain stakeholders that under the general CPT framework, pharmacists could be considered QHPs or clinical staff, depending on their role in a given service. However, under the current Medicare law which includes the PFS, we do not have ability to pay (or even price) services that are furnished and billed directly by pharmacists. Regarding office/outpatient E/M visit levels 2 through 5 in particular, because CPT does not define these codes as clinical staff codes and instead designed them to be directly furnished and reported by physicians and other QHPs, they cannot be used to bill the PFS for services performed by a pharmacist on an ''incident to'' basis. We understand and appreciate the expanding, beneficial roles certain pharmacists play, particularly by specially trained pharmacists with broadened scopes of practice in certain states, commonly referred to as collaborative practice agreements. We note that new coding might be useful to specifically identify these particular models of care.

4. Provision of Maintenance Therapy by Therapy Assistants

a. Finalization of the Interim Final Rule Related to Provision of Maintenance Therapy by Therapy Assistants During the PHE for COVID–19

As a means of increasing the availability of needed health care services during the PHE for COVID–19, we amended our therapy policy on an interim basis in the May 8th COVID–19 IFC (85 FR 27550 through 27629) to allow physical therapists (PT) and occupational therapists (OT) that have established a therapy maintenance program for a patient to assign a PTA or OTA to furnish the maintenance therapy services when clinically appropriate. We indicated as part of the CY 2021 PFS proposed rule that we would respond to comments we received in response to our amended policy for the provision of maintenance therapy services.

Comment: We received several comments, all of which expressed support for allowing therapy assistants to furnish maintenance therapy when delegated by a therapist, including one commenter that requested the CMS make the change permanent.

Response: We appreciate the commenters' support for our adopted interim policy to allow therapy assistants to furnish maintenance therapy services.

After considering comments, we are finalizing our interim policy from the May 8th COVID–19 IFC to allow physical and occupational therapists to delegate maintenance therapy services to therapy assistants as clinically appropriate through the end of the PHE for COVID–19.

b. Summary of Proposals and Public Comments Related to Provision of Maintenance Therapy by Therapy Assistants

In response to our request for feedback on scope of practice (noted above), consistent with E.O. 13890 (84 FR 53573 through 53576), respondents requested that we allow physical therapy assistants (PTAs) and occupational therapy assistants (OTAs) to furnish maintenance therapy services associated with a maintenance therapy program. Respondents commented that our Part B therapy policy was not consistent with policies for these services when provided to patients in skilled nursing facilities (SNF) and home health (HH) settings paid under Part A. Respondents also wrote that because a therapist is responsible for a patient's care over an episode, that this should allow the therapist to assign responsibility for maintenance therapy to an assistant when it is clinically appropriate. Some respondents stated that permitting PTAs and OTAs to furnish maintenance therapy services would give Medicare patients greater access to care and give therapists more flexibility in allocating therapy resources.

After considering respondents' concerns about the incongruity between our Part B and Part A maintenance therapy policies and as a means of increasing availability of needed health care services during the PHE for COVID–19, we amended our policy on an interim final basis in the May 8th COVID–19 IFC (85 FR 27550 through 27629) to allow the physical therapist (PT) or occupational therapist (OT) who establishes a maintenance program to assign a PTA or OTA to furnish maintenance therapy services when clinically appropriate.

We explained that making this change could free-up the PT or OT to furnish other services, particularly services related to the PHE for COVID–19 that require a therapist's assessment and intervention skills. We stated explicitly that the maintenance therapy services furnished by therapist-supervised OTAs and PTAs will be paid in the same manner as those we already pay for as rehabilitative therapy services. We referred readers to regulatory payment conditions for Part B outpatient occupational and physical therapy services (§§ 410.59 and 410.60, respectively) that require, as a basic rule, that the services be provided by an individual meeting qualifications in 42 CFR part 484 for an OT or PT, or an appropriately supervised OTA or PTA.

In the CY 2021 PFS proposed rule, we proposed to make permanent our Part B policy for maintenance therapy services effective January 1, 2021 in order to create greater conformity in payment policy for maintenance therapy services that are furnished and paid under Part B with those in SNF and HH settings under Part A. We noted that if finalized, our policy would dovetail with our

[21] CPT 2021 Professional Edition, p. xiv.

[22] CPT 2021 Professional Edition, pp.14–17.

[23] CPT 2021 Professional Edition, p.818.

amended policy set forth in the May 8th COVID–19 IFC (85 FR 27550 through 27629) that grants PTs and OTs the discretion to delegate maintenance therapy services to the PTAs and OTAs, as clinically appropriate, for the duration of the PHE for COVID–19. If the PHE for COVID–19 were to end prior to January 1, 2021, the therapist would need to personally furnish the maintenance therapy services until the finalized policy change took effect. We also noted that we planned to address comments from the May 8th COVID–19 IFC in conjunction with the comments from the CY 2021 PFS proposed rule in the CY 2021 PFS final rule.

Our policy for maintenance therapy services is explained in section 220.2 of chapter 15 of the Medicare Benefit Policy Manual (see *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf*). Maintenance programs that can be carried out by a patient alone or with the assistance of caregivers are not covered. Also, sections 230.1 and 230.2 of chapter 15 of the Medicare Benefit Policy Manual specify that a PTA or OTA may not provide skilled maintenance program services.

In considering this proposal, we reviewed regulatory requirements for conditions of payment for outpatient occupational therapy, physical therapy, and speech-language pathology services at §§ 410.59, 410.60, and 410.62; the regulation for therapy treatment plans at § 410.61; and the regulations specifying treatment plan certification and recertification requirements at § 424.24 for Part B occupational therapy, physical therapy, and speech-language pathology services along with the above mentioned manual provisions.

Given that we already make payment for rehabilitative services requiring improvement in the patient's functional status when they are furnished by PTAs and OTAs at the discretion of the supervising therapist treating the patient in accordance with the therapist-established plan of care, we noted that it would be appropriate for the therapist to use that same judgment to decide whether to delegate maintenance therapy services under the associated plan of care to a PTA or OTA. We stated that there is little difference between the rehabilitative therapy services furnished to improve a patient's functional status and those for maintenance therapy services other than the goals set by the therapist in the therapy plan. We do not believe that the therapist-only maintenance therapy requirement is needed in the case of outpatient physical or occupational therapy services. Instead, we believe that it would be appropriate for an OT or PT to use their professional judgment to assign the performance of maintenance therapy services to an OTA or PTA when it is clinically appropriate to do so.

As such, we proposed to allow, on a permanent basis, therapists to delegate performance of maintenance therapy services to an OTA or PTA for outpatient occupational and physical therapy services in Part B settings beginning January 1, 2021. This proposal would better align our Part B policy with that in SNFs and HH paid under Part A where maintenance therapy services may be performed by a therapist or a therapy assistant. Since our regulations at §§ 410.59, 410.60, 410.61, 410.62, and 424.24, do not distinguish between rehabilitative and maintenance therapy services, we did not propose to amend them. Instead, we proposed to revise sections 220.2, 230.1 and 230.2 of chapter 15 of the Medicare Benefit Policy Manual to clarify that PTs and OTs no longer need to personally perform maintenance therapy services and to specifically remove the prohibitions on PTAs and OTAs from furnishing such services. We noted that we believe the proposal to allow PTs and OTs to delegate maintenance therapy services to their supervised assistants is in keeping with E.O. 13890 and appeals by respondents to our request for feedback on scope of practice that followed, rather than the alternative option of maintaining the pre-COVID–19 policy of requiring PTs and OTs to personally furnish them, after the PHE for COVID–19 has ended.

We noted also that therapists and therapy providers should consult the CQ and CO modifier policies to consider whether these modifiers should be applied to claims for services furnished in whole or in part by PTAs and OTAs which will, beginning January 1, 2022, be paid at 85 percent of the amount that would otherwise apply for the service, as required by section 1834(v) of the Act, which was added to section 53107 of the Bipartisan Budget Act of 2018. See the CY 2020 PFS rulemaking for policies related to the application of CQ and CO modifiers and the associated regulatory requirements (84 FR 40558 through 40564 (proposed rule) and 84 FR 62702 through 60708 (final rule)).

We received public comments on the provision of maintenance therapy to be furnished by therapy assistants. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed uniform support for our proposal to allow therapy assistants to furnish maintenance therapy services. Commenters indicated that having Part B policy align with current Part A policy for Home Health and SNF settings will promote consistency as well as continuity of care across Medicare programs.

Response: We appreciate the commenters' support for our proposal to allow therapy assistants to furnish maintenance therapy services. After considering comments, we are finalizing our proposal to allow physical and occupational therapists to delegate maintenance therapy services to therapy assistants on a permanent basis as clinically appropriate.

5. Medical Record Documentation

a. Finalization of Interim Final Rule With Comment Period Provisions Related to Therapy Student Documentation During the PHE for the COVID–19 Pandemic

In the May 8th COVID–19 IFC (85 FR 27556 through 27557), to increase the availability of clinicians who may furnish healthcare services during the PHE, we announced a general policy that there is broad flexibility for all members of the medical team to add documentation in the medical record which is then reviewed and verified (signed) by the appropriate clinician. Specifically, we stated on an interim basis during the PHE for COVID–19, any individual who has a separately enumerated benefit under Medicare law that authorizes them to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date), rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We noted that although there are currently no statutory or regulatory documentation requirements that would impact payment for therapists when documentation is added to the medical record by persons other than the therapist, we discussed this issue in response to stakeholder concerns about burden and in consideration of the current PHE for COVID–19. Specifically, this policy will ensure that therapists, as members of the clinical workforce, are able to spend more time furnishing therapy services, including pain management therapies to patients that may minimize the use of opioids and other medications, rather than spending time documenting in the medical record. We emphasized that our established principle is focused on the

clinician, as described above who furnishes and bills for their professional services rather than the individuals who may enter information into the medical record. We emphasized that information entered into the medical record should document that the furnished services are reasonable and necessary.

We received public comments on Therapy Student Documentation. The following is a summary of the comments we received and our responses.

Comment: One commenter recommended that CMS make the therapy student documentation waiver under the PHE for COVID–19 permanent so that it aligns with the flexibility extended to physicians and several NPPs as promulgated in the CY 2020 PFS final rule.

Response: We appreciate the commenter's support of this provision for student documentation and making permanent the broad flexibility for all members of the medical team to add documentation in the medical record which is then reviewed and verified (signed) by the appropriate clinician.

Comment: One commenter supported these changes which will give more flexibility to practitioners and other providing clinically appropriate therapy services but asked that CMS clarify who would be considered other members of the ''treatment team'' in addition to those enumerated (that is, physicians, residents, nurses, and students)—in particular, whether this would encompass non-licensed member.

Response: We appreciate the commenters request for clarification. Any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team), or other members of the medical team.

Comment: One commenter agreed with CMS that these measures should be temporary, and should not persist once the PHE for COVID–19 has ended. The commenter stated that training-appropriate scope of practice standards are important to ensuring quality of care for our members.

Response: We appreciate the commenter's feedback. We are discussing this issue in response to stakeholder concerns about burden and in consideration of the current PHE for COVID–19. Specifically, this policy will ensure that therapists, as members of the clinical workforce, are able to spend more time furnishing therapy services, including pain management therapies to patients that may minimize the use of opioids and other medications, rather than spending time documenting in the medical record. The provision related to therapy student documentation was to increase the availability of clinicians who may furnish healthcare services during the PHE for COVID–19 and on an interim basis during the PHE for COVID–19.

In summary, we reiterate that our clarification about this policy as discussed in the May 8th COVID–19 IFC (85 FR 27556 through 27557) notes that any individual who has a separately enumerated benefit under Medicare law that authorizes them to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date), rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We emphasized that our established principle is focused on the clinician, as described above who furnishes and bills for their professional services rather than the individuals who may enter information into the medical record. We emphasized that information entered into the medical record should document that the furnished services are reasonable and necessary.

b. Medical Record Documentation Clarification

As we established in the CY 2020 PFS final rule (84 FR 62681 through 62684), and similarly expressed in the May 8th COVID–19 IFC (85 FR 27556 through 27557), any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We noted that although there are currently no documentation requirements that would impact payment for PTs, OTs, or SLPs when documentation is added to the medical record by persons other than the therapist, we are responding in this proposed rule to stakeholder requests for clarification. Specifically, we clarified that the broad policy principle that allows billing clinicians to review and verify documentation added to the medical record for their services by other members of the medical team also applies to therapists. We noted that this would help ensure that therapists are able to spend more time furnishing therapy services, including pain management therapies to patients that may minimize the use of opioids and other medications, rather than spending time documenting in the medical record. We emphasized that, while any member of the medical team may enter information into the medical record, only the reporting clinician may review and verify notes made in the record by others for the services the reporting clinician furnishes and bills. We also emphasized that information entered into the medical record should document that the furnished services are reasonable and necessary.

We received public comments on the medical record documentation clarification. The following is a summary of the comments we received and our responses.

Comment: Many commenters were in support of and commended CMS for including therapists in the list of practitioners who may review and verify documentation instead of having to re-document notes made by students for Medicare Part B patients and stated that this is a significant burden reduction that will allow for better use of therapists' time.

Two commenters appreciated this medical record documentation flexibility so long as the provision falls within existing scope of practice laws and only reduces the burden of re-documenting. The commenter noted that administrative burden is a major reason for physician burnout and by alleviating this burden and allowing others to share in the administrative process, physicians will spend less time documenting and perhaps have a decrease in burnout. Another commenter noted in rural areas, there are shortages of therapy and mental health professionals and that documentation and paperwork take time away from patients who need help.

A few commenters noted that this flexibility would better prepare clinicians to enter practice by increasing safety and education on how to document effectively and appropriately the skilled services they provide. One commenter questioned how this flexibility may impact documentation requirements pertaining to completion of the progress report and Medicare's billing rules in relation to therapy students. Another commenter requested licensed audiologists be added to the group that can review and verify (sign and date) the documentation entered into the medical record by members of

their medical team for their own, appropriately supervised services that are paid under the PFS.

One commenter requested that CMS issue guidance to clarify that it is possible that no additional documentation is required if the entirety of the documentation could be included from members of the medical team, thus allowing the billing practitioner to ''sign and verify'' the entire note.

Response: We appreciate commenters' support of this clarification to allow therapists to review and verify student documentation instead of therapists having to re-document notes made by students. We appreciate the insight provided by commenters about how the broad flexibility would aide in burden reduction and allow for better use of time by therapists.

This clarification similarly aligns with what was finalized in the CY 2020 PFS final rule which provided broad flexibility to the physicians, PAs and APRNs (regardless of whether they are acting in a teaching capacity) who document and who are paid under the PFS for their professional services. We explained that this principle would apply across the spectrum of all Medicare-covered services paid under the PFS. We emphasize that, while any member of the medical team may enter information into the medical record, only the billing clinician may review and verify notes made in the record by others for the services the reporting clinician furnishes and bills. As we emphasized in our proposal, information entered into the medical record should document that the services furnished are reasonable and necessary if the billing practitioner has signed and verified complete medical record documentation by other members of the medical team.

Comment: One commenter supported the CMS policy to provide added flexibility for NPPs authorized to deliver part B services including nurse practitioners, CNSs and PAs to document teaching physician involvement and another commenter noted they believe that the additional flexibility will significantly reduce burden for teaching physicians.

Response: We appreciate the support of this flexibility for NPPs to document teaching physician involvement. We would like to reiterate that this flexibility does not negate the teaching physician rules, or the need to document personal services or split share rules, or other aspects of the service provided.

Comment: One commenter urged CMS not to expand payment for independent NPPs and pressure inappropriate scope-of-practice expansion through these proposed rules. The commenter encouraged all advanced nurse practitioners and physician assistants to work within their respective licensed scope of practice in a team approach to expand access and ensure quality of care. Another commenter expressed concern that based on the language proposed by CMS, this policy might allow therapists to change or modify a physician's documentation, including their diagnostic evaluation and treatment plan.

Response: We appreciate the commenters concerns and want to emphasize that this medical record documentation clarification only applies to the clinician who is billing for their professional service. The intent of this clarification is to reduce burden and allow the billing practitioner to review and verify the documentation in the medical record instead of re-documenting information entered by students and other members of the medical team. The billing practitioner needs to ensure, as we reiterated in our clarification, that, while any member of the medical team may enter information into the medical record, they review and verify that the information in the medical record is accurate and complete for the services the reporting clinician furnishes and bills.

After considering the comments received, we note that we are reiterating what we finalized in the CY 2020 PFS final rule, that any individual who is authorized under Medicare law to furnish and bill for their professional services, whether or not they are acting in a teaching role, may review and verify (sign and date) the medical record for the services they bill, rather than re-document, notes in the medical record made by physicians, residents, nurses, and students (including students in therapy or other clinical disciplines), or other members of the medical team. We emphasize that, while any member of the medical team may enter information into the medical record, only the reporting clinician may review and verify notes made in the record by others for the services the reporting clinician furnishes and bills. We want to emphasize that information entered into the medical record must document that the furnished services are reasonable and necessary.

H. Valuation of Specific Codes

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010 and CY 2015. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the RUC identified a number of potentially misvalued codes each year using various identification screens, as discussed in section II.C. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values, and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of

new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule.

We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the federal government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with stakeholders, including the RUC, with regard to our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. The statute specifically defines the work component as the resources in time and intensity required in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the nonfacility setting.

We developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs contain a general discussion of our approach to reviewing RUC recommendations and

developing proposed values for specific codes. When they exist we also include a summary of stakeholder reactions to our approach. We note that many commenters and stakeholders have expressed concerns over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we used to make the adjustments is derived from their survey process. We are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We have observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we have adjusted work RVUs to account for significant changes in time, we have started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we have employed the different approaches to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we have used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

We do not imply that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs. Instead, we believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we have generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure.

Several stakeholders, including the RUC, have expressed general objections to our use of these methodologies and deemed our actions in adjusting the recommended work RVUs as inappropriate; other stakeholders have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we have employed to identify potential values that reconcile the RUC-recommend work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We received several comments regarding our methodologies for work valuation in response to the CY 2021 PFS proposed rule and those comments are summarized below.

Comment: Several commenters disagreed with our reference to older work time sources, and stated that their use led to the proposal of work RVUs based on flawed assumptions. Commenters stated that codes with ''CMS/Other'' or ''Harvard'' work time sources, used in the original valuation of certain older services, were not surveyed, and therefore, were not resource-based. Commenters also stated that it was invalid to draw comparisons between the current work times and work RVUs of these services to the newly surveyed work time and work RVUs as recommended by the RUC.

Response: We agree that it is important to use the recent data available regarding work times, and we note that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The work times currently associated with codes play a very important role in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times. It also would undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times used in the PFS ratesetting processes are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available, and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional

information regarding the use of old work time values that were established many years ago and have not since been reviewed in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: Several commenters disagreed with the use of time ratio methodologies for work valuation. Commenters stated that this use of time ratios is not a valid methodology for valuation of physician services. Commenters stated that treating all components of physician time (preservice, intraservice, postservice and post-operative visits) as having identical intensity is incorrect, and inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system, which is based on relative valuation. Commenters stated that in many scenarios, CMS selects an arbitrary combination of inputs to apply rather than seeking a valid clinically relevant relationship that would preserve relativity. Commenters suggested that CMS determine the work valuation for each code based not only on surveyed work times, but also the intensity and complexity of the service and relativity to other similar services, rather than basing the work value entirely on time.

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs.

We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. For example, among the codes reviewed in this current CY 2021 PFS final rule, CPT codes 10006 (*Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion*) and 57465 (*Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect*), 76513 (*Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy, unilateral or bilateral*), 93224 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional*) and 99439 *(Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes*) share the identical total work time of 15 minutes. However, these codes have very different proposed work RVUs of 1.00 and 0.81 and 0.53 and 0.39 and 0.61 respectively. In addition, CPT codes 10010 (*Fine needle aspiration biopsy, including CT guidance; each additional lesion*) and 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation*) both share the same intraservice and total work time of 25 minutes but each code has a different work RVU. These examples demonstrate that we do not value services purely based on work time; instead, we incorporate time as one of multiple different factors employed in our review process. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

We also want to clarify for the commenters that our review process is not arbitrary in nature. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). With regard to the invocation of clinically relevant relationships by the commenters, we emphasize that we continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters discouraged the use of valuation based on work RVU increments. Commenters stated that this methodology inaccurately treats all components of the physician time as having identical intensity and would lead to incorrect work valuations. Commenters stated that CMS should carefully consider the clinical information justifying the changes in physician work intensity provided by the RUC and other stakeholders.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We note that the RUC has also

used the same incremental methodology on occasion when it was unable to produce valid survey data for a service. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: Several commenters stated that they were concerned about CMS' lack of consideration for compelling evidence that services have changed. Commenters stated that CMS appeared to dismiss the fact that services may change due to technological advances, changes in the patient population, shifts in the specialty of physicians providing services or changes in the physician work or intensity required to perform services. Commenters requested that CMS address the compelling evidence that was submitted with the RUC recommendations when the agency does not accept the RUC recommendation.

Response: The concept of compelling evidence was developed by the RUC as part of its review process for individual codes to justify an increase in valuation. The RUC's compelling evidence criteria include documented changes in physician work, an anomalous relationship between the code and multiple key reference services, evidence that technology has changed physician work, analysis of other data on time and effort measures, and evidence that incorrect assumptions were made in the previous valuation of the service. While we appreciate the submission of this additional information for review, we emphasize that compelling evidence is a concept developed by the RUC for its own review process. Compelling evidence is not part of our statutory framework which requires that the valuation of codes should be based on time and intensity. We do consider changes in technology, patient population, etc. insofar as they affect the time and intensity of the service under review. However, we do not specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation process stipulated by statute.

In response to comments, in the CY 2019 PFS final rule (83 FR 59515), we clarified that terms ''reference services'', ''key reference services'', and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purposes of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate stakeholder feedback, we will seek to limit the use of the term, ''crosswalk,'' to those cases where we are making a comparison to a CPT code with the identical work RVU. We also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with stakeholders and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table 28 contains a list of codes and descriptors for which we proposed work RVUs; this included all codes for which we received RUC recommendations by February 10, 2020. As noted in the CY 2021 PFS proposed rule, the proposed work RVUs, work time and other payment information for all CY 2021 payable codes are available on the CMS website under downloads for the CY 2021 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code by code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table 29 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of the proposed rule (85 FR 50077), Determination of Practice Expense Relative Value Units (PE RVUs), we addressed certain refinements that would be common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We noted that for each refinement, we indicated the impact on direct costs for that service. We noted that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. We also noted that approximately half of the refinements listed in Table 29 result in changes under the $0.35 threshold and are unlikely to result in a change to the RVUs.

We also noted that the direct PE inputs for CY 2021 are displayed in the CY 2021 direct PE input files, available on the CMS website under the downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the CY 2021 PE RVUs as displayed in Addendum B.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We noted that we believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question would be available if the room is not being occupied by a particular patient. For additional information, we refer readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of the proposed rule (85 FR 50077), Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2021 we received invoices for several new supply and equipment items. Tables 31 and 32 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of the proposed rule (85 FR 50077), Determination of Practice Expense Relative Value Units, we encouraged stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encouraged stakeholders to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 31 and 32 also included the number of invoices received and the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs and we encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we did not use the price listed on the invoice that

accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the final PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We addressed code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We noted that the public use files for the PFS proposed and final rules for each year display the services subject to the MPPR for diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services. We also include a list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap for the upcoming calendar year. The public use files for CY 2021 are available on the CMS website under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For more information regarding the history of the MPPR policy, we refer readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263). For more information regarding the history of the OPPS cap, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

4. Proposed Valuation of Specific Codes for CY 2021

(1) Fine Needle Aspiration (CPT Codes 10021, 10004, 10005, 10006, 10007, 10008, 10009, 10010, 10011, and 10012)

In June 2017, the CPT Editorial Panel deleted CPT code 10022, revised CPT code 10021, and created nine new codes to describe fine needle aspiration procedures with and without imaging guidance. These ten codes were surveyed and reviewed for the October 2017 and January 2018 RUC meetings. In the CY 2019 PFS final rule, we finalized the RUC-recommended work RVU for seven of the ten codes in the family, while finalizing a lower work RVU for CPT codes 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*), 10009 (*Fine needle aspiration biopsy, including CT guidance; first lesion*), and 10021 (*Fine needle aspiration biopsy, without imaging guidance; first lesion*). For a full discussion of this review, we refer readers to the CY 2019 PFS final rule (83 FR 59517 through 59521).

Following the publication of the CY 2019 PFS final rule, RUC staff stated that CMS erroneously double-counted the utilization for new codes that had image guidance bundled. We disagreed that this constituted a technical error and communicated to the RUC in conversations following the publication of the rule that the surveying specialties could instead nominate the affected codes from these families as being potentially misvalued. At the January 2020 RUC meeting, the RUC reaffirmed its CY 2019 recommendations for physician work and direct PE for the ten codes in the Fine Needle Aspiration code family.

In discussing this group of codes, we would like to clarify again that we disagree with the RUC and do not believe that utilization was erroneously double-counted for this code family. We publish our proposed utilization crosswalk each year as a public use file available on the CMS website; the current such file is available under downloads for the CY 2021 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* During the CY 2019 rule cycle, we proposed the utilization crosswalk for the Fine Needle Aspiration family as it was recommended to CMS by the RUC, and we did not receive any comments on this subject until after the valuation of these codes had been finalized. We proposed and finalized the utilization crosswalk for this code family as recommended by the RUC without receiving any comments from the RUC or other stakeholders. If the RUC or other stakeholders believed that what CMS had proposed was incorrect or misunderstood what the RUC had recommended, there was an opportunity to comment during the 60 days following the publication of the proposed rule. We disagreed that the utilization crosswalk was erroneous, and we did not make a technical correction following the publication of the CY 2019 PFS final rule for this reason.

We also disagreed with the RUC that the utilization crosswalk was ''the principle reason CMS rejected the RUC recommendations'' for the codes in the Fine Needle Aspiration family, as stated in the RUC's CY 2021 recommendations for this code family. As we stated in the CY 2019 PFS proposed rule and restated in the CY 2019 PFS final rule, our refinements to the work RVUs of CPT codes 10021, 10005, and 10009 were primarily based on changes in surveyed work time and the relationship between the codes in the family. For example, this was our rationale for refining the work RVU of CPT code 10021 from the RUC-recommended value of 1.20 to the finalized value of 1.03: In reviewing CPT code 10021, we noted that the recommended intraservice time is decreasing from 17 minutes to 15 minutes (12 percent reduction), and the recommended total time is decreasing from 48 minutes to 33 minutes (32 percent reduction); however, the RUC-recommended work RVU is only decreasing from 1.27 to 1.20, which is a reduction of just over 5 percent. In the case of CPT code 10021, we believed that it was more accurate to propose a work RVU of 1.03 based on a crosswalk to CPT code 36440 to account for these decreases in the surveyed work time (83 FR 59518). We noted that this primary rationale for refining the work RVU did not mention the utilization crosswalk at all.

When we communicated to the RUC following the publication of the CY 2019 PFS final rule that the codes in the Fine Needle Aspiration family could be nominated as potentially misvalued, we indicated that we were open to receiving new information about the valuation of these codes. In reaffirming its recommendations from CY 2019, however, the RUC has not provided any

new information that was not already presented for the previous CMS review of these codes. Therefore, we did not propose any changes to the codes in the Fine Needle Aspiration family, as the reaffirmed CY 2021 RUC recommendations are identical to the CY 2019 RUC recommendations that already went through notice and comment rulemaking. We welcomed the submission of new information regarding these services that was not part of the previous CY 2019 review of the code family.

We received public comments on the Fine Needle Aspiration code family. The following is a summary of the comments we received and our responses.

Comment: Several commenters maintained that CMS inadvertently double counted each bundled image guidance code during their RUC recommendation evaluation in CY 2019 due to a misinterpretation of the RUC's utilization crosswalk recommendations. Commenters stated that after correcting for double counting the utilization for the newly created bundled codes, the work pool based on the RUC-recommended values would have instead resulted in a decrease by 15 percent using the CMS utilizations from the CY 2019 PFS proposed rule. Commenters stated that based on the CMS proposed reductions, the work pool for the family would decrease by 23 percent based on the utilization data available during the CY 2019 rulemaking.

Response: As we stated in the CY 2021 PFS proposed rule (85 FR 50152), we continue to disagree with the RUC and do not believe that utilization was erroneously double-counted for this code family. We proposed and finalized the utilization crosswalk for this code family as recommended by the RUC without receiving any comments from the RUC or other stakeholders and we did not make a technical correction following the publication of the CY 2019 PFS final rule for this reason.

Comment: Several commenters stated that they had new information to provide based on reviewing actual claim data from CY 2019 to assess the accuracy of the RVU pool estimates during the CY 2019 rulemaking process. Commenters stated that CMS' projected RVU pool for CY 2019 for the updated Fine Needle Aspiration code family was over twice as high as what actually occurred in 2019 even though the utilization for the newly created codes is largely identical to the source utilization from CPT codes 10021 and 10022. Commenters recommended CMS to finalize the RUC-recommended work RVUs for CPT codes 10005, 10009, and 10021.

Response: We appreciate the additional information provided by the commenters in their review of the claims data from CY 2019. However, we note that it is not typically part of our methodology to review the accuracy of the RUC-recommended utilization crosswalk against the claims data when it becomes available 2 years later. Historically, there have been many times when the projected crosswalk overestimated utilization for a new service. Also, there have been many times when the projected crosswalk underestimated utilization. In the absence of a systematic process to investigate the accuracy of these projected utilization crosswalks across a broad range of services, we do not believe that it would serve the interests of relativity to single out individual code families and compare them against their projected crosswalks. It would distort relativity to conduct this analysis in situations where it might be advantageous for valuation while failing to conduct the same analysis in situations where it might be disadvantageous.

More importantly, we continue to disagree with the RUC that the utilization crosswalk was ''the principle reason CMS rejected the RUC recommendations'' for the codes in the Fine Needle Aspiration family, as stated in the RUC's CY 2021 recommendations for this code family. As we stated in the CY 2019 PFS proposed rule, restated in the CY 2019 PFS final rule, and again restated in the CY 2021 PFS proposed rule, our refinements to the work RVUs of CPT codes 10021, 10005, and 10009 were primarily based on changes in surveyed work time and the relationship between the codes in the family. We noted that this primary rationale for refining the work RVU did not mention the utilization crosswalk at all. We continue to believe that the changes in surveyed work time and the relationship between the codes in the family support the work valuations finalized in CY 2019 rulemaking.

Comment: Several commenters disagreed with the rationale provided by CMS when the work RVUs for these codes were finalized in CY 2019 rulemaking. Commenters stated that CMS continued to use intraservice time ratios to revalue codes and then applied inappropriate crosswalks to justify their logic. Commenters stated that the CMS crosswalk codes, such as CPT code 36440 (*Push transfusion, blood, 2 years or younger*), are not clinically similar to the reviewed codes including the associated risks and required decision-making. Commenters stated that the work RVU for CPT code 10005 could be more appropriately crosswalked to CPT code 76978 (*Ultrasound, targeted dynamic microbubble sonographic contrast characterization (non-cardiac); initial lesion*) based on the identical intraservice work time, intensity, complexity similarities, and ultrasound service similarities. Commenters similarly stated that the work RVU of CPT code 10021 could be more accurately crosswalked to CPT code 95866 (*Needle electromyography; hemidiaphragm*). Commenters again suggested CMS to finalize the RUC's reaffirmed work RVUs for these services.

Response: We disagree with these valuation suggestions presented by the commenters as they reiterate the same arguments that we considered and ultimately did not finalize when the codes in the Fine Needle Aspiration were previously reviewed. For a full discussion of this subject, we direct readers to the CY 2019 PFS final rule (83 FR 59517–59521). We continue to believe that the changes in surveyed work time and the relationship between the codes in the family support the work valuations finalized in CY 2019 rulemaking.

Comment: Several commenters stated that for several equipment items, including the mayo stand (EF015), the exam table (EF023), and the portable ultrasound unit (EQ250), it appeared that there was a calculation error in CMS' direct PE refinement table. Commenters provided a spreadsheet which clarified the RUC's comments on individual refinements of direct PE inputs with suggested equipment times for these items.

Response: We disagree with the commenters and we continue to believe that the equipment times finalized in CY 2019 rulemaking are correct. The finalized equipment times for these three equipment items conform to the standard established policies for non-highly technical equipment. The equipment times recommended by the commenters do not conform to these standard equipment time formulas, instead adding additional time for the ''Complete post-procedure diagnostic forms, lab and x-ray requisitions'' (CA027) and ''Review home care instructions, coordinate visits/prescriptions'' (CA035) clinical labor activities. In particular, we note that the CA035 clinical labor activity is not part of the standard established policies for non-highly technical equipment formula; the RUC has mistakenly labeled it as such on some of their recommended PE spreadsheets. Since

these clinical labor activities are not part of the standard equipment time formula, and we have no reason to believe that they would be typical for the services in question; we continue to believe that the equipment times finalized in CY 2019 rulemaking are correct.

We did not propose any changes to the codes in the Fine Needle Aspiration family and although we appreciate the information supplied by the commenters, we are not finalizing any changes to these services. In the event that there is a new review of these services, as opposed to a reaffirmation of the previous review, we would look forward to receiving any additional information or new data.

(2) Tissue Expander Other Than Breast (CPT Code 11960)

This service was included in a larger group of similarly related codes that were recommended for review for the October 2019 RUC meeting. The RUC recommended re-reviewing this code at a more granular level for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 12.40 for CPT code 11960 (*tissue expander other than breast*). We proposed to maintain the current work RVU of 11.49 supported by a reference code, CPT code 45560 (*repair of rectocele (separate procedure)*), which has a work RVU of 11.50. CPT code 45560 shares the same intraservice time of 90 minutes with CPT code 11960 and has a slightly higher total time of 367 minutes. The recommended total time for CPT code 11960 decreased from 444 minutes to 357 minutes, with a slight increase in intraservice time of 78 minutes to 90 minutes. We noted that we believe the similar work RVU of the reference CPT code 45560, as well as the reduction in total time, supports maintaining the current work RVU of 11.49 for CPT code 11960. We proposed the RUC-recommended direct PE inputs for CPT code 11960 without refinements.

We received public comments on the Tissue Expander Other Than Breast.

The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the proposal to maintain the current work RVU of 11.49 for CPT code 11960 (*Tissue expander other than breast*) and stated that CMS should finalize the RUC-recommended work RVU of 12.40. In particular, commenters stated they believe that there is an anomalous relationship between current work RVU and current physician time reflected in an inappropriate intensity. The commenters also believe that we have not appropriately accounted for the RUC-recommended increase in intraservice time.

Response: We acknowledge that the RUC recommended an increase in intraservice time. However, we believe that when our review of recommended values reveals changes in time that have been unaccounted for in a recommended RVU, such as in the decrease of total time unaccounted for with CPT code 11960, we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. To validate further our valuations for work RVUs, we incorporate multiple methodologies, which also consider intensity of the service. For additional information regarding our use of methodologies for code valuation, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.H.2. of this final rule).

Comment: Commenters stated that they disagree with our use of the chosen reference code, CPT code 45560 (*Repair of rectocele (separate procedure)*). Commenters stated that they believe the chosen reference code does not accurately support the proposed work times for this code because it is ''low volume'' and it has been too long since the last survey to be an accurate comparison for determining an appropriate valuation. The commenters also stated that there is no evidence to support a clinical comparison between CPT code 11960 and the chosen reference code.

Response: We consider reference codes as supportive of a code valuation rather than as a direct ''cross-walk.'' CPT code 45560 has a work RVU of 11.50. It shares the same intraservice time of 90 minutes with CPT code 11960 and has a slightly higher total time of 367 minutes. We do not agree that codes must share the same patient population or utilization level to serve as an appropriate reference code. We also recognize that it is important to use recent data available regarding work times. However, we believe that while some reference codes may not have been recently surveyed, they still provide support for revision of work RVUs when survey times show a marked decrease in time.

After consideration of these public comments, we are finalizing the work RVU and direct PE inputs for CPT code 11960 as proposed.

(3) Breast Implant-Expander Placement (CPT Codes 11970, 19325, 19340, 19342, and 19357)

These services were included in a larger group of 22 breast reconstruction and similarly related codes that were recommended for survey for the October 2019 RUC meeting. At the October 2019 RUC meeting, these codes were recommended for a more granular review for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 8.01 for CPT code 11970 (*replacement of tissue expander with permanent implant*). We proposed a work RVU of 7.49 supported by a reference code CPT code 35701 (*exploration not followed by surgical repair, artery; neck (e.g., carotid, subclavian)*), which has a work RVU of 7.50. CPT code 35701 shares the same intraservice time of 60 minutes with CPT code 11970 and has a slightly higher total time of 229 minutes as compared to 216 minutes. In addition, during our review of CPT code 11970, we noted that the recommended intraservice time is decreasing from 78 minutes to 60 minutes and the recommended total time of 231 minutes is decreasing to 216 minutes. We also noted that the proposed work RVU of 7.49 for CPT code 11970 is equal to the total time ratio amount, which is the current total time compared to the RUC-recommended total time. We proposed the RUC-recommended direct PE inputs for CPT code 11970.

We disagreed with the RUC-recommended work RVU of 8.64 for CPT code 19325 (*breast augmentation with implant*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 11970 and 19325 is equivalent to the RUC-recommended interval of 0.63 RVUs. Therefore, we proposed a work RVU of 8.12 for CPT code 19325, based on the RUC-recommended interval of 0.63 additional RVUs above our proposed work RVU of 7.49 for CPT code 11970. We noted that we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We also supported the proposed work RVU of 8.12 based on a reference code, CPT code 25652 (*open treatment of ulnar styloid fracture*). CPT code 25652 shares the same intraservice time of 60 minutes and the same total time of 225 minutes with a lower work RVU of 8.06. In addition, during our review of CPT code

19325, we noted that the total time has decreased from 244 minutes to 225 minutes and the intraservice time has decreased from 90 minutes to 60 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19325.

We disagreed with the RUC-recommended work RVU of 11.00 for CPT code 19340 (*insertion of breast implant on same day of mastectomy (i.e. immediate)*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 19325 and 19340 is equivalent to the RUC-recommended interval of 2.36 RVUs. Therefore, we proposed a work RVU of 10.48 for CPT code 19340, based on the recommended interval of 2.36 additional RVUs above our proposed work RVU of 8.12 for CPT code 19325. We also supported our proposed work RVU of 10.48 based on a reference code, CPT code 47562 (*laparoscopy, surgical; cholecystectomy*). CPT code 47562 shares the same intraservice time of 80 minutes and only a slightly lower total time of 251 minutes with a similar work RVU of 10.47. In addition, during our review of CPT code 19340, we noted that the total time has decreased from 366 minutes to 261 minutes and the intraservice time has decreased from 120 minutes to 80 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19340.

We disagreed with the RUC-recommended work RVU of 11.00 for CPT code 19342 (*insertion or replacement of breast implant on different day from mastectomy*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 19325 and 19342 is equivalent to the RUC-recommended interval of 2.36 RVUs. Therefore, we proposed a work RVU of 10.48 for CPT code 19342, based on the recommended interval of 2.36 additional RVUs above our proposed work RVU of 8.12 for CPT code 19325. We also noted that the RUC-recommended work RVU of 11.00 is equal to the RUC-recommended work RVU for CPT code 19340 because they have stated that both services involve an identical amount of physician work and similar times. We also supported our proposed work RVU of 10.48 based on a reference code, CPT code 47562 (*laparoscopy, surgical; cholecystectomy*). CPT code 47562 shares the same intraservice time of 80 minutes and only a slightly lower total time of 251 minutes with a similar work RVU of 10.47. The total time for CPT code 19342 has decreased from 320 minutes to 252 minutes and the intraservice time has decreased from 115 minutes to 80 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19342.

We disagreed with the RUC-recommended work RVU of 15.36 for CPT code 19357 (*tissue expander placement in breast reconstruction, including subsequent expansion*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 11970 and 19357 is equivalent to the RUC-recommended interval of 7.35 RVUs. Therefore, we proposed a work RVU of 14.84 for CPT code 19357, based on the recommended interval of 7.35 additional RVUs above our proposed work RVU of 7.49 for CPT code 11970. We also supported our proposed work RVU of 14.84 based on a reference code, CPT code 37605 (*ligation; internal or common carotid artery*). CPT code 37605 shares the same intraservice time of 90 minutes and only a slightly lower total time of 342 minutes with a lower work RVU of 14.28. In addition, during our review of CPT code 19357, we noted that the total time has decreased from 468 minutes to 344 minutes and the intraservice time has decreased from 110 minutes to 90 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19357.

We received public comments on the Breast Implant-Expander Placement code family. The following is a summary of the comments we received and our responses.

Comment: Commenters disagreed with the proposed work RVU of 7.49 for CPT code 11970 and stated that CMS should finalize the RUC-recommended work RVU of 8.01. Commenters stated that they disagree with the use of the total time ratio methodology for the valuation of this code. The commenters stated that they believe the total time ratio is invalid because it uses 30-year-old total time from the Harvard Study. Additionally, commenters stated that they believe CMS did not consider intensity of the service while using this methodology, which they believe is actually much higher than what CMS has accounted for. Commenters stated that they believe CMS substituted an arbitrary determination of work values derived from time and a subjective estimate of intensity based on an unknown and clinically uniformed opinion.

Response: We disagree and continue to believe that the use of time ratios is an appropriate method for identifying potential work RVUs for particular PFS services. In regard to the age of the data from the Harvard study, if we were to operate under the assumption that previously recommended work times are now arbitrarily invalid, this would undermine the relativity of the work RVUs on the PFS in general, given that codes are, and have been over many years, often valued by comparisons to codes with similar times. For CPT code 11970, survey times showed a total time and intraservice time decrease. Therefore, we believe the total time ratio, as a comparison of the current work time versus the RUC-recommended work times, is an appropriate methodology to value the work for this CPT code. For additional information regarding our use of time ratios for code valuation, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.H.2. of this final rule).

Comment: Commenters disagreed with the proposed work RVU of 8.12 for CPT code 19325 and stated that CMS should finalize the RUC-recommended work RVU of 8.64. Commenters also disagreed with the proposed work RVU of 10.48 for CPT code 19340 and CPT code 19342 and stated that we should finalize the RUC-recommended work RVU of 11.00 for both CPT codes. Commenters also stated that they disagreed with the proposed work RVU of 14.84 for CPT code 19357 and stated that instead we should finalize the RUC-recommended work RVU of 15.36. Commenters stated that they do not support the use of an incremental methodology as an appropriate method for identifying work RVUs for these PFS services. In particular, commenters noted that they believe this methodology adds fragility to the relative value system, as an error in the foundation code could affect the entire code family.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. For additional information regarding

our use of an incremental difference for code valuation, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.H.2. of this final rule).

Comment: Commenters disagreed with our use of the chosen supporting reference codes throughout the code family. For CPT code 11970, CPT code 19325, and CPT code19357, commenters stated that they believe the chosen reference codes are too ''low-volume'' to accurately support the proposed work times for these codes. Additionally, commenters stated that for CPT code 19325, CPT code 19340, CPT code 19342, and CPT code 19357, that the work values for the reference codes chosen by CMS are too old to be accurate comparisons for determining appropriate valuations. The commenters also stated that several of the reference codes are not relevant for purposes of valuation because there is no evidence to support clinical comparison.

Response: We are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. Additionally, we use other methods to validate work RVUs, such as reference codes. When using reference codes to support a proposed work RVU, we do not consider them as a direct ''cross-walk'' between the CPT code that is being revalued and the chosen reference code. Instead, a reference code used as a supportive check in validating work times. We continue to believe that the relative value system of the PFS is such that all services are appropriately subject to comparisons to one another. We do not agree that codes must share the same patient population or utilization level to serve as an appropriate reference code. We also recognize that it is important to use the most recent data available regarding work times. However, we believe that while some reference code values may be considered older, they still provide support for revision of work RVUs when survey times show a marked increase or decrease in total and intraservice time, such as was the case for this code family.

Comment: Commenters stated that CMS must ensure that any RVU reduction of more than 19 percent is phased in over 2 years, under 1848(c)(7) of the Act. The commenter stated that the magnitude of the proposed RVU reductions for CPT codes 19340 and 19357 would trigger the phase-in requirements since they would be decreasing by more than 19 percent.

Response: Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. We proposed to exempt all of the CPT codes in the Breast Implant-Expander Placement family from the phase-in of significant RVU reductions required by section 1848(c)(7) of the Act due to the fact that they were designated as ''revised'' codes by CPT as a result of significant revisions to their code descriptors. Since all of the codes in the family fall under the revised designation, the phase-in requirement does not apply to them.

Comment: Commenters stated that they are concerned that reducing reimbursement for the services in this code family could limit access to breast reconstruction following mastectomy. The commenters cited a study done by Kamali P et al., titled: Immediate Breast Reconstruction among Patients with Medicare and Private Insurance: A Matched Cohort Analysis. Commenters also stated that they wanted to bring to our attention the Women's Health and Cancer Rights Act of 1998 (WHCRA). The commenters stated that this act provides coverage protection for patients who choose to have breast reconstruction following a mastectomy.

Response: We remain committed to supporting the health of all Medicare beneficiaries, as well as remaining vigilant in support of all services related to minority and women's health. While the WHCRA (Pub. L. 105–277, Title IX, Oct. 21, 1998) is an important federal law that furthers protections for women's healthcare rights and access to services, we note that Medicare does provide coverage for these important services.

After consideration of these public comments, we are finalizing the work RVU and direct PE inputs for the Breast Implant-Expander

(4) Breast Implant-Expander Removal (CPT Codes 11971, 19328, and 19330)

These services were included in a group of codes that were recommended for survey for the October 2019 RUC meeting as part of a large group of 22 breast reconstruction and similarly related services. At its October 2019 meeting, the RUC agreed that a 22-code family was too expansive. They recommended these codes be re-reviewed as part of a smaller and more granular code family for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 7.02 for CPT code 11971 (*removal of tissue expander w/out insertion of implant*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 11970 and 11971 is equivalent to the RUC recommended interval of 0.99 RVUs. Therefore, we proposed a work RVU of 6.50 for CPT code 11971, based on the recommended interval of 0.99 RVUs below our proposed work RVU of 7.49 for CPT code 11970. We noted that as stated previously, we believed the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within families of similarly revised codes. We also supported our proposed work RVU of 6.50 based on a reference code, CPT code 25671 (*percutaneous skeletal fixation of distal radioulnar dislocation*). CPT code 25671 shares the same intraservice time of 45 minutes and a slightly less total time of 210 minutes with a very similar work RVU of 6.46. In addition, during our review of CPT code 11971, we noted that the total time has decreased from 303 minutes to 215 minutes and the intraservice time has decreased from 90 to 45 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 11971.

We disagreed with the RUC-recommended work RVU of 7.44 for CPT code 19328 (*removal of intact breast implant*). Although we disagreed with the RUC-recommended work RVU, we proposed increasing the current work RVU from 6.48 to 6.92 to account for the increases in total and intraservice time. We also concurred that the relative difference in work between CPT codes 11971 and 19328 is equivalent to the RUC-recommended interval of 0.42 RVUs. Therefore, we proposed a work RVU of 6.92 for CPT code 19328, based on the recommended interval of 0.42 additional RVUs above our proposed work RVU of 6.50 for CPT code 11970. We also supported our proposed work RVU of 6.92 based on a reference code, CPT code 28289 (*Hallux rigidus correction with cheilectomy, debridement and capsular release of the first metatarsophalangeal joint; without implant*). CPT code 28289 shares the same intraservice time of 45 minutes and a slightly higher total time of 210 minutes with a very similar work RVU of 6.90. The total time for CPT code 19328 has increased from 173 minutes to 199 minutes and the intraservice time has increased from 38 to 45 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19328.

We proposed the RUC-recommended work RVU of 9.00 for CPT code 19330

(*removal of ruptured breast implant, including implant contents*). The survey total time for CPT code 19330 has increased from 218 minutes to 229 minutes and the intraservice time has increased from 62 minutes to 75 minutes. We also proposed the RUC-recommended direct PE inputs for this code without refinements.

We received public comments on the Breast Implant-Expander Removal code family. The following is a summary of the comments we received and our responses.

Comment: Commenters disagreed with the proposed work RVU of 6.50 for CPT code 11971 and stated that CMS should finalize the RUC-recommended work RVU of 7.02. Commenters also disagreed with the proposed work RVU of 6.92 for CPT code 19328 and stated that CMS should finalize the RUC-recommended work RVU of 7.44. Commenters stated that they do not support the proposed work RVU because they do not support the use of an incremental methodology as an appropriate tool for valuing services in this code family. In particular, commenters noted that they believe this methodology is further inappropriate because it uses a foundation code that is not within the same code family, which adds further fragility to the use of the incremental methodology for valuation of this code family.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity.

Comment: Commenters disagreed with our use of the chosen supporting reference codes for CPT code 11971 and CPT code 19328. The commenters stated that they believe there is not adequate clinical comparison for the work portion of the service. Commenters also stated that they believe the reference code values are too old because they are from outdated survey results and do not have adequately comparable intensities.

Response: When using referencing codes to support a proposed work RVU, we do not consider them as a direct ''cross-walk'' between the CPT code that is being revalued and the chosen reference code. Instead, reference codes are used as a supportive check in validating work times. We continue to believe that the relative value system of the PFS is such that all services are appropriately subject to comparisons to one another.

After consideration of these public comments, we find the arguments for maintaining consistency in methodology and reducing the risk of anomalies within the valuation of this code family to be compelling. We are finalizing the RUC-recommended work RVU of 7.02 for CPT code 11971 and the RUC-recommended work RVU of 7.44 for CPT code 19328. We are also finalizing the direct PE inputs as proposed.

(5) Modified Radical Mastectomy (CPT Code 19307)

The RUC recommended that CPT code 19307 (*Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle*) be surveyed for the January 2020 RUC meeting for site of service anomaly. The Relativity Assessment Workgroup identified services performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital E/M services within the global period and with 2018 Medicare utilization over 5,000. The RUC recommended lowering the work RVU to 17.99 which is the survey's 25th percentile.

We proposed the RUC-recommended work RVUs of 17.99 for CPT code 19307. We also proposed the RUC-recommended direct PE inputs for this code.

We received public comments on Modified Radical Mastectomy (CPT code 19307). The following is a summary of the comments we received and our responses.

Comment: Commenters were overall in support of CMS proposing the RUC recommendations for this code. One commenter noted strong support for the process and of the RUC. Additionally, the commenters suggested CMS to accept the RUC recommendations to extend the office and outpatient E/M work RVU increases to the office and outpatient visits included in 10- and 90-day globals.

Response: We appreciate the commenters' support for CMS proposing the RUC recommendation for Modified Radical Mastectomy (CPT code 19307) and note the commenters concern with regard to office and outpatient E/M work RVU increases to the office and outpatient visits included in 10- and 90-day global.

After consideration of these public comments, we are finalizing as proposed the RUC-recommended work RVU of 17.99 for CPT code 19307. We are also finalizing as proposed the RUC-recommended direct PE inputs for this code.

(6) Breast Lift-Reduction (CPT Codes 19316 and 19318)

These services were included in a larger code group of similarly related services that were recommended for review for the October 2019 RUC meeting. CPT code 19316 (*mastopexy*) and CPT code 19318 (*Breast reduction*) were then recommended for a more granular review for the January 2020 RUC meeting.

We proposed the RUC-recommended work RVU of 11.09 for CPT code 19316 (*mastopexy*) and 16.03 for CPT code 19318 (*Breast reduction*). We proposed the RUC-recommended direct PE inputs for this code family without refinements.

We did not receive public comments on this code family, and are finalizing as proposed.

(7) Secondary Breast Mound Procedure (CPT Codes 19370, 19371, and 19380)

These services were included in a large group of breast reconstruction codes that were recommended to be surveyed for the October 2019 RUC meeting. At the October 2019 RUC meeting, the RUC concurred with the more granular code families but recommended these codes be re-surveyed for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 10.0 for CPT code 19370 (*Revision of peri-implant capsule, breast, including capsulorrhaphy, and/or partial capsulectomy*). We proposed to maintain the current work RVU of 9.17 based on a supporting reference code, CPT code 28299 (*Correction, hallux valgus (bunionectomy*), with sesamoidectomy, when performed; with double osteotomy, any method), which has a work RVU of 9.29. CPT code 28299 shares a similar intraservice time of 75 minutes with CPT code 19370 and has a slightly higher total time of 256 minutes. In addition, we noted during our review of CPT code 19370 that the recommended total time has increased minimally from 253 minutes to 255 minutes, with a slight decrease in intraservice time of 82 minutes to 78 minutes. We noted that we believe the similar work RVU of the supporting CPT code 28299, as well as the minimal changes in physician work time for CPT code 19370, supports maintaining the current work RVU of 9.17. We proposed the RUC-recommended direct PE inputs for CPT code 19370 without refinements.

We disagreed with the RUC-recommended work RVU of 10.81 for CPT code 19371 (*Peri-implant*

capsulectomy, breast, complete, including removal of all intra-capsular contents). Although we disagreed with the RUC-recommended work RVU, we concur that the relative difference in work between CPT codes 19370 and 19371 is equivalent to the RUC-recommended interval of 0.81 RVUs. Therefore, we proposed a work RVU of 9.98 for CPT code 19371, based on the recommended interval of 0.81 additional RVUs above our proposed work RVU of 9.17 for CPT code 19370. We noted that as stated previously, we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We also supported our proposed work RVU of 9.98 based on a reference code, CPT code 25628 (*Open treatment of carpal scaphoid (navicular) fracture, includes internal fixation, when performed*). CPT code 25628 shares the same intraservice time of 90 minutes and a slightly higher total time of 277 minutes with a work RVU of 9.67. In addition, during our review of CPT code 19371, we noted that the total time for CPT code 19371 has decreased from 306 minutes to 261 minutes and the intraservice time has decreased from 117 to 90 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19371.

We disagreed with the RUC-recommended work RVU of 12.00 for CPT code 19380 (*Revision of reconstructed breast* (*e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)*). Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 19371 and 19380 is equivalent to the RUC recommended interval of 1.19 RVUs. Therefore, we proposed a work RVU of 11.17 for CPT code 19380, based on the recommended interval of 1.19 additional RVUs above our proposed work RVU of 9.98 for CPT code 19371. We also supported our proposed work RVU of 11.17 based on a reference code, CPT code 64569 (*Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generato*). CPT code 64569 shares the same intraservice time of 120 minutes and only a slightly higher total time of 312 minutes with a work RVU of 11.0. The total time increased from 277 minutes to 307 minutes and the intraservice time has increased from 89 minutes to 120 minutes. We proposed the RUC-recommended direct PE inputs for CPT code 19380.

We received public comments on the Secondary Breast Mound Procedure (CPT codes 19370, 19371, and 19380). The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with the proposal to maintain the current work RVU of 9.17 for CPT code 19370 (*Revision of peri-implant capsule, breast, including capsulorrhaphy, and/or partial capsulectomy*) and stated that CMS should finalize the RUC- recommended work RVU of 10.00. Some of the commenters disagreed with comparing the current intraservice time and total time from the Harvard study to the RUC-recommended physician time. The commenters also believed that we have not appropriately accounted for the CPT Editorial Panel's revised additional physician work that is now inclusive in the code descriptor and increased intensity.

Response: We disagree with the commenter. For CPT code 19370, survey times showed only a slight increase in total time and slight decrease in intraservice time. Therefore, we continue to believe that the survey time does not support increasing the work RVU; in particular, there was no significant change in total time.

Comment: Commenters disagreed with the proposed work RVU of 9.98 for CPT code 19371 (*Peri-implant capsulectomy, breast, complete, including removal of all intra-capsular contents*) and stated that CMS should finalize the RUC-recommended work RVU of 10.81. Commenters also disagreed with the proposed work RVU of 11.17 for CPT code 1980 (*Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)*) and stated that we should finalize the RUC-recommended work RVU of 12.00. Commenters stated that they do not support the use of an incremental methodology as an appropriate method for identifying work RVUs for these PFS services. In particular, commenters noted that they believe this methodology adds fragility to the relative value system, as an error in the foundation code could affect the entire code family.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We have no evidence to suggest that the use of an incremental difference between codes conflicts with the statute's definition of the work component as the resources in time and intensity required in furnishing the service. We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers again that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. For additional information regarding our use of an incremental difference for code valuation, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.H.2. of this final rule).

Comment: For CPT codes 19370, CPT code 19371, and CPT code 19380, commenters disagreed with our use of the chosen supporting reference codes throughout the code family stating they were not strong reference codes, and not relevant for purposes of valuation because there is no evidence of clinical comparison. A commenter also stated that the reference code used for CPT code 19380 had very low volume.

Response: We are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. Additionally, we use other methods to validate work RVUs, such as reference codes. When using referencing codes to support a proposed work RVU, we do not consider there to be a direct ''cross-walk'' between the CPT code that is being revalued and the chosen reference code. Instead, it is meant to be supportive in validating work times. We continue to believe that the relative value system of the PFS is such that all services are appropriately subject to comparisons to one another. We do not agree that codes must share the same patient population or utilization level to serve as an appropriate reference code. We also recognize that it is important to use recent available data regarding work times. However, we believe that while some reference code values may be considered older, they still provide support for revision of work RVUs when survey times show a marked increase or decrease in total and intraservice time, such as was the case for this code family.

After consideration of public comments, we are finalizing the work RVU and direct PE inputs for the

Secondary Breast Mound Procedure code family as proposed.

(8) Hip-Knee Arthroplasty (CPT Codes 27130 and 27447)

CPT codes 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft*) and 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) were identified as potentially misvalued codes under the CMS high expenditure procedural code screen in the CY 2014 PFS final rule with comment period (78 FR 74334). These codes were reviewed by the AMA RUC who provided recommendations for work RVUs and physician time for these services for CY 2014. We agreed with the RUC recommendation to value CPT code 27130 and CPT code 27447 equally and thus established the same CY 2014 interim final work RVUs for these two procedures (78 FR 74334). This change resulted in a 1.12 work RVU increase for the visits in the global period. We added the additional work to the AMA RUC-recommended work RVU of 19.60 for CPT codes 27130 and 27447, resulting in an interim final work RVU of 20.72 for both services.

In the CY 2015 PFS final rule with comment period (79 FR 67632), we discussed how in the CY 2014 PFS final rule with comment period, we sought public comment regarding the appropriate work RVUs for these services and the most appropriate reconciliation for the conflicting information regarding time values for these services as presented to us by the physician community. We did not find the rationales provided for modifying the interim final work values established in CY 2014 compelling, and thus we finalized the CY 2014 interim final values for these procedures based upon the best data we had available and to preserve appropriate relativity with other codes.

In the CY 2019 PFS final rule (83 FR 59500 through 595303), CPT code 27130 and CPT code 27447 were added to the list of potentially misvalued codes. A stakeholder submitted information requesting that CMS nominate these codes as potentially misvalued. The stakeholder stated that there were substantial overestimates in pre-service and post-service time including follow-up inpatient and outpatient visits that do not take place included in the valuation of the service. As a result, the codes were resurveyed for the October 2019 RUC meeting.

We proposed the RUC-recommended work RVU of 19.60 for CPT code 27130 and the RUC-recommended work RVU of 19.60 for CPT code 27447. We also proposed the RUC-recommended direct PE inputs for both codes. Additionally, we solicited comment from the medical community on how to consider and/or include pre-optimization time (pre-service work and/or activities to improve surgical outcomes) going forward. We also noted that we were interested in stakeholders' thoughts on what codes could be used to capture these pre-optimization activities that could be billed in conjunction with the services discussed previously. Overall, we noted interest in continuing our ongoing dialog with stakeholders about how CMS might pay more accurately for improved clinical outcomes that may result from increased efficiency in furnishing care through activities, such as pre-optimization and are appreciative of information provided by the medical community. We invited the medical community to continue to engage with CMS on this and other topics.

We received public comments on Hip-Knee Arthroplasty (CPT codes 27130 and 27447). The following is a summary of the comments we received and our responses.

Comment: Many commenters were overall opposed to the proposal to reduce the work RVUs associated with CPT codes 27447 and 27130. Commenters noted that pre-optimization time is not captured in the current RUC survey. Commenters requested that CMS forgo any changes or delay adoption of the reduced work RVU for these procedures until an accurate assessment of this time can be determined. The commenters noted that delaying the adoption of these RVUs would provide time for CMS to work with stakeholders to better capture pre-optimization work performed by physicians to improve surgical outcomes. One commenter recommended the creation of a G code to account for arthroplasty pre-optimization work.

Two commenters appreciated CMS' interest in capturing these pre-optimization activities and seeking comment from the medical community on how to consider and/or include pre-optimization time going forward. Some stakeholders articulated that CMS may not have fully accounted for the preoperative work required to make value-based care cost-effective and high-quality. Commenters note, in light of the pandemic, that any cuts in payment to health care providers or medically necessary services would be harmful, and a reduction in work RVU is not justified by a reduction in time spent on patients, but will undercut the transition to bundled models.

One commenter was in support of CMS accepting the RUC recommendation for hip and knee arthroplasty and believes accepting the RUC recommendation will address the reimbursement imbalance, increase the primary care workforce, and improve the finances in primary care. Another commenter opposed the reduction because, if both the CF and RVU changes take effect, it would be a 15 percent reduction for physician payment. The commenter noted the RUC methodology does not capture the patient pre-optimization work related to the APM incentive that improves patient outcomes and lowers costs.

One commenter noted that patients with a higher BMI are more complex and the RVU should go up or a separate category be made for complicated joint replacement for those with a Body Mass Index (BMI) over 40. Additionally, the commenter noted that implants (for these procedures) should be reimbursed to facilities at cost or cost plus 10 percent, which would save millions of dollars per calendar year; and the commenter also believed lowering the RVUs may cause physicians to stop taking Medicare and reduce access to care.

One commenter noted overwhelming evidence that physicians and/or QHPs are spending more time with the typical patient in pre-service optimization work and stated that they believe CMS has broad authority to remedy the issues presented by the RUC recommendations for preservice time. Another commenter stated that there was logical outgrowth to add preservice time to the existing code.

One commenter noted that there are issues with the existing CPT codes in capturing arthroplasty pre-optimization activities or changes in practice patterns, and that creation of a new G code would account for arthroplasty pre-optimization work. For these procedures, this time includes patient screening and education, as well as coordinating with other health care providers to help manage the entire episode of care.

Response: We appreciate the commenters' feedback about maintaining the work RVU and potential resource costs that are not reflected in the RUC recommendation. We are also appreciative of the dialog we have had with stakeholders. We continue to assess the accuracy of service valuations, including global services paid under the PFS, and believe it would be prudent before considering

further changes to better understand how existing codes that could be billed prior to these procedures do not reflect the pre-optimization activities as described by stakeholders.

After considering the comments received, we are finalizing the RUC-recommended work RVU of 19.60 for CPT code 27130 and the RUC-recommended work RVU of 19.60 for CPT code 27447. We are also finalizing the RUC-recommended direct PE inputs for both codes. As we continue to consider this issue and how to best reflect pre-optimization in the valuation for the services, we welcome information from stakeholders as to which services may be included or which coding selections would be appropriate for various services that are or would be provided outside of the global period. We continue to be interested in stakeholders' thoughts and would like to discuss and consider the potential for more accurate coding, and what kind of coding framework, if there is currently none, could be used to capture these pre-optimization activities.

(9) Toe Amputation (CPT Codes 28820 and 28825)

These services were identified by the RUC Relativity Assessment Workgroup through a site of service anomaly screen based on the review of 3 years of data (2015, 2016 and 2017) for services with utilization over 10,000 in which a service is typically performed in the inpatient hospital setting, yet only a half discharge day management identified by CPT code 99238 is included. Prior to conducting the RUC survey, the specialty societies recommended that it would be appropriate for these services to have their global period changed from 090-day to 000-day so the site of service is less of a contributing factor to the codes' valuation. These codes were surveyed as a 000-day global service, and we proposed them as 000-day global services.

We disagreed with the RUC-recommended work RVU of 4.10 for CPT code 28820 (*Amputation, toe; metatarsophalangeal joint*). We noted that we believe that it would be more accurate to propose a work RVU of 3.51, and we are supporting this value with a crosswalk to CPT code 33958 (*Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed*)), which has a work RVU of 3.51, to account for the decrease in the surveyed work time. We do not believe the RUC-recommended reduction in work RVU from the current value of 5.82 is commensurate with the RUC-recommended 102-minute reduction in total time. We believe that a further reduction in work RVUs is warranted given the significant reduction in RUC-recommended physician time.

We disagreed with the RUC-recommended work RVU of 4.00 for CPT code 28825 (*Amputation, toe; interphalangeal joint*). We proposed a work RVU of 3.41 based on the RUC-recommended increment relationship between this code and CPT code 28820 (a difference of −0.10), which we apply to our proposed value for the latter code. We noted that we do not believe the RUC-recommended reduction in work RVU from the current value of 5.37 is commensurate with the RUC-recommended 97-minute reduction in total time. We also noted that we believe that a further reduction in work RVUs is warranted given the significance of RUC-recommended reduction in physician time.

For the direct PE inputs, we proposed to refine the pre-service clinical labor times to conform to the 000-day global period standards for both codes in the family for CPT codes 28820 and 28825. We also proposed to refine the clinical labor times for the ''Provide education/obtain consent'' (CA011) and the ''Prepare room, equipment and supplies'' (CA013) activities to conform to our established standard time of 2 minutes each in the non-facility setting for CPT codes 28820 and 28825. We proposed to refine the equipment time to conform to these changes in the clinical labor time for both codes.

We received public comments on the Toe Amputation (CPT codes 28820 and 28825).The following is a summary of the comments we received and our responses.

Comment: Commenters stated that CMS made this proposal without demonstrating that the agency also considered the disparity between the physician work intensity of the post-operative services that were previously bundled in 28820 and the physician work intensity of the skin-to-skin time of the service.

Response: We disagree with the commenter that we did not consider the disparity in intensity between the post-operative services that were previously bundled in CPT code 28820 and the skin-to-skin time of the service. Consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. This includes changes in the resource of time associated with the post-operative services that were previously bundled in CPT code 28820. We clarify again that we do not treat all components of physician time as having identical intensity. If we were to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. In the case of CPT codes 28220 and 28222, we believe that in many cases the work time was reduced substantially but the work RVU only minimally, which resulted in an implied increase in the intensity of work that does not appear to be valid, and ultimately creates work intensity anomalies.

Comment: Commenters stated that the crosswalk code that CMS used to support its proposal to reject the RUC recommendation, CPT code 33958, is not an appropriate reference code to use for making valuation decisions. The commenter stated that CPT code 33958 is an atypical 000-day global code that includes a bundled inpatient hospital visit making it inappropriate to use as a direct work value crosswalk for a service that does not include bundled visits and it is a low volume service.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: One commenter stated that they would also like to remind CMS of both the Agency's and the RUC's longstanding position that treating all components of physician time (pre-service, intra-service, post-service and post-operative visits) as having identical intensity is incorrect and that inconsistently applying it to only certain services under review creates inherent payment disparities in a payment system which is based on relative valuation.

Response: We reiterate our previous clarification that we do not treat all components of physician time as having

identical intensity. As we have consistently stated, when our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs.

Comment: Commenters stated that it does not appear that CMS considered the change in the global surgical period from a 90-day global to a 000-day global when referencing the decrease in total time for the procedure, which would make sense for a change in the global period and the associated intensity for the procedure. The intra-service time for the procedure did not change.

Response: We noted that in reviewing the recommended values for CPT codes 28820 and 28825, the change in global periods was taken into consideration. However, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. This includes changes in the resource of time associated with the post-operative services that were previously bundled in CPT code 28820.

Comment: Several commenters stated that CMS should not impose the standard 000-day clinical labor times for CA011 and CA013 with respect to CPT codes 28820 and 28825 without regard to the clinically significant information that these are major procedures that are typically performed in a facility setting.

Response: We have reviewed all the information provided by commenters and we believe it would be appropriate to maintain standard times for particular clinical labor tasks that can be applied consistently to many codes, as they are valued over several years, similar in principle to the use of physician preservice time packages. We believe that setting and maintaining such standards provides greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. Therefore, we maintain that these refinements are consistent with the clinical labor times of a 000-day global service.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for the Toe Amputation codes as proposed.

(10) Shoulder Debridement (CPT Codes 29822 and 29823)

In September 2019, the CPT Editorial Panel approved revision of CPT code 29822 (*Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies]*)) and CPT code 29823 (*Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies]*)) to clarify limited and extensive debridement by specifying the number of discrete structures debrided and providing examples of the structures.

We proposed the RUC-recommended work RVU of 7.03 for CPT code 29822 and 7.98 for CPT code 29823 without refinement.

For the direct PE inputs, we proposed the RUC recommendations CPT codes 29822 and 29823 without refinement.

We did not receive public comments on this code family, and are finalizing as proposed.

(11) Absorbable Nasal Implant Repair (CPT Codes 30468)

In September 2019, the CPT Editorial Panel approved the addition of CPT code 30468 (*Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)) to report repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)*).

We proposed the RUC-recommended value of 2.80 work RVUs without refinement for CPT code 30468.

For the direct PE inputs, we also proposed the RUC-recommended values without refinement.

We received public comments on the Absorbable Nasal Implant Repair family (CPT code 30468). The following is a summary of the comments we received and our responses.

Comment: Several commenters stated their support for our proposal to adopt the RUC-recommended values without refinement.

Response: We thank commenters for their feedback and support.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for CPT code 30468 as proposed.

(12) Lung Biopsy-CT Guidance Bundle (CPT Code 32408)

CPT codes 32405 (*Biopsy, lung or mediastinum, percutaneous needle*) and 77012 (*Computed tomography guidance for needle placement (e.g., biopsy, aspiration, injection, localization device), radiological supervision and interpretation*) were identified by the AMA through a screen of code pairs that are reported on the same day, same patient and same NPI number at or more than 75 percent of the time. The CPT Editorial Panel deleted CPT code 32405 and replaced it with 32408 (*Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed*).

We did not propose the RUC-recommended work RVU of 4.00, which is the survey median, because we believe this value somewhat overstates the increase in intensity. Although we do not imply that the decrease in time, when considering the aggregate time values for CPT codes 32405 and 77012, as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in the work RVU. Intraservice and total time ratios using the aggregate time values of current CPT codes 32405 and 77012 suggest a significantly lower work RVU; however, we did not believe a decrease from the current aggregate value of 32405 and 77012 was warranted. We noted that we believe there is some overlap in physician work and time for the two current services, and that the recommended increase to 4.00 does not appropriately recognize this overlap. Therefore, we proposed a work RVU of 3.18, which is the sum of the work RVUs of the two base codes.

We proposed the RUC-recommended direct PE inputs without refinement.

We received public comments on Lung Biopsy-CT Guidance Bundle (CPT code 32408). The following is a summary of the comments we received and our responses.

Comment: A commenter disagreed with our valuation methodology, stating that it inappropriately relies on time-based ratios. The commenter stated this methodology is flawed and inaccurately treats all components of the physician time as having identical intensity and is incorrect. In addition, the commenter suggested it lacks the rigor of the survey

process and RUC panel evaluation. The commenter stated that CMS does not provide any supporting rationale or clinical information for the proposed work RVU of 3.18 other than debating survey times, primarily the intraservice time and total time ratios for this service, then justifying the proposed work RVU with the work RVU sum of deleted code 32405 and imaging code 77012.

The commenter also states that CMS overlooked the compelling evidence rationale for why this service is presently misvalued, and that cancer treatment protocols have evolved significantly to require more definitive tissue diagnosis including biomolecular marker profiles. The new code 32408 has increased the total time and the intensity/complexity, warranting the RUC-recommended work RVU of 4.00

Response: We disagree and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. Please see above for our discussion of compelling evidence rationale. We do consider changes in technology, patient population, etc., insofar as they affect the time and intensity of the service under review. However, we do not specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation framework stipulated by statute. In addition, we reiterate that our proposal for this code was based on our analysis which indicated that there is some overlap in the work described in the two base services CPT codes 32405 and 77012. We continue to believe that a work RVU that is in excess of the aggregate work RVU of these two codes would result in an overestimation of intensity.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs for CPT code 32408 as proposed.

(13) Atrial Septostomy (CPT Codes 33741, 33745, 33746)

Septostomy procedures are performed on extremely small newborns and neonates with severe forms of congenital heart disease and are lifesaving/temporizing procedures that do not provide definitive therapy to these critically ill patients. These procedures are not typical of the Medicare population and are of low volume. CPT code 92992 (*Atrial septectomy or septostomy; transvenous method, balloon (e.g., Rashkind type) (includes cardiac catheterization)*) and CPT code 92993 (*Atrial septectomy or septostomy; blade method (Park septostomy) (includes cardiac catheterization)*), are carrier-priced codes. These services were not formally designated as potentially misvalued in the CY 2019 PFS final rule (83 FR 59500), but we did make mention that the RUC had signaled its intention to review these two codes. Both services were referred to the CPT Editorial Panel by the specialty societies who indicated that CPT code 92992 may not have included related imaging guidance, and also commented that CPT code 92993 was antiquated and rarely performed. The CPT Editorial Panel deleted both CPT codes and proposed to replace them with the following new CPT codes.

CPT code 33741 (*Transcatheter atrial septostomy (TAS) for congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (e.g., Rashkind, Sang-Park, balloon, cutting balloon, blade)*), is one of three codes intended to replace the two deleted Septostomy codes. For CPT code 33741, the RUC recommended an RVU only crosswalk to CPT code 33340 (*Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation*), which has a work RVU of 14.00. The RUC recommended 20 minutes of preservice evaluation time, 15 minutes of preservice positioning time, 15 minutes preservice scrub/dress/wait time, 55 minutes intraservice time and 45 minutes immediate postservice time, for 150 minutes total time. We proposed the RUC-recommended work RVU of 14.00 and physician times without refinement.

CPT code 33745 (*Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (e.g., atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt*) is another new procedure code proposed by the CPT Editorial Panel. The service is currently performed on neonate infants to children with severe forms of congenital heart disease, by having a stent implanted inside of an infant's beating heart (and not within a blood vessel). This stent replaces the methods described in the deleted atrial septostomy codes utilizing the balloon and blade method. The RUC recommended 25 minutes preservice evaluation time, 15 minutes preservice positioning time, 15 minutes preservice scrub/dress/wait time, 92 minutes intraservice time and 60 minutes immediate postservice time, for 207 minutes total time. The RUC recommended 20.00 work RVUs for CPT code 33745. We proposed to adopt the RUC-recommended work RVUs and physician times.

CPT code 33746, (*Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (e.g., atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location (List separately in addition to code for primary procedure)*), is the add-on code to the proposed new procedure CPT code 33745, for 60 minutes of physician intraservice time. The RUC recommended a work RVU of 10.50 for CPT code 33746. This value for the add-on code, in comparison to the recommended work value of 20.00 RVUs with 92 minutes/intraservice time and 207 minutes of total time for CPT code 33745, appears to be unsupportable given the 60 minutes of additional physician intraservice time. We proposed a work RVU of 8.00 for add-on CPT code 33746, which is the 25th percentile value from the survey and of similar valuation from reference CPT code 93592 (*Percutaneous*

transcatheter closure of paravalvular leak; each additional occlusion device (List separately in addition to code for primary procedure)).

This family of CPT codes are facility-only services and have no direct PE inputs.

We received public comments on the proposed values for the Atrial Septostomy CPT codes 33741, 33745, 33746. The following is a summary of the comments we received and our responses.

Comment: Commenters were supportive of CMS proposing the work RVUs as recommended by the AMA RUC for CPT code 33741, at 14.00, and for CPT code 33745, at 20.00. Commenters disagreed with CMS proposing 8.00 work RVUs for CPT code 33746, that differs from the AMA RUC recommended value of 10.50. Commenters did not believe that the work RVU of 8.00 from CPT reference code 93592 (also an add-on code with the same amount of physician time), and from the survey's 25th-percentile work RVU value adequately reflected the resources involved in furnishing the service and suggested instead the survey's 50th-percentile median value of 10.50 RVUs due to the intensity of the work in CPT code 33746, which involves the typical patient who is a small child or infant. The commenters stated that add-on code 33746 is not intended as an extension of an initial stent procedure described by CPT code 33745 and that CPT code 33746 is the placement of a second stent where the work is more intense than the primary procedure, CPT code 33745.

Response: For the new proposed CPT codes 33741 and 33745, the AMA RUC-recommended work RVUs values are considered higher in relationship to the physician times to perform the procedures and they note that this higher relationship is due to these procedures' higher than typical work intensity. The surveyed work RVU for CPT code 33741 at the 25th-percentile was 10.99 but the AMA RUC-recommended value was 14.00, which was lower than the 50th-percentile median value of 17.00 RVUs and about midpoint between these upper and low quartiles. The surveyed work RVU at the 25th-percentile for CPT code 33745 was 20.00 which the AMA RUC recommended.

The surveyed work RVU for add-on code CPT code 33746 at the 25th-percentile was 8.00 but the AMA RUC recommended the work RVU of 10.50 from the 50th-percentile median value, based on rationale similar to the rationale discussed above. For CPT code 33746, on the measure of physician time alone for 60 minutes we see comparable add-on codes with the identical amounts of physician time, valued at much less than their recommended 10.50 work RVUs, and much less than the CMS' referenced CPT code 93592's 8.00 work RVUs. Seeing that AMA RUC surveyed work RVU at the 25th percentile yielded a value of 8.00 and that our comparator CPT code 93592 is also valued at 8.00 for 60 minutes of physician time, we continue to believe that 8.00 work RVUs is the correct value for CPT code 33746.

After consideration of the comments, we are finalizing the work RVU for CPT code 33741, CPT code 33745, and CPT code 33746, as proposed.

(14) Percutaneous Ventricular Assist Device Insertion (CPT Codes 33995, 33990, 33991, 33992, 33997, and 33993)

In May 2019, the CPT Editorial Panel approved the revision of four codes to clarify the insertion and removal of right and left heart percutaneous ventricular assist devices (PVAD), and the addition of two codes to report insertion of PVAD venous access and removal of right heart PVAD. These codes were surveyed with 000-day global periods and reviewed at the October 2019 RUC meeting.

We proposed the RUC-recommended work RVUs for all six codes in the family. We proposed a work RVU of 6.75 for CPT code 33990 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only*), a work RVU of 6.75 for CPT code 33995 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only*), a work RVU of 8.84 for CPT code 33991 (*Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture*), a work RVU of 3.55 for CPT code 33992 (*Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), separate and distinct session from insertion*), a work RVU of 3.00 for CPT code 33997 (*Removal of percutaneous right heart ventricular assist device, venous cannula, separate and distinct session from insertion*), and a work RVU of 3.10 for CPT code 33993 (*Repositioning of percutaneous right or left heart ventricular assist device, with imaging guidance, at separate and distinct session from insertion*).

Stakeholders contacted CMS regarding the valuation of the codes in this family following the arrival of the RUC recommendations. They stated that the RUC recommendations did not accurately reflect the work time of these procedures, which they stated to be increasing due to the adoption of new technology. The stakeholders requested that CMS propose to maintain the current work RVUs for the codes in this family and to crosswalk the work RVU of the new codes to existing codes.

We disagreed with the stakeholders and proposed the RUC-recommended work RVUs for each code in this family as noted previously. We noted that in this case where the surveyed work times for the existing codes are decreasing and the utilization of CPT code 33990 is increasing significantly (quadrupling in the last 5 years), we have reason to believe that practitioners are becoming more efficient at performing the procedure, which, under the resource-based nature of the RVU system, lends support for proposing the RUC's recommended work RVUs. Although the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We disagreed with the stakeholders that the incorporation of this new technology would necessarily be grounds for maintaining the current work RVU, as improvements in technology are commonplace across many different services and are not specific to this procedure. As detailed earlier, we also have reason to believe that the improved technology has led to greater efficiencies in the procedure which, under the resource-based nature of the RVU system, lends further support for proposing a lower work RVU for the existing CPT codes.

The RUC did not recommend and we did not propose any direct PE inputs for this facility only code family. We proposed a 000-day global period for all six codes as surveyed by the RUC.

We received public comments on the codes in the Percutaneous Ventricular Assist Device Insertion family. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the CMS decision to propose the RUC-recommended work RVUs for each code in the family and recommended that CMS finalize the proposal.

Response: We appreciate the commenters' support for our proposals.

Comment: A commenter stated that the RUC recommendations included in the PFS proposed rule did not accurately reflect the full work associated with percutaneous ventricular assist device (PVAD) procedures. The commenter stated that

the RUC recommendations do not reflect increases in intra-procedure time resulting from the increased usage of SmartAssist technology and that if work value reductions continue over multiple years, it will impede physician adoption of these new technologies, resulting in a negative impact on patient access.

Response: We appreciate the information provided by the commenter and we share in their concerns regarding the need to maintain patient access to these services. However, as we stated in the proposed rule, we have reason to believe that practitioners are becoming more efficient at performing the procedures, which, under the resource-based nature of the RVU system, gives support for proposing the RUC's recommended work RVUs. We disagree with the commenter that the incorporation of this new technology would necessarily be grounds for maintaining the current work RVU, as improvements in technology are commonplace across many different services and are not specific to this procedure. We continue to believe that the RUC-recommended work RVUs are the most accurate valuations for the codes in this family.

After consideration of the public comments, we are finalizing our proposed work RVUs for the codes in the Percutaneous Ventricular Assist Device Insertion family. We did not propose and we are not finalizing any direct PE inputs for this facility only code family.

(15) Esophagogastroduodenoscopy (EGD) With Biopsy (CPT Code 43239)

In the CY 2019 PFS final rule (83 FR 59500), CPT code 43239 (*Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple*) was publicly nominated for review under the potentially misvalued code initiative. As requested, the specialty societies conducted a survey for the April 2019 RUC meeting. The RUC survey results showed that the current work RVU of 2.39, which is below the survey 25th percentile work RVU of 2.50, accurately reflects the physician work for CPT code 43239.

We proposed to maintain the current work RVU of 2.39 as recommended by the RUC. We proposed the RUC-recommended direct PE inputs for CPT code 43239 without refinement.

We received public comments on Esophagogastroduodenoscopy (EGD) with Biopsy (CPT code 43239). The following is a summary of the comments we received and our responses.

Comment: The commenters all agreed with the CMS proposal to maintain the current work RVU of 2.39 as recommended by the RUC. The commenters also all agreed with the CMS proposal of the RUC-recommended direct PE inputs with without refinement.

Response: We appreciate the commenters' support for CMS proposing the RUC recommendation for CPT code 43239.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 2.39 for CPT code 43239. We are also finalizing the RUC-recommended direct PE inputs for CPT code 43239 without refinement.

(16) Colonoscopy (CPT Code 45385)

In the CY 2019 PFS final rule (83 FR 59500), CPT code 45385 (*Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique*) was publicly nominated for review under the potentially misvalued code initiative. As requested, the specialty societies conducted a survey for the April 2019 RUC meeting. The RUC survey results showed that the current work RVU of 4.57, which is slightly above the survey 25th percentile work RVU of 4.50, accurately reflects the physician work for CPT code 45385.

We proposed to maintain the current work RVU of 4.57 as recommended by the RUC. We proposed the RUC-recommended direct PE inputs for CPT code 45385 without refinement.

We received public comments on Colonoscopy (CPT code 45385). The following is a summary of the comments we received and our responses.

Comment: The commenters all agreed with the CMS proposal to maintain the current work RVU of 4.57 as recommended by the RUC. The commenters also all agreed with the CMS proposal of the RUC-recommended direct PE inputs with without refinement.

Response: We appreciate the commenters' support for our proposal to adopt the RUC recommendation for CPT code 45385.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 4.57 for CPT code 45385. We are also finalizing the RUC-recommended direct PE inputs for CPT code 45385 without refinement.

(17) Transrectal High Intensity Focused US Prostate Ablation (CPT Codes 55880)

In May 2019, the CPT Editorial Panel established a new code to report ablation of malignant prostate tissue with high intensity focused ultrasound (HIFU), including ultrasound guidance. For CPT code 55880, we did not propose the RUC recommendation to use the survey median work RVU of 20.00 to value this service because we believe total time ratios to the two key reference codes, CPT codes 55840 (*Prostatectomy, retropubic radical, with or without nerve sparing*) and 55873 (*Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)*) indicate that this value is somewhat overstated and does not accurately reflect the physician time, and because an analysis of all 090-global period codes with similar time values indicates that this service is overvalued.

We proposed a work RVU of 17.73 based on a crosswalk to CPT code 69930 (*Cochlear device implantation, with or without mastoidectomy*) which has similar total time and identical intraservice time values and is more consistent with other codes of similar time. We proposed the RUC-recommended PE inputs without refinement.

We received public comments on Transrectal High Intensity Focused US Prostate Ablation (CPT code 55880). The following is a summary of the comments we received and our responses.

Comment: Commenters noted that, for CPT code 55880, the RUC recommended the survey 25th percentile work RVU of 20.00, not the survey median work RVU, as it is misstated in the proposed rule.

Response: We regret the error, and we note that the RUC indeed recommended the survey 25th percentile work RVU.

Comment: In response to this section, the RUC commented that they are increasingly concerned that CMS is eschewing the bedrock principles of valuation within the RBRVS (namely, magnitude estimation, survey data and clinical expertise) in favor of arbitrary mathematical formulas and, in their opinion, making distinctions in the different types of physician time, which are ''CMS/Other'' time source, ''Harvard'' time source, and ''RUC'' time source (from physician surveys). The RUC suggested CMS use valid survey data and review the actual relativity for all elements (physician work, time, intensity and complexity) when developing work values for services and not foster flawed methodologies.

Response: As we have discussed in previous rules, we agree that it is important to use the most recent data available regarding time, and we note that when many years have passed between when physician times are measured, significant discrepancies can occur. However, we also continue to believe that our operating assumption regarding the validity of the existing time values as a point of comparison is critical to the integrity of the current relative value system. The physician times and intensities currently

associated with codes play important roles in PFS ratesetting in their comparativeness to each other, in establishing work RVUs. The PFS is grounded in and reliant on the original relativity of the RBRVS, and then as services, codes and values evolve over the years, the PFS statute contemplates maintaining and building on that base-level of relativity. If we were to question the assumption that previously recommended work times had routinely been over- or underestimated, this would undermine the basis for relativity of the work RVUs on the PFS. Given that the process under which codes are often valued by comparison to codes with similar times, we acknowledge the distinction between ''CMS/Other'' times, ''Harvard'' times, and ''RUC'' physician surveyed times, but we do not believe we can apply different validation weights to any of these sources of time values while remaining consistent with our obligation to consider time and intensity as these are currently reflected in the fee schedule. They are all physician time data collected over many years. We understand that some time values may not have been reviewed or re-surveyed in a number of years, but that alone is not an indicator of the current relative accuracy of a time value.

We believe that, over the years as more codes are being reviewed and examined, the entire collective fee schedule of procedure codes should align in a very reliable and accurate relative value system reflecting each code's relativity with respect to other codes (in their work RVUs, in their procedure times, and in their work intensities). We recognize that adjusting work RVUs for changes in physician times is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we always try to apply various methodologies to identify several potential work values for individual codes before deciding on the one we find most appropriate. Our review of code values under the PFS not only examines the relationships between work, time, and intensity, but we also look at magnitude and rank order anomalies, particularly in families or groups of codes that are closely related but may differ slightly in degrees found in their clinical descriptions and possibly in the typical beneficiary populations that each code might serve. Among these codes, we try to maintain the accurate relative relationships in terms of time, work, and intensity measurements. In some cases, where there are marked improvements in medical techniques and technologies, we may find efficiencies in physician's work for certain services that warrant decreases in physician's times, but we also recognize that some improvements may introduce greater complexity and either an increase in intensity and/or in physician times. We reiterate that we believe it would be irresponsible to ignore or discount ''CMS/Other'' times or ''Harvard'' times in our data system, and that we need to consider all times and all intensities and all clinically relevant relatedness (or non-relatedness) of procedure codes to each other in establishing more refined work RVUs for PFS services. Also note that physician times considered to be ''RUC'' physician times as they are listed in the RUC database are not always necessarily AMA RUC surveyed times. We may have adjusted AMA RUC surveyed times in our annual review of all HCPCS codes; and the same can be said of times that the AMA labels as ''Harvard'' or ''CMS/Other'' physician times.

Comment: Many commenters stated that the proposed work RVU was too low to adequately reflect the work, skill and complexity required for this procedure. Commenters were concerned about patient access, stating that a significant number of Medicare beneficiaries with prostate cancer will not have access to this procedure. Commenters encouraged CMS to finalize the RUC-recommended work RVU of 20.00. Commenters stated that CMS did not provide any supporting rationale or clinical information for the proposed work RVU of 17.73 other than debating survey times, primarily the total time ratios between a service that is not currently covered to the two key reference codes, then justifying our proposed work RVU with a crosswalk to CPT code 69930. Commenters stated that this crosswalk is flawed in that it was surveyed 12 years ago, and it is clinically a very different procedure. A commenter suggested CPT code 42420 (*Excision of the parotid tumor or parotid gland*) with a work RVU of 19.53 as a more appropriate crosswalk as it is a more intense procedure than our proposed crosswalk CPT code 69930.

Response: Our proposed work RVU of 17.73 is not solely derived from time ratios. Our analysis included comparisons to other codes of similar time values as well as to codes with similar numbers of the total number of post-op visits, as well as a consideration of the RUC-recommended key reference services. These factors all indicated a work RVU lower than the recommended 20.00. Comparison of relative intensity values further indicates this RVU is somewhat overvalued. Our proposed value of 17.73 produces an intensity value of 0.066, which is very similar to the intensity value for our crosswalk CPT code 69930, which is 0.067. We disagree that the patient populations of these two codes are too different; the description and vignettes of CPT code 69930 do not indicate that this is primarily a pediatric procedure. Further, we reiterate that, although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk. We continue to believe the time values and relative intensity of this procedure indicate that a work RVU of 17.73 is a more accurate valuation, and we are finalizing this work RVU as proposed.

After consideration of the public comments, we are finalizing as proposed a work RVU of 17.73, as well as the RUC-recommended direct PE inputs without refinement.

(18) Computer-Aided Mapping of Cervix Uteri (CPT Code 57465)

In September 2019, the addition of CPT code 57465 (*Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect (List separately in addition to code for primary procedure)*) was approved by the CPT Editorial Panel to report computer-aided mapping of cervix uteri during colposcopy. The RUC recommended the survey median work RVU of 0.81 for this service.

We proposed the RUC-recommended value of 0.81 for CPT code 57465. We also proposed the RUC-recommended direct PE inputs for this code.

We solicited comment on a new medical supply indicated on the PE spreadsheet submitted by the RUC. A ''computer aided spectral imaging system (colposcopy) disposal speculum'' was noted in the RUC PE meeting materials. This name suggests it is digital. However, on the actual invoice submitted, the supply item in question was listed as a ''disposable medium speculum'' with no mention of a spectral imaging system or a digital component. We researched this speculum and could not find any evidence that it has a digital component. Therefore, we proposed to change the name of this new supply item to ''disposable speculum, medium'' (SD337) to reflect the actual product on the invoice submitted. We sought clarification as to what aspect of the

speculum is digital or if a cheaper, non-digital speculum would suffice. We noted for example that the vaginal specula (SD118) supply has a CY 2021 price of $1.12 and we were able to find disposable medium specula readily available online for a price of roughly $1.00. We proposed the new SD337 supply at the $5.80 price as listed on the invoice submitted in the RUC materials and sought comment as to why other disposable speculums at a lower price would not be typical for this procedure.

We received public comments on the Computer-Aided Mapping of Cervix Uteri code family (CPT code 57465). The following is a summary of the comments we received and our responses.

Comment: Commenters were overall in support and appreciated CMS proposing the RUC-recommended work RVU and the direct PE inputs for code 57465. We also received comments with additional information on the SD337 supply item in question. Commenters stated that in order for the map to be successfully generated, there are stringent technical requirements of the vaginal speculum that require it to be attached to the optical head of the system. Commenters stated that the specula are therefore custom designed to meet performance standards, and are an integral part of the imaging system. One commenter noted that the speculum referenced is typical. The coating on the plastic that enhances the image is necessary, and without its light reflection on plastic interferes with the image processing.

Response: We appreciate the additional information provided from commenters and the commenters' agreement with the proposed name change and that the item referenced is typical for the service noted.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 0.81 for CPT code 57465. We are also finalizing the proposed RUC-recommended direct PE inputs for this code. We are finalizing the new SD337 supply at the $5.80 price as listed on the invoice submitted in the RUC materials based on the public comments submitted. To clarify the nature of the supply, we are renaming SD337 to ''digital imaging speculum'' to reflect what the commenters stated would be more accurate.

(19) Colpopexy (CPT Codes 57282 and 57283)

The CPT codes 57282 (*Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)*) and 57283 (*Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)*) were identified by the RUC Relativity Assessment Workgroup as services performed less than 50 percent of the time in the inpatient setting yet include inpatient hospital E/M services within the global period and the 2018 Medicare utilization is over 5,000. This code family was surveyed and reviewed for the January 2020 RUC meeting. For CY 2021, the RUC recommended a work RVU of 13.48 for CPT code 57282, and a work RVU of 13.51 for CPT code 57283.

We disagreed with the RUC-recommended work RVUs for the CPT code family of 57282 and 57283. We proposed a work RVU of 11.63 for CPT code 57282, and also proposed to maintain the current work RVU of 11.66 for CPT code 57283. For CPT code 57283, we based our disagreement on the total time ratio between the current time of 349 minutes and the recommended time established by the survey of 231 minutes. This ratio equals 66 percent, and 66 percent of the current work RVU of 11.66 for CPT code 57283 equals a work RVU of 7.70. When we reviewed CPT code 57283, we found that the recommended work RVU was higher than other codes with similar time values. This is supported by the reference CPT codes we compared to CPT code 57283 with 90 minutes of intraservice time; reference CPT code 19350 (*Nipple/areola reconstruction*) has a work RVU of 9.11 with 229 minutes of total time, and reference CPT code 47563 (*Laparoscopy, surgical; cholecystectomy with cholangiography*) which has a work RVU of 11.47 with 238 minutes of total time. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we noted that we believe that since the two components of work are time and intensity, significant decreases in time should be reflected in decreases to work RVUs. The recommendation from the RUC acknowledged that the time had decreased for CPT code 57283, and also noted that there has been an increase in intensity due to a change in technique and knowledge necessary to perform the service. In the case of CPT code 57283, we noted that we believe it would be more accurate to propose maintaining the current work RVU of 11.66 instead of the RUC-recommended work RVU of 13.51 to account for these decreases in the surveyed work time while still accounting for the increase in intensity. We also noted that the intensity of CPT code 57283 would nearly double by maintaining the proposed work RVU of 11.66, due to the significant decreases in surveyed work time, which we believe supported the RUC's contention that the intensity of this code has increased over time.

For CPT code 57282, we disagreed with the RUC-recommended RVU of 13.48. We noted that the significant decrease in total time for code 57282 suggests an RVU lower than 13.48. Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference in work between CPT codes 57282 and 57283 is equivalent to the RUC-recommended interval of 0.03 RVUs. We noted that we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Therefore, we proposed a work RVU of 11.63 for CPT code 57282, based on the RUC-recommended interval of 0.03 RVUs below our proposed work RVU of 11.66 for CPT code 57283.

We proposed the RUC-recommended direct PE inputs for the CPT code family of 57282 and 57283 without refinement.

We received public comments on the Colpopexy code family (CPT codes 57282 and 57283). The following is a summary of the comments we received and our responses.

Comment: The commenters disagreed with our proposal to value CPT code 57282 using an incremental methodology, and stated that the proposal inaccurately treats all components of the physician time as having identical intensity. The commenters would prefer that CMS finalize the RUC-recommended value rather than values derived by increments. Moreover, commenters stated that CMS proposed the RUC work RVU increment (0.03) between CPT codes 57282 and 57283 for this code family, yet disagreed with the RUC-recommended work RVU.

Response: We believe the use of an incremental difference between codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. Historically, we have frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. We noted that the RUC has also used the same incremental methodology on occasion when it was unable to produce valid survey data for a service.

Comment: Commenters stated that the RUC recommendation for CPT code 57282 was based on robust survey results and requested that CMS adopt the RUC-recommended work values. The commenters stated that the current work value and time for CPT code 57282 were derived from the Harvard studies, and therefore, are not resource based. Commenters stated that they could not support comparing the original Harvard value of this service, which is over 25 years old and whose source is unknown, to time and work derived from a recent survey. Commenters stated that CPT code 57282 has never been surveyed by the RUC and the IWPUT for the current times and work RVU (0.014) are inappropriately low for this intense major surgical procedure, not that much higher than the intensity for pre-service scrub/dress/wait time, which strongly implies the current total times are inflated relative to the current work RVU and not valid for comparison to the new times. Commenters stated that the increased intra-service time can be attributed to the support sutures being placed at multiple points of attachment, which was not done in the past. Commenters stated that the largest difference in the total time comes from the hospital visit time assigned by Harvard in 1992.

Response: We agree that it is important to use the recent data available regarding time, and we acknowledge that when many years have passed between when work time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. The times currently associated with codes play a very important element in PFS ratesetting, both as points of comparison in establishing work RVUs and in the allocation of indirect PE RVUs by specialty. If we were to operate under the assumption that previously recommended work times had routinely been underestimated or overestimated, this would undermine the relativity of the work RVUs on the PFS in general, given the process under which codes are often valued by comparisons to codes with similar times and it undermine the validity of the allocation of indirect PE RVUs to physician specialties across the PFS.

Instead, we believe that it is crucial that the code valuation process take place with the understanding that the existing work times, used in the PFS ratesetting processes, are accurate. We recognize that adjusting work RVUs for changes in time is not always a straightforward process and that the intensity associated with changes in time is not necessarily always linear, which is why we apply various methodologies to identify several potential work values for individual codes. However, we want to reiterate that we believe it would be irresponsible to ignore changes in time based on the best data available and that we are statutorily obligated to consider both time and intensity in establishing work RVUs for PFS services. For additional information regarding the use of old work time values in our methodology, we refer readers to our discussion of the subject in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: We received several comments regarding the decrease in total times for CPT codes 57282 and 57283. For CPT code 57282, a few commenters stated that the largest difference in the total time comes from the hospital visit time assigned by Harvard in 1992, which makes CMS' rationale to recommend a lower work RVU based on the ''significant decrease in total time'' completely flawed and unjustified. For CPT code 57283, the commenters disagreed that the decreased total time should result in a lower work RVU than the RUC recommendation, and stated that although the current times for CPT code 57283 have decreased according to the RUC survey data, the overall intensity and complexity has increased significantly.

Response: For CPT codes 57282 and 57283, we disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe we have the obligation to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services will be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: Some comments stated that the proposed rule did not discuss the RUC's compelling evidence rationale for why CPT codes 57282 and 57283 are presently undervalued, suggesting that CMS missed considering this rationale. Commenters stated that there has been a change in the physician work necessary to perform these services based on a change in technique and knowledge of the problem. Commenters stated that there has been a change in technology due to functional MRI studies which have increased what is known about pelvic organ prolapse and what structures are important to successful repair. Some commenters went on to describe the extent of dissection required and the change in technique which is now standardized when performing CPT codes 57282 and 57283.

Response: We agree with the commenters that due to changes in technology for CPT codes 57282 and 57283 we had reason to believe that practitioners are becoming more efficient at performing these procedures. While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We do not agree with the commenters that a change in the work pattern, and more dissections and greater use of sutures, would necessarily be grounds for increasing the work RVUs as recommended by the RUC, as improvements in technology are commonplace across many different services and are not specific to these procedures. We also have reason to

believe that the improved technology has led to greater efficiencies in these procedures which, under the resource-based nature of the RVU system, lends further support for the proposed work RVU of 11.63 for CPT code 57282 and 11.66 for CPT code 57283. Also, compelling evidence is not part of our statutory guidelines which require that the valuation of codes should be based on time and intensity. We do consider changes in technology, patient population, etc. insofar as they affect the time and intensity of the service under review. However, we do not specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation process stipulated by statute.

Comment: Several commenters stated that CMS is incorrect in proposing a work RVU of 11.66 for CPT code 57283 based on referencing codes 19350 and 47563. CPT code 19350, involves an incision made externally on the breast to dissect a small amount of tissue at the site where the nipple will be made. The surgical site is external to the body without proximate anatomical structures that would be affected by a subcutaneous incision. Also, CPT code 19350 can be performed under local anesthesia and is performed in the office setting 19 percent of the time. CPT code 47563 does not include the amount of dissection and tissue reattachment that CPT code 57283 does, and the radiographic work included in CPT code 47563 is not comparable to the intensity or risk of CPT code 57283.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate code comparison or an appropriate crosswalk.

Comment: Commenters appreciated that CMS proposed to accept the RUC-recommended direct PE inputs for CPT codes 57282 and 57283.

Response: We appreciated the commenters for their support.

After consideration of the public comments, we are finalizing the proposed work RVU of 11.63 for CPT code 57282 and the work RVU of 11.66 for CPT code 57283. We are also finalizing the RUC-recommended direct PE inputs for the codes in the Colpopexy family of codes (CPT codes 57282 and 57283) without refinement.

(20) Laparoscopic Colpopexy (CPT code 57425)

The CPT code 57425 (*Laparoscopy, surgical, colpopexy (suspension of vaginal apex)*) was identified by the RUC Relativity Assessment Workgroup as a service performed less than 50 percent of the time in the inpatient setting yet includes inpatient hospital E/M services within the global period and the 2018 Medicare utilization is over 5,000. This service was surveyed and reviewed for the January 2020 RUC meeting.

We disagreed with the RUC-recommended work RVU of 18.02 for CPT code 57425 and proposed to maintain the current RVU of 17.03 based on the total time ratio between the current time of 404 minutes and the recommended time established by the survey of 351 minutes. This was supported by the reference CPT codes we compared to CPT code 57425 with the same intraservice time; reference CPT code 26587 (*Reconstruction of polydactylous digit, soft tissue and bone*) which has a work RVU of 14.50, and reference CPT code 20696 (*Application of multiplane (pins or wires in more than 1 plane), unilateral, external fixation with stereotactic computer-assisted adjustment (e.g., spatial frame), including imaging; initial and subsequent alignment(s), assessment(s), and computation(s) of adjustment schedule(s)*) which has a work RVU of 17.56. Both CPT codes 26587 and 20696 have 180 minutes of intraservice time, which is equal to the 180 minutes of intraservice time in the RUC recommendation for CPT code 57425, and over 400 minutes of total time. The total time for CPT code 57425 decreased from 404 to 351 minutes and the RUC did not appear to take this into account. Therefore, we proposed to maintain the current work RVU of 17.03.

We proposed the RUC-recommended direct PE inputs for CPT code 57425 without refinement.

We received public comments on the Laparoscopic Colpopexy code family (CPT code 57425). The following is a summary of the comments we received and our responses.

Comment: The commenters disagreed that a decrease in total time for CPT code 57425 should result in a lower work RVU than the RUC recommendation since the intraservice time required to perform CPT code 57425 increased significantly. The commenters also stated that using a total time ratio approach in lieu of the RUC survey data for CPT code 57425 is erroneous.

Response: For CPT code 57425, we disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values recommended by the RUC and other commenters do not account for information provided by surveys that suggests the amount of time involved in furnishing the service has changed significantly. We reiterate that, consistent with the statute, we are required to value the work RVU based on the relative resources involved in furnishing the service, which include time and intensity. When our review of recommended values reveals that changes in the resource of time have been unaccounted for in a recommended RVU, then we believe it is appropriate to account for that change in establishing work RVUs since the statute explicitly identifies time as one of the two elements of the work RVUs. We recognize that it would not be appropriate to develop work RVUs solely based on time given that intensity is also an element of work, but in applying the time ratios, we are using derived intensity measures based on current work RVUs for individual procedures. Were we to disregard intensity altogether, the work RVUs for all services would be developed based solely on time values and that is definitively not the case, as indicated by the many services that share the same time values but have different work RVUs. Furthermore, we reiterate that we use time ratios to identify potentially appropriate work RVUs, and then use other methods (including estimates of work from CMS medical personnel and crosswalks to key reference or similar codes) to validate these RVUs. For more details on our methodology for developing work RVUs, we direct readers to the discussion CY 2017 PFS final rule (81 FR 80272 through 80277).

Comment: Commenters stated that CMS did not discuss the RUC's compelling evidence rationale in the proposed rule text for why CPT code 57425 is presently undervalued, and suggested CMS missed considering this rationale. The commenters further stated that the surgical techniques and technology for CPT code 57425 have changed drastically. Specifically, commenters stated that the technique has been refined and is now much more standardized than when CPT code 57425 was last surveyed in 2003. This decreased the complication rate and has changed the physician work. In addition, commenters stated that there is a change in technology due to functional MRI studies which have increased what is known about pelvic

organ prolapse and what is important for a successful repair. Some commenters stated that the dissection is difficult and requires more time, as shown in the RUC survey, for CPT code 57425.

Response: We agree with the commenters that due to a change in technology for CPT code 57425 we had reason to believe that practitioners are becoming more efficient at performing the procedure. While the incorporation of new technology can sometimes make services more complex and difficult to perform, it can also have the opposite effect by making services less reliant on manual skill and technique. We do not agree with the commenters that a change in the work practice and new technology would necessarily be grounds for increasing the work RVU to 18.02 as recommended by the RUC, as improvements in technology are commonplace across many different services and are not specific to this procedure. We also have reason to believe that the improved technology has led to greater efficiencies in the procedure which, under the resource-based nature of the RVU system, lends further support for maintaining the current work RVU value of 17.03 for CPT code 57425 as proposed. Also, compelling evidence is not part of our statutory guidelines which require that the valuation of codes should be based on time and intensity. We do consider changes in technology, patient population, etc., insofar as they affect the time and intensity of the service under review. However, we do not specifically address the RUC's compelling evidence criteria in our rulemaking since it is outside the purview of the code valuation process stipulated by statute.

Comment: Some commenters stated that CMS is incorrect in proposing the current work RVU of 17.03 for CPT code 57425 when referencing CPT codes 26587 and 20696 because both procedures are performed on an external part of the body. Commenters went on to describe how the difficulty performing CPT codes 26587 and 20696 is not as great as performing CPT code 57425. For CPT code 26587, the physician is removing an external amount of tissue that includes bone and could be considered a sixth toe or finger, and has little risk to other organs or permanent disability. Commenters stated that there are not any close major blood vessels or an entire nerve plexus that must be avoided with CPT code 26587, while CPT code 57425 involves the placement of a synthetic mesh which must be performed properly to avoid erosion into a viscus, causing permanent long-term harm and multiple follow up surgeries. In addition, commenters stated that CPT code 26587 is a low volume Medicare procedure and was last reviewed by the RUC in 2001. CPT code 20696 is fixating an external metal frame onto someone's leg, which involves less risk and more space and visualization to perform than CPT code 57425.

Response: We continue to believe that the nature of the PFS relative value system is such that all services are appropriately subject to comparisons to one another. Although codes that describe clinically similar services are sometimes stronger comparator codes, we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate code comparison or an appropriate crosswalk. We looked to CPT codes 26587 and 20696 as reference codes for comparison to CPT code 57425 based on their total time ratios. Few other supporting codes with similar intraservice time and total time were found. The current work RVU of 17.03 is closer to the higher end of the RVUs within this reference code bracket that uses 26587 on the low end, and 20696 on the high end.

Comment: Commenters supported the CMS proposal of the RUC-recommended direct PE inputs for CPT code 57425.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing maintaining the current work RVU of 17.03 as proposed for CPT code 57425. We are also finalizing the RUC-recommended direct PE inputs for the codes in the Laparoscopic Colpopexy family of codes (CPT code 57425) without refinement.

(21) Intravitreal Injection (CPT Code 67028)

CPT code 67028 (*Intravitreal injection of a pharmacologic agent*) was identified via the RUC's Relativity Assessment Workgroup as a code where the original valuation was based on a crosswalk code that had since been revalued. The RUC recommended that CPT code 67028 should be surveyed for the April 2019 RUC meeting. We proposed the RUC-recommended work RVU of 1.44 for CPT code 67028.

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Clean room/equipment by clinical staff'' (CA024) activity from the RUC-recommended 5 minutes to 3 minutes for CPT code 67028, because 3 minutes is the standard time for this clinical labor activity code, and we disagree that there would typically be a need for 2 additional minutes for cleaning, sterilizing, and re-packaging a reusable eyelid speculum in a sterile package to prepare for its next case. Additionally, 3 minutes is the standard time for cleaning the room *and* cleaning the equipment; although we agreed that these cleaning tasks would take place, we do not believe that the removal of the same day E/M visit would result in the need for 2 additional minutes of cleaning time. We noted that we are proposed to maintain the current time for this clinical labor activity, which was previously finalized in the CY 2011 PFS final rule at the standard value of 3 minutes (75 FR 73353). We also proposed to refine the equipment times to match the change in clinical labor time.

We received public comments on CPT code 67028. The following is a summary of the comments we received and our responses.

Comment: A commenter stated that they agreed with the CMS proposal of the RUC-recommended work RVU of 1.44. However, the commenter disagreed with the proposal to refine the clinical labor time for the ''Clean room/equipment by clinical staff'' (CA024) activity from the RUC-recommended 5 minutes to 3 minutes. The commenter stated that the 5 minutes listed for time to clean the room/equipment was not increased because of the absence of a same day E/M visit; rather, it was increased to appropriately reflect the current time it takes to clean/disinfect the room and equipment. The commenter stated that the eyelid speculum is soaked in an antiseptic solution for a fixed period of time, then scrubbed, repackaged, and sterilized in an autoclave, and that an infection from an unsterile piece of equipment for this intraocular procedure can directly lead to endophthalmitis which is permanently blinding. The commenter also stated that they disagreed with the CMS refinement of the equipment time for the vaccine refrigerator (ED043) equipment since the medication must be logged into an inventory tracking system and it is now typical for each physician to hire a private temperature monitoring service that requires a recurring fee.

Response: We disagree with the commenter regarding the refinements to the direct PE inputs for CPT code 67028. As we stated in the proposed rule, 3 minutes is the standard time for cleaning the room as well as cleaning the equipment, not one or the other. Although we appreciate the additional information stating that this cleaning time is not associated with an E/M visit, we do not agree that 2 minutes of additional clinical time would be

typical for this procedure, especially given that CPT code 67028 currently allocates the standard 3 minutes of clinical labor time for cleaning activities. For the vaccine refrigerator (ED043) equipment, the refinement to the equipment time was made to conform to the refinement in clinical labor time associated with cleaning the room. We also note that any fees associated with a monitoring service for the refrigerator's temperature would be an indirect cost akin to office rent and therefore would not be included in the direct PE inputs.

After consideration of the public comments, we are finalizing our proposed work RVU of 1.44 and our proposed direct PE inputs for CPT code 67028.

(22) Dilation of Eustachian Tube (CPT Codes 69705 and 69706)

In September 2019, the CPT Editorial Panel created two new codes, CPT code 69705 (*Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); unilateral*) and CPT code 69706 (*Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); bilateral*) to describe the dilation of the eustachian tube via surgical nasopharyngoscopy, unilateral and bilateral. We proposed the RUC-recommended work RVUs of 3.00 and 4.27 for CPT codes 69705 and 69706, respectively. For the direct PE inputs, we proposed the RUC-recommended values without refinement.

We received public comments on the Dilation of Eustachian Tube (CPT codes 69705 and 69706). The following is a summary of the comments we received and our responses.

Comment: Several commenters stated their support for CMS proposing the RUC-recommended values without refinement.

Response: We thank commenters for their feedback and support.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Dilation of Eustachian Tube family as proposed.

(23) X-Ray of Eye (CPT Code 70030)

CPT code 70030 (*Radiologic examination, eye, for detection of foreign body*) was identified through an updated screen of CMS/Other source codes with Medicare utilization over 20,000. We proposed the RUC-recommended work RVU of 0.18 for this service. We proposed the RUC-recommended direct PE inputs without refinement.

We received public comments on the X-Ray of Eye family (CPT code 70030). The following is a summary of the comments we received and our responses.

Comment: A commenter appreciated CMS' acceptance of the RUC recommendation for this code.

Response: We appreciate the support for our proposals.

After consideration of the public comments, we are finalizing the proposed work RVU of 0.18 as well as the proposed direct PE inputs for CPT code 70030.

(24) CT Head-Brain (CPT Codes 70450, 70460, and 70470)

In the CY 2019 PFS final rule (83 FR 59500 through 59503), a stakeholder nominated CPT code 70450 (*Computed tomography, head or brain; without contrast material*) as potentially misvalued, citing GAO and MedPAC reports that suggest that work RVUs are overstated for procedures such as these, and the specialty society surveyed family codes 70460 (*Computed tomography, head or brain; with contrast material(s)*) and 70470 (*Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections*). We proposed the RUC recommendation to maintain the current work RVUs of 0.85, 1.13, and 1.27 for CPT codes 70450, 70460, and 70470, respectively. For CPT code 70450, we note that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70486 (*Computed tomography, maxillofacial area; without contrast material*), which has similar physician time and the same work RVU, is appropriate. For CPT code 70460, we noted that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70487 (*Computed tomography, maxillofacial area; with contrast material(s)*), which has similar physician time and the same work RVU is appropriate. Similarly, for CPT code 70470, we noted that the surveyed times are nearly identical to the current times for these services, and we believe that the RUC's reference to CPT code 70488 (*Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections*), which has similar physician time and the same work RVU, is appropriate. We also noted that these codes are relatively consistently valued compared to other codes with similar time values and a global period of XXX. We proposed the RUC-recommended direct PE inputs without refinement.

We received public comments on the CT Head-Brain (CPT codes 70450, 70460, and 70470). The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to adopt the RUC-recommended work RVUs and PE inputs.

Response: We appreciate the support for our proposals from the commenters.

After consideration of the public comments, we are finalizing as proposed work RVUs of 0.85, 1.13, and 1.27 for CPT codes 70450, 70460, and 70470 respectively.

(25) Screening CT of Thorax (CPT Codes 71250, 71260, 71270, and 71271)

In October 2018, AMA staff identified the CMS/Other Source codes with 2017 Medicare utilization over 30,000. HCPCS code G0297 (*Low dose ct scan (ldct) for lung cancer screening*) was identified. In January 2019, the RUC recommended to refer to CPT Editorial Panel to establish a permanent code for this procedure. In May 2019, the CPT Editorial Panel revised three codes and added one code to distinguish diagnostic computed tomography, thorax from computed tomography, thorax, low dose for lung cancer screening.

For CPT code 71250 (*Computed tomography, thorax; without contrast material*), we did not propose the RUC recommendation to maintain the current work RVU of 1.16 as we believe this does not accurately reflect the reduction in physician work time, and because an analysis of all XXX-global period codes with similar time values indicates that this service is overvalued. Instead, we recommended proposing a work RVU of 1.08 based on the ratio of current to RUC-recommended intraservice time. As support for this value, we note that it falls slightly below CPT code 76391 (*Magnetic resonance (e.g., vibration) elastography*), which has a work RVU of 1.10 and also has higher physician time values.

Similarly, for CPT code 71260 (*Computed tomography, thorax; with contrast material(s)*), we did not propose the RUC recommendation to maintain the current work RVU of 1.24 as we believe this does not accurately reflect the reduction in physician time, and proposed a work RVU of 1.16 based the ratio of current to RUC-recommended intraservice time. Although we disagreed with the RUC-recommended work RVU, we concurred that the relative difference between CPT codes 71250 and 71260 is equivalent to the RUC-recommended interval of 0.08 RVUs. As stated previously, we noted

that we believe the use of an incremental difference between these CPT codes is a valid methodology for setting values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity. We noted that the proposed work RVU of 1.16 maintains the RUC-recommended interval of 0.08 additional RVUs above our proposed work RVU of 1.08 for CPT code 71250.

For CPT code 71270 (*Computed tomography, thorax; without contrast material, followed by contrast material(s) and further sections*), we did not propose the RUC recommendation to maintain the current work RVU of 1.38 as we believed this does not accurately reflect the reduction in physician time, and instead, we proposed a work RVU of 1.25 with a crosswalk to CPT code 93284 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system*) and we supported this value by noting that it is slightly higher than values suggested by the ratio of current to RUC-recommended intraservice time For CPT code 71271 (*Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)*), we did not propose the RUC-recommended work RVU of 1.16, but proposed a work RVU of 1.08 so that the value of this code is consistent with that of CPT code 71250 as current code G0297 is valued based on the value of CPT code 71250, and to maintain the relative relationship among these codes. In the CY 2016 PFS final rule (80 FR 70974) we finalized that CPT code G0297 should be identically valued to CPT code 71250.

We proposed the RUC-recommended direct PE inputs without refinement for CPT codes 71250, 71260, and 71270. For the direct PE inputs for CPT code 71271, we proposed 2 minutes for the clinical labor activity CA011: ''Provide education/obtain consent'' rather than the RUC-recommended 3 minutes to be consistent with other non-contrast screening codes, and we proposed 4 minutes for the clinical labor activity CA038 ''Coordinate post-procedure services'' rather than the RUC-recommended 6 minutes to be consistent with other screening services, and because we did not see any compelling evidence that this service has changed significantly since G0297 was implemented for CY 2015 to warrant the recommended 2 additional minutes.

We received public comments on the codes in the Screening CT of Thorax family. The following is a summary of the comments we received and our responses.

Comment: A commenter disagreed with the use of intraservice time ratios to account for changes in time, arguing that it negates CMS' longstanding position that we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs.

A commenter attributed the decreases in intra-service times for CPT codes 71250 and 71270 to survey variation. The commenter stated that reductions in pre and post-service time values do not necessarily justify a reduction in physician work value as intraservice work has a higher intensity than pre-service and post-service work. Additionally, the commenter stated that at these lower ends of time in the RBRVS, it is unreliable to draw conclusions based on single minute increments, which may simply be a result of rounding to whole integers.

Response: While we agree that the surveyed intraservice times are not substantially lower than they are currently, we disagree that the differences in total time values are negligible or that they should not be accounted for in work RVU. In addition, we note that we considered the RUC-recommended values based on the relationship between work RVU and time as well as through comparisons to other CPT codes of similar time values. We continue to believe that in light of this analysis, the RUC-recommended values are overestimations.

Comment: For CPT code 71250, a commenter disagreed with the use of a comparison to a magnetic resonance (MR) code with higher physician times, CPT code 76391 (*Magnetic resonance (e.g., vibration) elastography*). The commenter stated that this is a suboptimal comparison as CPT code 76391 involves work predominantly focused on a single organ (the liver) with, in general, a single pathology (fibrosis). In contrast, the commenter stated that CPT code 71250 requires evaluation of numerous structures in the thorax including the heart, lungs, mediastinum, pleura and pleural space, bones, etc. which can be affected by a multitude of pathologies. For CPT code 71260, the RUC objected to the CMS statement that the proposed work RVUs maintain the RUC-recommended relative difference between CPT codes 71250 and 71260, stating that time survey data and comparison codes, not ratios and intervals, were used in arriving at the value of 1.24 for CPT code 71260.

Response: We reiterate that a comparison to all XXX-global period codes with similar time values indicated that the RUC-recommended work RVU was overestimated for CPT code 71250. While we recognize that the RUC did not base its recommended valuation for CPT code 71260 on an incremental relationship, we continue to believe the use of an incremental difference between codes is a valid methodology for considering appropriate values, especially in valuing services within a family of revised codes where it is important to maintain appropriate intra-family relativity.

Comment: For CPT code 71270, a commenter disagreed with the use of a crosswalk to CPT code 93284 (*Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system*) because these codes describe completely different clinical work.

Response: We do consider clinical information associated with physician work intensity provided by the RUC and other stakeholders as part of our review process, although we remind readers that we do not agree that codes must share the same site of service, patient population, or utilization level to serve as an appropriate crosswalk.

Comment: For CPT code 71271, the RUC noted that HCPCS code G0297 is CMS/Other sourced. Therefore, how the times and values were established is unknown or flawed. The RUC also agreed that the physician work involved in the new code for low-dose screening exam is comparable to the diagnostic exam performed in CPT code 71250. While CMS finalized a policy that HCPCS code G0297 should be identically valued to CPT code 71250 in the CY 2016 PFS final rule (80 FR 70974–70975), the G-code is currently not valued the same. CPT code 71250 is currently valued higher than HCPCS code G0297 because CPT code 71250 was revalued in 2016; its work RVU increasing from 1.02 to 1.16, however HCPCS code G0297 was not revalued at that time and remains currently valued at 1.02. The RUC suggested CMS to accept a work RVU of 1.16 for CPT code 71271 and requests deletion of HCPCS code G0297. In the event this G-code is

not deleted, the RUC requests that HCPCS code G0297 be crosswalked to 71271 and the same value and inputs be assigned.

Response: Our proposed work RVU of 1.08 for HCPCS code 71271 is partly based on our assumption that this code has an identical work RVU to CPT code 71250. Our proposed values will restore parity between the two codes by increasing the work RVU for the former to match our proposed value for the latter.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Screening CT of Thorax family as proposed.

(26) X-Ray Bile Ducts (CPT Codes 74300, 74328, 74329, and 74330)

CPT codes 74300 (*Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation*) and 74328 (*Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*) were identified through a screen of CMS/Other Source codes with 2017 Medicare utilization over 30,000. CPT codes 74329 (*Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*) and 74330 (*Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*) were included as part of the same code family and the family was surveyed. The codes describe x-rays of the liver, pancreas, and bile ducts. They are performed in facilities and have no direct PE inputs.

We disagreed with the RUC-recommended work RVU of 0.32 for CPT code 74300. We proposed a work RVU of 0.27 based on a crosswalk to CPT code 74021 (*Radiologic examination, abdomen; 3 or more views*), one of the reference services from the RUC survey and that has an intraservice time of 4 minutes, nearly identical to the RUC's recommendation of 5 minutes of intraservice time for CPT code 74300. The proposal was supported by CPT code 93922 (*Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries*) with a work RVU of 0.25 and an intraservice time of 5 minutes and a total time of 10 minutes. These times are nearly identical to the RUC's recommended intraservice of 5 minutes and total time of 10 minutes for CPT code 74300.

We proposed the RUC-recommended work RVU of 0.47 for CPT code 74328 (*Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation*), with an intraservice time of 10 minutes and a total time of 20 minutes.

We disagreed with the RUC's recommended work RVU of 0.50 for CPT code 74329 (*Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation*). We proposed a crosswalk to CPT code 74328 at a work RVU of 0.47 because the intraservice and total times for both codes are identical and we noted that we believe the work involved in the biliary ductal and pancreatic ductal systems is similar.

We disagreed with the RUC's recommended work RVU of 0.70 for CPT code 74330 (*Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation*) and we proposed a work RVU of 0.56 based on the proposal of the RUC's recommendation for CPT code 74328 to create internal consistency within the code family, based on our time ratio methodology and further supported by a reference to CPT code 93228 (*External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional*) with nearly identical and total time values to CPT code 74330.

The RUC did not recommend and we did not propose any direct PE inputs for these codes.

We received public comments on the X-Ray Bile Ducts code family. The following is a summary of the comments we received and our responses.

Comment: A few commenters did not support the proposal of 0.27 work RVUs for CPT code 74300, stating that based on the RUC survey data, the overall intensity and complexity to perform CPT code 74300 is greater than that required to perform the key reference service of CPT code 74021. Commenters also stated that the crosswalk to CPT code 74021 was inappropriate due to the service time difference between the codes.

Response: Based on the survey results, we disagree that the overall intensity and complexity to perform CPT code 74300 is greater than that required to perform CPT code 74021. Based on the survey results, only the technical skill component of intensity suggested that CPT code 74300 may be more intense than CPT code 74021, with 67 percent of respondents stating that CPT code 74300 was more intense. Comparing CPT code 74300 to its key reference service CPT code 74321, 50 percent of survey respondents reported that CPT code 74300 had identical intensity, 50 percent of survey respondents reported physical effort as having identical or less intensity, and 67 percent of survey respondents reported psychological stress as having identical or less intensity. We also disagree that the crosswalk to CPT code 74021 was inappropriate because the RUC used CPT code 74021 as a key reference survey in its survey. Thus, we are finalizing 0.27 work RVUs for CPT code 73400 as proposed.

Comment: A few commenters supported the CMS proposal of 0.47 work RVUs for CPT code 74328.

Response: We appreciate commenters' support and are finalizing 0.47 work RVUs for CPT code 74328 as proposed.

Comment: A few commenters did not support the proposal of 0.47 work RVUs for CPT code 74329. These commenters asserted that the work associated with assessing the pancreatic ductal system in CPT code 74329 and is more intense and complex than CPT code 74328. They also stated that codes with identical times are not assigned the same RVU because both the AMA RUC and CMS recognize that procedures with equivalent times do not have equivalent intensities.

Response: While it may be true that codes that have identical times can have different intensities, because the survey did not use CPT code 74328 as a key reference service for the valuation of CPT code 74329, we do not believe the survey results provided sufficient evidence to support the assertion that CPT code 74329 is more intense. Thus, we are finalizing 0.47 work RVUs for CPT code 74329 as proposed.

Comment: A few commenters did not support the proposal of 0.56 work RVUs for CPT code 74330. These commenters were concerned that we did not apply our time ratio methodology correctly. The commenters also disagreed with the use of time ratio methodologies for work valuation for these services. Commenters stated that this use of time ratios is not a valid methodology for the valuation of physician services.

Response: To clarify, we used an intraservice time ratio and not a total time ratio. We disagree with the commenters and continue to believe that the use of time ratios is one of several appropriate methods for identifying potential work RVUs for PFS services.

We have responded to concerns about our methodology earlier in this section

of this final rule. For additional information regarding the use of use of time ratios in our methodology, we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274). Thus, we are finalizing 0.56 work RVUs for CPT code 74330 as proposed.

After consideration of the public comments, we are finalizing the work RVUs for the codes in the X-Ray Bile Ducts family as proposed. We did not propose and we are not finalizing any direct PE inputs for these codes.

(27) Venography (CPT Codes 75820 and 75822)

The review of CPT code 75820 (*Venography, extremity, unilateral, radiological supervision and interpretation*) was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 20,000 claims in a year. CPT code 75820 currently has a work RVU of 0.70 with 14 minutes of total time. This service involves the supervision and interpretation of a contrast injection and imaging of either the upper or lower extremity. For CPT code 75820, the RUC recommended 12 minutes preservice time, 20 minutes intraservice time, 10 minutes postservice time and 42 minutes of total time. The specialty societies' survey at the 25th percentile yielded a 1.05 work RVU, and it is the RUC's recommended work value. We proposed the RUC-recommended value for CPT code 75820.

CPT code 75822 (*Venography, extremity, bilateral, radiological supervision and interpretation*) is reviewed as part of the family of codes included with CPT code 75820. CPT code 75822 has a current 1.06 work RVU and 21 minutes of total time. The RUC recommended 15 minutes preservice time, 30 minutes intraservice time, 12 minutes postservice time and 57 minutes of total time, and the survey's 25th percentile work RVU of 1.48. The service is similar to CPT code 75820, except that this CPT code is bilateral, involving the supervision and interpretation of a contrast injection and imaging of both of either the upper or lower extremities. The RUC recommended 1.48 work RVU and 57 minutes of total time for CPT code 75822. We proposed these RUC-recommended values for CPT code 75822.

We received public comments on the Venography services CPT codes 75820 and 75822. The following is a summary of the comments we received and our responses.

Comment: The commenters appreciated CMS' proposal of the AMA RUC recommended RVU values.

Response: We appreciate the commenters' support for our proposal to adopt the RUC recommendations for CPT codes 75820 and 75822.

After consideration of the public comments, we are finalizing the RUC recommendations for CPT codes 75820 and 75822, as proposed.

(28) Introduction of Catheter or Stent (CPT Code 75984)

The RUC recommended reviewing CPT code 75984 (*Change of percutaneous tube or drainage catheter with contrast monitoring (e.g., genitourinary system, abscess) radiological supervision and interpretation*) after more utilization data was available, which resulted in this service being surveyed and reviewed for the April 2019 RUC meeting. We proposed the work RVU of 0.83 as recommended by the RUC. We proposed the RUC-recommended direct PE inputs for CPT code 75984 without refinement.

We received public comments on the Introduction of Catheter or Stent family (CPT code 75984). The following is a summary of the comments we received and our responses.

Comment: Commenters supported the CMS proposal of 0.83 for the work RVU as recommended by the RUC, as well as the proposal of the direct PE inputs without refinements.

Response: We appreciate the commenters' support for our proposal to adopt the RUC recommendations for CPT code 75984.

After consideration of the public comments, we are finalizing the RUC-recommended work RVU of 0.83 for CPT code 75984. We are also finalizing the RUC-recommended direct PE inputs for CPT code 75984 without refinement.

(29) Medical Physics Dose Evaluation (CPT Code 76145)

The CPT Editorial Panel created CPT code 76145 (*Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report*), which is a new PE-only code. Because of the high amount of clinical staff time and the fact that there are not analogous services, the PE Subcommittee requested that the specialty societies conduct a PE survey. In addition, they stated that the service is stand-alone, meaning that the medical physicist works independently from a physician and there are no elements of the PE that are informed by time from a physician work survey. Following the meeting, the specialty societies developed a PE survey which was reviewed and approved by the Research Subcommittee. We proposed the RUC-recommended direct PE inputs for CPT code 76145 without refinement.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposal to implement the RUC-recommended direct PE inputs for CPT code 76145 without refinement.

Response: We appreciate the support for our proposals from the commenters.

Comment: Commenters recommended that CMS remove the Deficit Reduction Act (DRA) cap designation for CPT code 76145, stating that this is not an imaging service but a patient-specific organ dose assessment and evaluation performed by a medical physicist that can be utilized across a broad spectrum of cardiology and interventional radiology services. These dose calculations are commonly associated with interventional procedures and not diagnostic imaging studies.

Response: We are persuaded by the commenters that this service does not describe an imaging service as defined for purposes of the ''DRA cap,'' also known as the ''OPPS cap,'' under section 1848(b)(4)(B) of the Act. We note it is more akin to physics consultation services similar to those described by CPT codes 77331 (*Special dosimetry (e.g., TLD, microdosimetry) (specify), only when prescribed by the treating physician*), 77336 (*Continuing medical physics consultation, including assessment of treatment parameters, quality assurance of dose delivery, and review of patient treatment documentation in support of the radiation oncologist, reported per week of therapy*), and 77370 (*Special medical radiation physics consultation*). Therefore, we are not including CPT code 76145 within the codes that are subject to the adjustment under section 1848(b)(4) will not be subject to the OPPS cap.

After consideration of the public comments, we are finalizing the direct PE inputs for CPT code 76145 as proposed and removing this code from the OPPS Cap List.

(30) Ophthalmic Ultrasound Anterior Segment (CPT Code 76513)

CPT code 76513 (*Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy*) was identified by the RUC due to volume growth, attributed to improved equipment. The CPT Editorial Panel has

since revised this code to clarify that it is either unilateral or bilateral (it was previously unilateral). It was then surveyed. The code describes a test for glaucoma and is performed on the same day as an office/outpatient evaluation and management (O/O E/M) visit. The CPT and RUC removed CPT code 76513 from its former code family, creating a family of 1 service.

In reviewing this code, we noted that the recommended total time is decreasing from 19 minutes to 15 minutes (21 percent) while the RUC-recommended work RVU is decreasing from 0.66 to 0.60 (9 percent). We did not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we did not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we noted we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 76513, we noted that we believe that it would be more accurate to propose a work RVU of 0.53 based on a crosswalk to CPT code 74230 (*Radiologic examination, swallowing function, with cineradiography/videoradiography, including scout neck radiograph(s) and delayed image(s), when performed, contrast (e.g., barium) study*) with identical intraservice and total times.

For the direct PE inputs, we proposed to make two refinements to the clinical labor times of CPT code 76513. We proposed a reduction of 1 minute for the clinical labor task CA009: ''Greet patient, provide gowning, ensure appropriate medical records are available'' because the EHR information should already be linked from the preceding O/O E/M visit and the entry of information would be redundant and paid under indirect PE. We also proposed a reduction of 1 minute for the clinical labor task CA011: ''Provide education/obtain consent'' to be consistent with the time for this clinical labor task for the services in CPT code 76513's former code family.

We received public comments on CPT code 76513. The following is a summary of the comments we received and our responses.

Comment: A few commenters disagreed with the CMS proposed work RVU of 0.53 and stated that CMS should finalize the RUC-recommended work RVU value of 0.60. Commenters stated that CPT code 76513 is more complex and intense than the proposed crosswalk of CPT code 74320 due to a wider number of potential diagnoses, and requires placing a probe with water bath on the patient's cornea, which is more uncomfortable than swallowing contrast, requiring extra skill and effort to obtain appropriate images.

Response: We appreciate the additional information from the commenters regarding the intensity of CPT codes 76513 and 74320. In light of this additional information, we agree with the commenters that the diagnostic ophthalmic ultrasound service described by 76513 may have a higher intensity than the radiologic examination service described by CPT code 74320. Therefore, we are finalizing the RUC-recommended work RVU of 0.60 for CPT code 76513.

Comment: A few commenters stated that the crosswalk or methodology used in the original valuation of CPT code 76513 is unknown and not resource-based, and therefore, it was invalid for CMS to compare the current time and work to the surveyed time and work.

Response: We appreciate the commenters' concerns regarding our interpretation of older work time sources and their use in the code valuation process for establishing work RVUs for these services. We agree that it is important to use the most recent data available regarding work times, and we acknowledge that when many years have passed between when time is measured, significant discrepancies can occur. However, we also believe that our operating assumption regarding the validity of the existing values as a point of comparison is critical to the integrity of the relative value system as currently constructed. We have responded to concerns about our methodology earlier in this section. For additional information regarding the use of old work time values that were established many years ago and have not since been reviewed; we refer readers to our discussion of the subject in the Methodology for Establishing Work RVUs section of this rule (section II.N.2. of this final rule), as well as a longer discussion in the CY 2017 PFS final rule (81 FR 80273 through 80274).

Comment: A few commenters disagreed with our reduction of 1 minute of clinical labor task CA009: ''Greet patient, provide gowning, ensure appropriate medical records are available'' and stated that our assumption that the EHR information should already be linked from the preceding O/O E/M visit was incorrect. Commenters stated that it is not typical for the EHR and the ultrasound equipment to be linked and that staff time is required to enter the data into the ultrasound equipment software and ensure that it matches the information in the main EHR and therefore it would be inappropriate to reduce the RUC-recommended staff time.

Response: While we appreciate the additional information that the EHR and the ultrasound equipment are not linked, we believe that the staff time required to enter the data into the equipment constitutes a data entry task and paid under indirect PE. Therefore, we are finalizing our proposed reduction of 1 minute of clinical staff time for CPT code 76513.

Comment: A few commenters also disagreed with our proposed reduction of 1 minute for the clinical labor task CA011: ''Provide education/obtain consent.'' Commenters stated that this test involves placement of a device directly onto the ocular surface, with a risk of corneal abrasion and associated loss of vision. Thus, a clear and detailed explanation of what to expect was necessary to reduce patient anxiety and increase the patient's ability to cooperate with the exam. Thus, patient consent would require the RUC-recommended 3 minutes.

Response: We appreciate the additional information from the commenters regarding the steps that are involved in providing education and obtaining consent and we agree with the commenters that the additional minute of time would be required. Thus, we are finalizing the RUC-recommended 3 minutes of clinical staff time.

After consideration of the public comments, we are not finalizing our proposed work RVU of 0.53 for CPT code 76513 and are instead finalizing the RUC-recommended work RVU of 0.60. We are finalizing the direct PE inputs as proposed, with the exception of the proposed reduction of 1 minute for the clinical labor task CA011 as detailed above.

(31) Dual-Energy X-Ray Absorptiometry (CPT Code 77080)

We did not make any proposals regarding CPT code 77080 (*Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)*) in the proposed rule. Following the publication of the CY 2021 PFS proposed rule, a stakeholder contacted CMS and stated that Medicare payment for the CPT code 77080 has declined in the nonfacility setting from $140 in 2006 to approximately $40 in 2020. The stakeholder stated that due to policies proposed in the CY 2021 PFS proposed rule, payment for DXA would be subject to an eight percent decrease bringing the payment rate to $36.78. The stakeholder

suggested CMS to address DXA payment in the CY 2021 PFS final rule.

In response to the stakeholder, we note that the payment decreases for CPT code 77080 were produced by two factors: The adoption of the current PE methodology during CY 2007–2010 and the code's last RUC review in CY 2014. Payment for CPT code 77080 has been stable at approximately $40 for the last 6 years. We also note that our ratesetting methodology proposed a modest increase in total RVUs for CY 2021 for CPT code 77080. However, the proposed decrease of 10.6 percent to the CF resulted in the proposed payment for CPT code 77080 decreasing by approximately eight percent. This decrease would result from implementation of budget neutrality adjustment to the PFS conversion factor, and would not be caused by any policy changes associated with CPT code 77080. We remind stakeholders that, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs under the PFS cause expenditures for the year to change by more than $20 million, we are statutorily obligated to make budget neutrality adjustments to ensure that expenditures do not increase or decrease by more than $20 million. For additional information, we direct readers to the Regulatory Impact Analysis (section VIII.) of this rule. We may consider future rulemaking regarding CPT code 77080 under the misvalued code initiative if there is continued stakeholder concern regarding the valuation of this service.

(32) Radiation Treatment Delivery (CPT Code 77401)

CPT code 77401 (*Radiation treatment delivery, superficial and/or ortho voltage, per day*) was identified by the RUC Relativity Assessment Workgroup through a screen of high-volume growth, for services with 2017 Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2012 through 2017. In January 2019, the RUC recommended to refer to this service to the CPT Editorial Panel to better define the set of services associated with delivery of superficial radiation therapy (SRT).

We proposed the following direct PE refinements: A reduction of 2 minutes for the clinical labor task CA024: ''Clean room/equipment by clinical staff,'' to the standard 3 minutes, and we did not propose to include the new equipment item ER119 ''Lead Room,'' as we noted that we did not have enough information on what this equipment item contains, and we are requesting more information to allow us to determine if it is more accurately priced as direct or indirect PE. CPT code 77401 is a PE only code and we proposed to maintain the current work RVU of 0.00.

We received public comments on the Radiation Treatment Delivery (CPT code 77401). The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that while they still believe more should be done with regard to the work RVUs for 77401 in order to make this treatment option more fair and equitable, the commenters greatly appreciate CMS' willingness to increase the PE RVUs for SRT. The commenters stated that this is a much needed increase for the modality as a whole and should result in an increase in availability for patients that truly need access to this technology for non-melanoma skin cancer and keloids.

Response: We appreciate the support for our proposals from the commenters.

Comment: Commenters provided information on the recommended new equipment item ER 119 (''Lead Room''), noting that all states require a lead shielded room for radiation therapy. Some commenters said that physicians can also utilize this room for other services when not using the SRT. Some commenters stressed that although the lead lined room may be used for other services when there is no patient receiving superficial radiation therapy (SRT), there should not be payment for the lead room when SRT is not being performed.

Response: We continue to believe that, given the fact that the lead-shielded room may be used for other types of services as indicated by commenters, this item is not allocable specifically to CPT code 77401, but is rather a general practice cost akin to office rent expenses. Therefore, we consider the lead-shielded room to be indirect PE, and we are finalizing the direct PE inputs as proposed, without including the lead lined room.

Comment: Commenters disagreed with the proposed reduction of 2 minutes for the clinical labor task CA024: ''Clean room/equipment by clinical staff'', to the standard 3 minutes. Commenters stated that the 2 minutes were added by the RUC because the room and the equipment must be cleaned after each use and this has increased at least 5 fold under COVID. Commenters stated that the standard 3 minutes is for the room only and is insufficient to do both and that CMS should restore the 2 minutes that were removed.

Response: The commenters stated that 5 minutes are necessary to clean both the room and the equipment; however, the standard time of 3 minutes already assumes that both the room and equipment will be cleaned. Therefore, we are finalizing this PE refinement as proposed.

After consideration of the public comments, we are finalizing the direct PE inputs for this service as proposed.

(33) Proton Beam Treatment Delivery (CPT Codes 77520, 77522, 77523, and 77525)

In April 2018, the RUC's Relativity Assessment Workgroup (RAW) identified CPT code 77522 (*Proton treatment delivery; simple, with compensation*) and CPT code 77523 (*Proton treatment delivery; intermediate*) as contractor-priced Category I CPT codes with 2017 estimated Medicare utilization over 10,000 services. Although the RAW agreed with the specialty society that this family of codes should remain contractor priced, the RUC determined that these services should be surveyed for PE. CPT codes 77520 (*Proton treatment delivery; simple, without compensation*) and 77525 (*Proton treatment delivery; complex*) were added to the family and the group was surveyed for PE for the April 2019 RUC meeting.

We noted in the proposed rule that we encountered significant difficulties in reviewing the recommended direct PE inputs for the codes in the Proton Beam Treatment Delivery family. These difficulties were largely associated with determining a price for the two new equipment items in the code family, the Proton Treatment Vault (ER115) and the Proton Treatment Delivery System (ER116). These equipment items had extraordinarily high prices of $19,001,914 and $30,400,000 respectively on the invoices submitted with the code family. By way of comparison, the highest equipment price currently existing in our database for CY 2021 is the ''SRS system, Linac'' (ER082) equipment item at $4,233,825. We noted concerns that establishing equipment pricing for the proton treatment vault and delivery system at a rate that is so much higher than anything else in our equipment database could distort relativity.

We also noted concerns about the information provided on the submitted invoices used for the pricing of these two new equipment items. The invoices for both the Proton Treatment Vault and the Proton Treatment Delivery System contained building construction costs such as asphalt paving, masonry and carpentry expenses, drywall packaging, and the installation of electrical

systems. We noted that we understood that these proton treatment equipment items are extremely capital-intensive and require the construction of custom-built offices to house the equipment. However, the expenses associated with constructing new office facilities fall outside of our direct PE methodology, and would be more accurately classified as a form of building maintenance or office rent under indirect PE. We did not agree that construction costs should be included as a form of direct PE because they are not individually allocable to a particular patient for a particular service. Although we agreed that the proton beam treatment practitioners do need to bear the costs associated with the storage of this equipment, we noted that this is a form of indirect PE under our methodology. Therefore, we noted that we did not believe that it would serve the interests of relativity to include these building construction costs for the proton treatment equipment as a type of direct PE expense.

As a result, we proposed to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525 instead of proposing active pricing for these services. We noted that we believe that maintaining contractor pricing will allow the limited providers of these very expensive services to adapt more quickly to shifts in the market-based costs associated with the proton treatment equipment. The RUC similarly expressed concern in its recommendations about the extremely high cost of this equipment, agreed that these services were extremely hard to value, and noted the difficulties that had taken place in surveying the family of codes. The recommendations from the RUC also noted that proton treatment is a rapidly changing technology and the change in the treatment equipment often requires extensive modification to the vault. We also noted that we believe that these frequent changes can be more accurately captured through contractor pricing as opposed to the need to update the pricing of the proton treatment equipment on an annual basis.

As discussed in the proposed rule, if we were to propose active pricing for the codes in this family, we believe that we would need to remove the building construction costs from the Proton Treatment Vault and the Proton Treatment Delivery System as forms of indirect PE, which would substantially lower their overall equipment prices. We would also refine the equipment times to the standard formula for highly technical equipment, which would result in 3 minutes less time for each equipment item (such as 14 minutes for all three equipment items in CPT code 77522).

We received public comments on the codes in the Proton Beam Treatment Delivery family. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525 instead of proposing active pricing for these services. Commenters stated that they applauded CMS for carefully considering the unintended consequences of pricing high equipment cost items using the current CMS methodology and agreed that contractor pricing will allow proton therapy practitioners to adapt quickly to shifts in the market-based costs associated with the proton treatment equipment. Commenters stated that until there is a way to accurately reflect the price of this advanced technology, they agreed with the proposal and requested that CMS maintain contractor pricing for the proton treatment delivery codes.

Response: We appreciate the support for our proposals from the commenters.

Comment: One commenter stated that although they currently supported the continuation of contractor pricing, the commenter also could envision proton beam treatment pricing at some percentage of OPPS rates (*e.g.,* 95 percent of OPPS payment amount) as CMS looks to potentially value PE RVUs using OPPS rates. The commenter stated that while this rate might not adequately cover the PE component in some larger facilities, it would allow continued support for other facilities showing significant positive patient outcomes.

Response: We appreciate the feedback from the commenter regarding the potential use of OPPS payment rates for PFS pricing.

Comment: One commenter disagreed with the CMS proposal to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525 and recommended that CMS finalize the RUC recommendations. The commenter stated that although it is not the purview of the RUC to make recommendations about pricing and useful life of equipment, CMS should accept the direct PE inputs for CPT codes 77520, 77522, 77523, and 77525 as submitted by the RUC.

Response: We disagree with the commenter and continue to believe that the unique nature of the equipment costs associated with these services poses problems for our PE methodology. We believe that maintaining contractor pricing will incorporate these costs into the payment rate while also allowing the limited practitioners of these very expensive services to adapt more quickly to shifts in the market-based costs associated with the proton treatment equipment.

After consideration of the comments, we are finalizing our proposal to maintain contractor pricing for CPT codes 77520, 77522, 77523, and 77525.

(34) Immunization Administration (CPT Codes 90460, 90461, 90471, 90472, 90473, and 90474 and HCPCS Codes G0008, G0009, and G0010)

Especially in the context of the current PHE for COVID–19, it is evident that consistent beneficiary access to vaccinations is vital to public health. Many stakeholders have raised concerns regarding the reductions in payment rates for vaccine administration services over the past several years. The codes that describe these services have generally been valued based on a direct crosswalk to CPT code 96372 (*Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular*). Because we proposed and finalized reductions in valuation for that code for CY 2018 and because the reductions in overall valuation have been subject to the multi-year phase-in of significant reductions in RVUs, the payment rate for the vaccine administration codes has been concurrently reduced.

In the CY 2020 PFS final rule, we acknowledged that it is in the public interest to ensure appropriate resource costs are reflected in the valuation of the immunization administration services that are used to deliver vaccines, and noted that we planned to review the valuations for these services in future rulemaking. For CY 2020, we maintained the CY 2019 national payment amount for immunization administration services described by HCPCS codes G0008 (*Administration of influenza virus vaccine*), G0009 (*Administration of pneumococcal vaccine*), and G0010 (*Administration of hepatitis b vaccine*) in the interim.

The RUC has recently resubmitted recommendations from 2009 regarding the appropriate valuation for the broader range of vaccine administration services, including CPT codes 90460 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered),* 90471 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular*

injections); 1 vaccine (single or combination vaccine/toxoid)), and 90473 (*Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)*). In its recommendation, the RUC noted that the current RVUs assigned are directly crosswalked from CPT code 96372 (like the vaccine administration G-codes had been) and the resulting payment rates are substantially lower than current Centers for Disease Control and Prevention (CDC) regional maximum charges. The RUC also pointed out that appropriate payment for immunization administration that reflects resource cost is critical in maintaining high immunization rates in the United States, as well as having the capacity to respond quickly to vaccinate against preventable disease outbreaks.

We agreed with the RUC's assertions regarding the importance of appropriate resource-based valuations for vaccine administration services. We also recognized that the importance of these services is increased in the context of the current PHE for COVID–19, especially should there be a vaccine for this particular disease.

We reviewed and considered the 2009 RUC-recommended direct PE inputs for CPT codes 90460–90474 (as well as the related G-codes) in place of the existing policy, based on a crosswalk to CPT code 96372. However, the RUC-recommended direct PE inputs from 2009 would result in significant decreases in valuation for these 6 CPT codes, even compared to the current crosswalk. At the time of the proposed rule, we did not believe that either the existing crosswalk or the RUC recommendations from over a decade ago reflect the relative resource costs associated with these services. Without updated information to use in developing rates specific to these codes based on direct PE inputs, and in consideration of the importance of these services for Medicare beneficiaries, as well as the public health concerns raised by commenters, we believed that it would be most appropriate to value these services using a crosswalk methodology that better reflects the relative resources involved in furnishing all of these services.

Therefore, we proposed to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000 (*Introduction of needle or intracatheter, vein*). CPT code 36000 is a service with a nearly identical work RVU (0.18 as compared to 0.17 for CPT codes 90460, 90471, and 90473) and a similar clinical vignette. We noted that we believe that the additional clinical labor, supply, and equipment resources associated with the furnishing of CPT code 36000 more accurately capture the costs associated with these immunization codes. We also noted that this crosswalk would result in payment rates for vaccine administration services at approximately the same CY 2017 rates that were paid prior to the revaluation of CPT code 96372, which had previously served as the basis of the crosswalk. We noted that we believe that the proposed crosswalk is the most accurate valuation of these services and would also serve to ensure the appropriate relative resources involved in furnishing all of these services is reflected in the payment for these critical immunization and vaccination services in the context of the health needs of Medicare beneficiaries.

Regarding the add-on codes associated with these services, CPT codes 90461 (*Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered*), 90472 (*Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)*), and 90474 (*Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)*), we noted that the previous valuation methodology set their RVUs at approximately half of the valuation for the associated base codes, described above. Absent additional information, we proposed to maintain that approach by valuing the three add-on codes at half of the RVUs of the aforementioned crosswalk to CPT code 36000.

Finally, we proposed this valuation to apply to all of these existing vaccine administration codes, using the valuation of CPT code 90471 for base codes and CPT code 90472 for add-on codes. We also noted that should a vaccine for COVID–19 or other infectious disease become available during CY 2021, we would anticipate applying the same approach to valuing the administration of such vaccines, regardless of whether separate coding for such services would need to be introduced.

We received public comments on the codes in the Immunization Administration family. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000. Commenters stated that the current vaccine administration rates do not adequately cover the costs of purchasing, storing, monitoring, and administering vaccines and that appropriate valuation and reimbursement for these services is critical to ensuring widespread access to vaccines. Commenters agreed that the current crosswalk does not recognize the resources needed to provide the immunization procedure and that the proposed crosswalk to CPT code 36000 more accurately captures the direct clinical labor and resources needed to perform immunizations.

Response: We appreciate the support for our proposals from the commenters.

Comment: Many commenters supported the proposal to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000 while also disagreeing with the proposal to value the three add-on codes (CPT codes 90461, 90472, and 90474) at half of the RVUs of the aforementioned crosswalk to CPT code 36000. Commenters stated that the value of the work RVU for the add-on Immunization Administration codes is not half of the base codes but rather 88 percent of the value of the base codes. Commenters requested that CMS apply the same magnitude relationship between the base and add-on codes as in the previous valuation.

Response: We appreciate the feedback from the commenters regarding the relationship between the base codes and add-on codes in this family. After reviewing the issue and looking at the historic relationship in payment rates for the base codes and add-on codes, we agree with the commenters that the add-on codes have typically been valued at 88 percent of the RVU of the base codes, not half of the value. Therefore, we are finalizing the value of the three add-on codes at 88 percent of the RVUs assigned to the immunization administration codes.

Comment: Several commenters stated that they supported the proposals for this code family; however, they noted that there has been some confusion about the actual payment amount because RVUs for the CMS-issued immunization administration HCPCS ''G'' codes are not listed in the files sent to the contractors nor made available to the public. The commenters suggested CMS to include the crosswalked values for the immunization codes in the RVU files to ensure that the crosswalk is accurately implemented, and that stakeholders can identify the rate

Medicare will pay for vaccine administration.

Response: HCPCS codes G0008, G0009, and G0010 are used to bill Medicare for administration of the preventive vaccines described under section 1861(s)(10) of the Act. They are not technically valued under the PFS, as they do not fit within the statutory definition of physicians' services in section 1848(j)(3) of the Act. CMS established HCPCS codes G0008, G0009, and G0010 to describe the administration of these preventive vaccines. As a result, no RVUs or payment amounts are shown for these codes in the PFS tables, and payment for them is not made under the PFS. While it is true that we have established payment rates for these codes using a crosswalk to the values of codes listed on the PFS, these three HCPCS codes do not have PFS rates themselves.

Comment: Several commenters requested that in the future CMS should ensure a long-term sustainable valuation for vaccine administration by severing any linkage to other non-related CPT codes. The commenters recommend CMS consider determining the value of vaccine administration codes based on actual, updated physician time and PE inputs for vaccine administration.

Response: We agree with the commenters that it would be helpful to be able to value the vaccine administration codes using direct PE inputs instead of relying on crosswalks to other services; however, as we mentioned in the proposed rule, we reviewed and considered the 2009 RUC-recommended direct PE inputs and found that they would result in significant decreases in valuation for the six vaccine administration CPT codes, even compared to the current crosswalk. We would welcome the results of an updated formal review of these services as well as any additional information that may be helpful for improved valuation.

Comment: Several commenters supported the proposal and further suggested CMS to use its available authority to make this proposed change in vaccine administration valuation effective prior to January 1, 2021. Commenters stated that timely and appropriate payment for immunization administration that reflects resource cost is critical in maintaining high immunization rates in the United States as well as having the capacity to respond quickly to vaccinate against preventable disease outbreaks.

Response: While we share the concerns of the commenters regarding the importance of appropriate payment for vaccine administration, this final rule takes effect beginning for CY 2021. We did not propose to modify payment policies for these services for any earlier timeframe and we continue to believe that the payment policies that we finalized last year were appropriate for these services.

Comment: One commenter stated that Medicare pays a travel allowance to cover the transportation and personnel expenses for specimen collection from an individual or a patient in an inpatient facility other than a hospital. The commenter recommended that CMS establish a travel fee for providers/practitioners of current adult vaccines and for COVID–19 vaccinations to support access to immunizations, following the same approach and with the same value as established for specimen collection.

Response: Travel and transportation fees are considered to be a form of indirect PE under our methodology and would not be included as a direct cost. Therefore, we do not believe it would be appropriate to establish a separate payment for these costs under the PFS or otherwise.

Comment: One commenter disagreed with the rationale that CMS provided to crosswalk the PE RVUs for this set of codes to equal those for CPT code 36000. The commenter stated that CPT code 36000 is a bundled service that is not recognized for payment by CMS, nor has it ever been reviewed by the RUC; and this code includes a multispecialty visit pack that would be a duplication of resources for the vaccination codes, and that also includes an angiocatheter, which would never be used for vaccine administration. The commenter stated that arbitrarily assigning a specific PE RVU to this set of vaccination codes was another example of CMS's failure to consistently apply the same standards to all codes in the PFS, and as such, takes payment for resources away from one group of health care providers and assigns it to another group of health care providers.

Response: We note that our proposal to crosswalk valuation for the vaccine administration services was based on methodological approaches that have long been used for valuation under the PFS and reflect our best estimate of resource cost for these services at the time of the proposal. As we mentioned in the proposed rule, we reviewed and considered the 2009 RUC-recommended direct PE inputs and found that they would result in significant decreases in valuation for the six vaccine administration CPT codes, even compared to the current crosswalk. We would welcome the results of an updated formal review of these services as well as any additional information that may be helpful for improved valuation.

After considering the comments, we are not finalizing our proposal to crosswalk the valuation of CPT codes 90460, 90471, and 90473 and HCPCS codes G0008, G0009, and G0010 to CPT code 36000. We are instead finalizing a policy to maintain the CY 2019 payment for all nine of the services in this family, including the add-on codes. We note that maintaining the CY 2019 rates for these services will also maintain the historical relationship between the base administration codes and the add-on CPT codes 90461, 90472, and 90474, instead of our proposal to value the add-on codes at 50 percent of the base codes. As previously discussed, in our proposal, we approximated a cost for these services, but acknowledge the concerns that were raised in the comments we received and will continue to seek additional information that specifically reflects the resource costs and inputs that should be considered to establish payment for these services on a long-term basis. Again, we would welcome the results of an updated formal review of these services as well as any additional information that may be helpful for valuation in the immediate future.

(35) Liver Elastography (CPT Code 91200)

CPT code 91200 (*Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report*) was targeted for review through the RUC's new technology/new services screen. The RUC reviewed 3 years of available Medicare claims data (2016, 2017 and 2018) and surveyed the code for the January 2020 meeting.

We proposed the RUC-recommended work RVU of 0.21. We also proposed the RUC-recommended direct PE inputs for CPT code 91200 without refinement.

We received public comments on CPT code 91200. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal of the RUC-recommended work RVU and direct PE inputs for CPT code 91200.

Response: We appreciate the support for our proposals from the commenters.

Comment: Several commenters discussed the clinical benefits of liver elastography treatments using Fibroscan equipment. Commenters stated that this service expedites patient diagnosis and keeps care centered in the office while allowing for non-invasive screenings of this population to identify those

patients with advanced fibrosis and cirrhosis who are at high risk for complications and costly care, allowing for earlier successful outpatient intervention. Commenters recommended that Fibroscan reimbursement should be increased, not decreased, which will allow expanded utilization and access for more GI physicians providing more widespread use of this effective and non-invasive practice based technology.

Response: We appreciate the additional information provided by commenters regarding the clinical benefits of the technology. However, the PFS is a resource-based payment system and we agree with the RUC that the resources associated with furnishing this service have decreased over time as the technology has become more widespread.

Comment: Several commenters disagreed with the proposed price for the Fibroscan with printer (ER101) equipment. Commenters stated that the proposed price of $102,495 is not supported by customer invoices or StrategyGen's market research and that there is no available data that supports a 31 percent reduction in equipment pricing. The commenters recommended pricing the ER101 equipment at $136,449 based on the submission of seven new invoices. The commenters stated that the average cost on the invoices was $180,000, which included hardware costs and service contracts, and their recommended pricing of $136,449 included the cost for CAP, which is an integral FibroScan component and not an optional addition. This price also included training and an S+ probe.

Response: We appreciate the additional information provided by the commenters, especially the submission of invoices for use in pricing the Fibroscan equipment. Based on this additional information, we agree with the commenters that the CAP is an integral part of the Fibroscan equipment and should be included in the price of the equipment. However, training expenses are an indirect cost under our PE methodology and therefore are not included in the price of the equipment. We also noted that the S+ probe was only included on 2 of the 7 submitted invoices and as a result we do not believe that this is typically part of the cost of the Fibroscan equipment. (By contrast, the CAP option was present in all cases.) Therefore, we are finalizing an update in the price of the Fibroscan (ER101) to $125,096.21 based on an average of six invoices, as we were unable to use one invoice since it did not have individually itemized costs.

Comment: Several commenters stated that Medicare and commercial payor utilization data for CPT code 91200 demonstrate that the usage of FibroScan in the physician office setting is well below 50 percent. Commenters stated that at a 50 percent usage rate, each FibroScan would generate 6,250 exams per year, or 24 per day, resulting in 3,656,250 total national exams per year but the Medicare database identifies 39,556 actual in-office claims in 2018 and 51,000 in 2019, resulting in less than 1 scan per day. Commenters stated that CMS can assign an equipment utilization rate of lower than 50 percent and the change is warranted by actual claims data. Commenters requested that CMS establish an equipment utilization rate of 10 percent for CPT code 91200.

Response: We disagree with the commenters that an equipment utilization rate of 10 percent would be typical for the Fibroscan. We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act. It would distort relativity to assign a utilization rate of 10 percent for the Fibroscan equipment which would have the same effect as a fivefold increase in the price of the equipment. We continue to agree with the RUC's recommended direct PE inputs for CPT code 91200.

After considering the comments, we are finalizing the RUC-recommended work RVU of 0.21 and the RUC-recommended direct PE inputs for CPT code 91200. We are also finalizing an update in the price of the Fibroscan (ER101) equipment to $125,096.21.

(36) Remote Retinal Imaging (CPT Codes 92227, 92228, and 92229)

The AMA CPT Editorial Panel revised CPT code 92227 (*Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral*) and CPT code 92228 (*Imaging of retina for detection or monitoring of disease; with remote physician or qualified health professional review and report, unilateral or bilateral*) that are reported for the treatment of diabetic retinopathy. Two practice sites are involved in these services: The acquiring site (for example, a primary care practice) and the reading site (for example, the ophthalmology practice). Both codes can be used to report diagnostic and monitoring services and the distinction is in whom provides the service: Physician (CPT code 92228) or clinical staff only (CPT code 92227). Thus, only CPT code 92228 includes work, accounting for the physician at the reading site. For both CPT codes 92227 and 92228, direct PE pays for the clinical staff at both sites.

The AMA CPT Editorial Panel also created CPT code 92229 (*Imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral*) for point-of-care automated analysis that uses innovative artificial intelligence technology to perform the interpretation of the eye exam, without requiring that an ophthalmologist interpret the results. CPT code 92229 can be used at a primary care practice site and the artificial intelligence technology interprets the test instead of a remotely located ophthalmologist. Because no physician is involved, this service is PE only. We considered CPT code 92229 to be a diagnostic service under the PFS and are created separate payment for it.

For CPT code 92228, we proposed the RUC's recommended work RVU of 0.32. CPT codes 92227 and 92229 are PE only codes, and proposed a work RVU of 0.00 for both codes.

For both CPT codes 92227 and 92228, we proposed the AMA RUC's recommended direct PE inputs. We proposed two refinements to the direct PE inputs for CPT code 92229. We proposed a reduction of 1 minute for the clinical labor task CA009, ''Greet patient, provide gowning, ensure appropriate medical records are available,'' to be consistent with the amount of clinical labor for this task in CPT codes 92228 and 92227. We did not propose the RUC's recommendation of a $25 ''per click'' analysis fee for remote imaging because we considered this a service fee that constitutes a form of indirect PE and that this cost is appropriately captured via the indirect PE methodology as opposed to being included as a separate direct PE input. We did not believe that the analysis fee would be allocated to the use of an individual patient for an individual service, and can be better understood as an indirect cost similar to other administrative expenses.

We received public comments on the Remote Retinal Imaging family. The following is a summary of the comments we received and our responses.

Comment: For CPT code 92228, a few commenters supported our proposals for 0.32 work RVUs with no refinements to the direct PE inputs.

Response: We appreciate the commenters' support and are finalizing 0.32 work RVUs and no refinements to the direct PE inputs as proposed.

Comment: For CPT code 92227, a few commenters supported our proposals for 0.00 work RVUs with no refinements to the direct PE inputs.

Response: We appreciate the commenters' support and are finalizing 0.00 work RVUs with no refinements to the direct PE inputs as proposed.

Comment: We received no comments on our proposal for 0.00 work RVU for CPT code 92229.

Response: We are finalizing 0.00 work RVUs for CPT code 92229 as proposed.

Comment: Several commenters disagreed with our proposals for the direct PE inputs for CPT code 92229. A few commenters disagreed with our reduction of 1 minute of clinical labor task CA009: ''Greet patient, provide gowning, ensure appropriate medical records are available.'' Commenters stated that it is not typical for the EHR and the imaging and analyzing software to be linked and that staff time is required to enter the data into the imaging and analyzing software and ensure that it matches the information in the main EHR and therefore it would be inappropriate to reduce the RUC-recommended staff time.

Response: While we appreciate the additional information that the EHR and the imaging and analyzing software are not linked, we believe that the staff time required to enter the data into the imaging and analyzing constitutes a data entry task and is paid under indirect PE. Therefore, we are finalizing our proposed reduction of 1 minute of clinical staff time for CPT code 92229.

Comment: Several commenters also disagreed with the elimination of the analysis fee for remote imaging. They asserted that the analysis fee is a direct cost because it is directly attributable to a specific patient and incurred for each patient. The commenters also stated that because the analysis is conducted by artificial intelligence (AI) software, there would be no service if the software was not used on a per patient basis.

Response: As the PE data have aged and AI applications are emerging, we recognize that issues involving the use of AI are complex. While we agree that the costs for AI applications should be accounted for in payment, AI applications are not well accounted for in our PE methodology. In recent years, we have considered other services that use algorithms or artificial intelligence components to render key portions of a service. For example, in the CY 2018 OPPS final rule (82 FR 59284), we discussed the fractional flow reserve computed tomography (FFRCT) service. We noted that that the service, which we considered to be separate and distinct from the original coronary computed tomography angiography service is not an image processing service but rather, the diagnostic output from the FFRCT reports functional flow values that can only be obtained using FFRCT. We found FFRCT to be similar to other technologies that use algorithms, artificial intelligence, or other new forms of analysis to determine a course of treatment, where the analysis portion of the service cannot adequately be reflected under the PFS payment methodology. Accordingly, we established contractor pricing for the service and have continued to gather information from stakeholders on payment that appropriately reflects resource cost for this service under the PFS payment methodology for the codes below. Our recent reviews of the overall cost for the service and specifically for the analysis component of the service related to the analysis services listed below have shown the costs to be similar, to the costs reflected in payment under the CY 2021 OPPS final rule for CPT code 0503T (analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model).

We look forward to continuing to seek out new data sources and ongoing conversations with stakeholders to help in updating the PE methodology and the underlying data to better reflect such services. In the meantime, we are finalizing payment based on contractor pricing for CPT code 92229.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 92227 and 92228 as proposed and are finalizing contractor pricing for CPT code 92229 as detailed above.

(37) Auditory Evoked Potentials (CPT Codes 92584, 92650, 92651, 92652, and 92653)

CPT codes 92585 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive*) and 92586 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited*) were identified through a RAW requested screen of CMS/Other Source codes with 2017 Medicare utilization over 30,000. Since these codes were last valued, audiologists, the primary reporter of these services, can now report Medicare services independently. As a result, the audiologist work for these services is moving from PE to work.

To better describe tests of auditory function, the CPT created CPT code 92584 (*Electrocochleography*) and replaced CPT codes 92585 and 92586 with four new services. We proposed the RUC-recommended work RVUs of 1.00 for CPT code 92584, 1.00 for CPT code 92651 (*Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report*), 1.50 for CPT code 92652 (*Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report*), and 1.05 for CPT code 92653 (*Auditory evoked potentials; neurodiagnostic, with interpretation and report*). CPT code 92650 (*Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis*) is a screening service and is not payable by Medicare. Therefore, we did not propose a valuation for this code; however, we noted we will display RUC-recommended values associated with the code.

We proposed the RUC-recommended direct PE inputs for this code family without refinement.

We received public comments on the Auditory Evoked Potentials codes (CPT codes 92584, 92650, 92651, 92652, and 92653). The following is a summary of the comments we received and our responses.

Comment: Commenters uniformly expressed support for our proposal to accept the RUC-recommended work RVUs and direct PE inputs for CPT codes 92584, 92651, 92652, and 92653.

Response: We appreciate the commenters' support.

Comment: Commenters requested that CMS publish the RUC-recommended work, PE, and malpractice RVUs for CPT code 92650. CPT code 92650 is a key component of universal newborn hearing screening programs that are widely furnished across the country. As such, it is critical for CMS to display the total RVUs—to include the RUC's recommended work, PE, and MP RVUs—to allow state Medicaid agencies, newborn hearing programs, and commercial insurers to appropriately value 92650.

Response: We did not propose values for CPT code 92650 because it is not a covered Medicare service. However, we will post the RUC-recommended RVUs for this code.

Comment: Commenters also noted a discrepancy between Addendum B—which indicates 92650 is an active code (status indicator ''A'')—and the narrative in the proposed rule, which states that 92650 is a screening code and not payable by Medicare.

Response: We acknowledge the error and have corrected it in Addendum B.

Comment: Commenters requested that CMS create a professional and technical

component (PC/TC) split for CPT codes 92650, 92651, 92652, and 92653. Other audiology codes including CPT codes 92585 and 92586, which are being replaced by 92650–92651, also included the PC/TC split.

Response: We appreciate commenters' suggestion that we create PC/TC splits for CPT codes 92650, 92651, 92652, and 92653. When we reviewed the code descriptors and the RUC recommendations for the codes, we noted that the direct PE for the new codes no longer includes clinical staff time. We also noted that the now deleted codes included clinical staff time that was assigned to an audiologist. We understood that the new codes represented changes to the service; audiologists were now able to bill independently for the work. During our review, we did not consider a PC/TC split and were surprised by the commenters' suggestion. Looking forward, we may consider this suggestion during future rulemaking.

After considering the comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Auditory Evoked Potentials family as proposed.

(38) Vestibular Evoked Myogenic Potential Testing (CPT Codes 92517, 92518, and 92519)

In response to a 2017 RAW request, AMA staff compiled a list of CMS/Other codes with Medicare Utilization of 30,000 or more. CPT code 92585 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive*) was identified as one of the codes. In 2018, the AMA/RUC referred CPT code 92585 and its family member CPT code 92586 (*Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; limited*) to the February 2019 CPT Editorial Panel meeting to clarify code descriptors and define the terms ''limited'' and ''comprehensive'' auditory evoked potentials.

During the discussion of CPT codes 92585 and 92586 at the February 2019 CPT Editorial Panel meeting, specialty societies introduced a new procedure, Vestibular Evoked Myogenic Potential (VEMP), and suggested new coding. As a result, the CPT Editorial Panel created 3 new codes: CPT code 92517 (*Vestibular evoked myogenic potential testing, with interpretation and report; cervical (cVEMP)*); CPT code 92518 (*Vestibular evoked myogenic potential testing, with interpretation and report; ocular (oVEMP)*); and CPT code 92519 (*Vestibular evoked myogenic potential testing, with interpretation and report; cervical and ocular*). The RUC reviewed the three codes at its April 2019 meeting.

We proposed the RUC-recommended work RVU of 0.80 for CPT codes 92517 and 92518. For CPT code 92519, we proposed the RUC-recommended work RVU of 1.20. We also proposed the RUC-recommended direct PE inputs without refinement for these three VEMP codes.

We received public comments on the Vestibular Evoked Myogenic Potential Testing family (CPT codes 92517, 92518, and 92519). The following is a summary of the comments we received and our responses.

Comment: Commenters wrote to express support for our proposal to accept the RUC-recommended work RVUs.

Response: We appreciate the support of commenters.

Comment: Commenters requested that CMS create a professional and technical component (PC/TC) split for the new codes. These commenters noted that audiologists who perform services in a facility setting require a mechanism to accurately report the professional component for their services. Commenters cited other vestibular testing codes such as CPT codes 92548 and 92549 that have a PC/TC split.

Response: We appreciate commenters' interest in the creation of a PC/TC split for CPT codes 92517, 92518, and 92519. When we reviewed the code descriptors and the RUC recommendations, we noted that the direct PE for this set of new codes did not include clinical staff time. As a result, we did not consider a PC/TC split. However, as a result of the commenters' suggestion, we may consider the PC/TC split a topic of future rulemaking.

After consideration of public comments, we are finalizing the work RVUs and direct PE inputs for the codes in the Vestibular Evoked Myogenic Potential Testing family as proposed.

(39) Complete Electrocardiogram (CPT Codes 93000, 93005, and 93010)

In the CY 2019 PFS final rule (83 FR 59452), CPT code 93000 was nominated for review under the potentially misvalued code initiative. The RUC reviewed these services at the April 2019 meeting where the specialty societies explained that the family of electrocardiogram (ECG) codes were relatively unique in that CPT code 93000 (*Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report*) is the global service which is billed in the hospital setting, CPT code 93005 (*Electrocardiogram, routine ECG with at least 12 leads; tracing only, without interpretation and report*) is the technical component and CPT code 93010 is the professional component.

We proposed the RUC-recommended work RVU of 0.17, which is the current value for both codes, for CPT codes 93000 and 93010. CPT code 93005 is a PE only technical component code, and we proposed to maintain the current work RVU of 0.00.

For the direct PE inputs, we proposed the RUC-recommended values without refinement.

We did not receive public comments on this code family, and therefore, we are finalizing as proposed.

(40) External Extended ECG Monitoring (CPT Codes 93224, 93225, 93226, 93227, 93241, 93242, 93243, 93244, 93245, 93246, 93247, and 93248)

In September 2019, the CPT Editorial Panel replaced four Category III codes with 8 new Category I codes to report external electrocardiographic (ECG) recording by continuous rhythm recording and storage for periods longer than 48 hours. The existing Holter monitor codes (CPT codes 93224 through 93227) that include up to 48 hours of continuous recording were also reviewed as part of this family of services at the January 2020 RUC meeting.

We proposed the RUC-recommended work RVU for all 12 codes in the family. We proposed a work RVU of 0.39 for CPT codes 93224 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional*) and 93227 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional*); a work RVU of 0.50 for CPT codes 93241 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*) and 93244 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation*); and a work RVU of 0.55 for CPT codes 93245 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation*) and 93248 (*External electrocardiographic recording for more*

than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation).

The other six codes in the family are technical component codes that do not have a work RVU; we proposed a work RVU of 0.00 for CPT codes 93225 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)*), 93226 (*External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report*), 93242 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), 93243 (*External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report*), 93246 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)*), and 93247 (*External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report*).

For the direct PE inputs, we proposed to refine the clinical labor time for the ''Perform procedure/service—NOT directly related to physician work time'' (CA021) activity for CPT codes 93241, 93243, 93245, and 93247. We proposed to reduce the clinical labor time by 5 minutes for each code as the description of the tasks taking place in the recommended materials includes activities that are considered to be indirect PE under our methodology. The recommended materials stated that ''incoming patch deliveries are sorted and distributed to work queues. The return box is opened, diary book removed, top housing is removed using a custom tool to expose USB connection, and device is plugged in to extract serial number and diagnostic logs.'' These unboxing and filing activities are classified as administrative expenses under our PE methodology, and therefore, do not constitute clinical labor as a direct expense. We proposed to remove 5 minutes from the clinical labor to reflect these activities, which are indirect as opposed to direct costs. We also proposed to refine the equipment time for the desktop computer (ED021) to reflect these changes in the clinical labor time.

We noted an inconsistency in the RUC-recommended direct PE inputs for CPT codes 93241 and 93245. Both of these codes are the ''global component'' for their respective group of codes, such that the direct costs for CPT codes 93242–93244 must sum up to the direct cost of CPT code 93241 and the direct costs for CPT codes 93246 through 93248 must sum up to the direct cost of CPT code 93245. However, CPT codes 93241 and 93245 each contained 2 pairs of non-sterile gloves (SB022) whereas their constituent technical component codes (93242 and 93246 respectively) only contained a single pair of non-sterile gloves. Therefore, we proposed to refine the quantity of the non-sterile gloves down to 1 pair for CPT codes 93241 and 93245 to correct this inconsistency. We noted we also considered increasing the quantity of the gloves to 2 as in CPT codes 93224 through 93227. However, we believed that only 1 pair of gloves would typically be needed to attach the ECGs, as the patient does not return to have the ECGs removed in CPT codes 93241 through 93248 as opposed to CPT codes 93224 through 93227 where the patient does return for ECG removal.

We proposed the RUC-recommended equipment time of 1,474 minutes for the Holter monitor (EQ127) equipment included in CPT codes 93224 and 93226, based on an equipment time of 34 minutes during the procedure along with 1,440 minutes (24 hours) of equipment time thereafter. We noted that an external stakeholder wrote to request that the number of minutes of equipment time for the Holter monitor be increased from 1,440 minutes (24 hours) to 2,160 minutes (36 hours) to reflect the average length of equipment time. The stakeholder wrote that the 24-hour and 48-hour test were each performed approximately 50 percent of the time and stated that the most accurate number of equipment minutes would be the average time. The RUC disagreed with the stakeholder's request in its review because it concluded that there was insufficient evidence to warrant a change from the current 24 hours of equipment time; the RUC-recommended equipment time for the Holter monitor was based on the typical rather than the average service. We proposed the RUC-recommended equipment time of 1,474 minutes because our PE methodology is indeed based on the typical case, specifically what would be typical and reasonable and necessary for the procedure in question. Although we appreciated the feedback from the stakeholder, our previously finalized PE methodology establishes pricing based on the typical case. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

The recommendations for this family of codes contain one new supply item, the ''extended external ECG patch, medical magnetic tape recorder'' (SD339). We did not receive a traditional invoice to establish a price for this supply item, instead receiving pricing information from two sources: A weighted median of claims data with the cost of the other direct PE inputs removed, and a top-down approach calculating the cost of the supply per service based on summing the total costs of the health care provider and dividing by the total number of tests furnished. The former methodology yielded a supply price of approximately $440 while the latter methodology produced an estimated supply price of $416.85. Stakeholders also submitted a series of invoices from the clinical study marketplace with a price of $595. Although we are appreciative of the data provided by the stakeholder, we require an invoice representative of commercial market pricing to establish a national price for a new supply or equipment item. Although we are aware of the unusual circumstances surrounding the ''extended external ECG patch, medical magnetic tape recorder'' in terms of how it uploads data to the health care provider, we cannot establish supply pricing based on an analysis of claims data and in absence of a representative invoice.

Therefore, we proposed to employ a crosswalk to an existing supply for use as a proxy price until we have an invoice to use for the ''extended external ECG patch, medical magnetic tape recorder'' item. We proposed to use the ''kit, percutaneous neuro test stimulation'' (SA022) supply as our proxy item at a price of $413.24. Although this kit is not clinically similar to the extended external ECG patch, we believe that it is the closest match from a pricing perspective to employ as a proxy until we are able to arrive at an invoice that is representative of commercial market pricing. We welcomed the submission of invoices or other additional information for use in pricing the ''extended external ECG patch, medical magnetic tape recorder'' supply.

We received public comments on the codes in the External Extended ECG Monitoring family. The following is a

summary of the comments we received and our responses.

Comment: Several commenters supported the proposal of the RUC-recommended work RVUs for all of the codes in the External Extended ECG Monitoring family.

Response: We appreciate the support for our proposals from the commenters.

Comment: One commenter supported the proposal to refine the quantity of the non-sterile gloves down to 1 pair for CPT codes 93241 and 93245 to correct an inconsistency in the RUC recommendations. The commenter agreed that this corrected a summing error.

Response: We appreciate the support for our proposals from the commenter.

Comment: Several commenters disagreed with the proposal to reduce the clinical labor time for the ''Perform procedure/service—NOT directly related to physician work time'' (CA021) activity for CPT codes 93241, 93243, 93245, and 93247 by 5 minutes. Commenters stated that delivery and assignment tasks may be fair to characterize as administrative, but accessing the device, connecting it, and downloading data is more akin to the CA032 activity code (''Scan exam documents into PACS. Complete exam in RIS system to populate images into work queue.'') when clinical data is put into the system. Commenters recommended that CMS reduce clinical staff time by 1 minute, not 5, to account for the delivery sorting, distribution, and box opening.

Response: We continue to disagree with the commenters and maintain that the proposed reduction of 5 minutes of clinical labor time is warranted as the activities listed by commenters are forms of indirect PE. Data entry tasks such as connecting a device and downloading data are typically considered to be forms of indirect PE unless they are directly allocable to a particular patient for a particular service. We do not agree that the suggested comparison to the CA032 activity code would be accurate for these services, as the CA032 activity code requires the use of a PACS workstation, which is not present in any of these CPT codes.

Comment: Several commenters disagreed with CMS' position regarding equipment time for the wearable holter monitor (EQ127) device. Commenters stated that they had presented evidence to the RUC demonstrating that about half of the services described by CPT code 93226 involve 24 hours of monitoring and about half are for 48 hours; based on this, the commenter suggested that the ''typical'' service was 36 hours—the average of 24 and 48 hours. The commenter stated that the RUC and CMS did not agree as both take the view that the ''typical'' service requires a binary choice between 24 and 48 hours. The commenter stated that they believe a more accurate methodology for valuing equipment time is to look to objective and quantifiable data such as the average number of hours of use rather than the ''either/or'' methodology which inevitably undervalues approximately 50 percent of tests.

Response: Although we appreciated the feedback from the stakeholder, as we stated in the proposed rule, our previously finalized PE methodology establishes pricing based on the typical case and not the average result. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology CY 2007 PFS proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

Comment: We received many comments regarding our proposal to price the ''extended external ECG patch, medical magnetic tape recorder'' (SD339) supply via a proxy item at a price of $413.24. Several commenters supported the proposed proxy pricing, stating that because the independent diagnostic testing facilities that furnish the extended ECG services are also the manufacturers of the devices, there are no invoices that reflect the sale or purchase of this supply item or the related software required to scan and analyze the extended ECG data recorded on this patch. These commenters stated that CMS should finalize the pricing as proposed and advised caution when reviewing pricing for what appear to be extended ECG system components, and to assess whether the invoiced items represent the supplies and equipment required to furnish the typical case of the service described by the new codes.

Other commenters strongly disagreed with the proposed proxy pricing for the SD339 supply. Commenters stated that they were alarmed that CMS's proposal would result in payment rates far in excess of the costs incurred when performing these services in direct violation of CMS's stated principles for reimbursement rates. One commenter stated that CMS proposed rates at more than four times where they should be valued under its standard PE cost accounting methodology. Several commenters stated that the SD339 patch was available for purchase at roughly $100 to $120 if bought in bulk quantities, which the commenters stated made sense because these ECG patches are not high tech equipment. Several commenters were concerned that CMS had not followed its traditional methodology for supply pricing by valuing the SD339 patch without receiving an invoice submission. Commenters stated that the proposed proxy pricing incorporated the research and development costs associated with developing the patch, which are typically indirect costs under the PE methodology, and CMS was therefore double-paying for these expenses by including them as a direct cost. Commenters also raised concerns that providers of these services might be able to make up to $200 per patient through the sale of discounted patch kits by profiting from the spread between the CMS payment and the much lower cost of the product. Commenters stated that this could create an incentive for significant overutilization of these services. One commenter submitted a lengthy report suggesting that CMS reject the proxy supply input approach and value the external ECG patch not as a supply but as a form of reusable equipment. This commenter submitted a series of invoices to support their contention that the external ECG patch would be more accurately priced as a reusable form of equipment at a much lower reimbursement rate.

One commenter who supported the proposed proxy pricing later submitted a second comment responding to the commenters' criticisms of the proposal. This commenter stated that the devices and systems described by the invoices presented by other commenters were not consistent with the diagnostic system typically used to furnish the services described by these new codes. The commenter stated that there were systemic differences between the extended external ECG patch and the items described by the invoices referenced by other commenters. The commenter reiterated that the proposed proxy price should be finalized as it is supported by peer-reviewed clinical evidence from the specialty societies.

Response: Given the conflicting information and assertions provided by commenters, we are unable to identify accurate national pricing for the ''extended external ECG patch, medical magnetic tape recorder'' (SD339) supply. To allow additional time to receive more pricing information, we are finalizing contractor pricing for CY 2021 for the four codes that include this supply input (CPT codes 93241, 93243, 93245, and 93247). We will retain the SD339 supply in our pricing database while removing the proxy price pending additional information. We welcome the

submission of additional invoices or other pricing information to assist us to determine the most accurate values for these services.

After consideration of the comments, we are finalizing the work RVUs and direct PE inputs for CPT codes 93224, 93225, 93226, 93227, 93242, 93244, 93246, and 93248. We are finalizing contractor pricing for CPT codes 93241, 93243, 93245, and 93247 as detailed above.

(41) Complete Transthoracic Echocardiography (TTE) With Doppler (CPT Code 93306)

In the CY 2019 PFS final rule (83 FR 59500), a submitter nominated CPT code 93306 (*Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with spectral Doppler echocardiography, and with color flow Doppler echocardiography*) as potentially misvalued, citing GAO, MedPAC, and Urban Institute reports that suggest the work RVUs are overstated. Although the code was most recently surveyed in 2016, the specialty societies and the RUC stated that there has been a change in the technique and technology used to perform the procedure, so they resurveyed the code. The RUC recommended decreasing the work RVU from 1.50 to 1.46 and we proposed this value.

Although we proposed the RUC-recommended direct PE inputs without refinement, we noted that the RUC's recommendation included both 25 mL and 50 mL of ultrasound transmission gel. We proposed a supply quantity of 25 mL and sought clarification on the correct amount.

We received public comments on the proposed valuation of CPT code 93306. The following is a summary of the comments we received and our responses.

Comment: A few commenters were supportive of our proposals for the work RVUs and direct PE inputs for the codes in this family.

Response: We appreciate the support for our proposals from the commenters.

Comment: A few commenters confirmed that the correct supply quantity of the ultrasound transmission get was 25 mL.

Response: We appreciate the clarification and are finalizing the ultrasound transmission gel supply quantity as proposed.

After consideration of the public comments, we are finalizing the work RVUs and direct PE inputs for CPT code 93306 as proposed.

(42) Pacing Heart Stimulation (CPT Code 93623)

Review of CPT code 93623 (*Programmed stimulation and pacing after intravenous drug infusion (List separately in addition to code for primary procedure)*), was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 30,000 claims in a year. This service is to create an arrhythmia by an intravenous drug infusion and it is an add-on code with 60 minutes of total time and a current work RVU of 2.85.

The RUC recommended the 25th percentile survey value of 2.04 work RVUs and 20 minutes of intraservice time.

The revision of CPT code 93623 physician's time adjusting from the current 60 minutes to 20 minutes is a significant change. We noted that we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we noted that we believe that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. In the case of CPT code 93623, we believed that it would be more accurate to propose a work RVU of 0.98 based on CPT code 76810 (*Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, after first trimester (> or = 14 weeks 0 days), transabdominal approach; each additional gestation (list separately in addition to code for primary procedure)*) with 20 minutes of intraservice time. We proposed a work RVU of 0.98 with 20 minutes of intraservice time for CPT code 93623.

This CPT code is a facility-only service and has no direct PE inputs.

We received public comments on the Pacing Heart Stimulation CPT code 93623. The following is a summary of the comments we received and our responses.

Comment: Commenters disagreed with our selection of CPT code 76810 as an equivalent comparator to CPT code 93623 in regard to the work RVUs and the number of total minutes derived from the 'CMS Other' category listed in CMS's physician time file. Commenters stated that the nature of the type of work and intensity for the service described by CPT code 76810 are vastly different from Pacing Heart Stimulation. The commenters strongly suggested that CMS accept the 25th percentile work RVU of 2.04 from their recent survey of 46 cardiologists.

Response: We continue to believe that CPT code 76810 is a valid reference for purposes of valuing CPT code 93623, and that the physician time change from the current 60 minutes to 20 minutes indicates a reduction in work RVUs. As we have discussed in previous rules, we continue to believe that our use of the existing time values as a point of comparison is critical to the integrity of the current relative value system and we do not accept the characterizing of a time source as ''CMS-Other'' as being less valid. As for CPT code 76810 having only total time instead of intraservice time, for add-on codes, total time is almost always the equivalent of intraservice time, and both of these add-on codes have 20 minutes of total time. We do not regard the 20 minutes of physician time assigned to CPT code 76810 to be any different from the 20 minutes of physician time with CPT code 93623. While the clinical nature of the work for CPT code 76810 is different from the clinical nature of the work for CPT code 93623, our review of the assigned RVU is based on a comparison of the physician times and intensity assigned to each code, which are the same.

After consideration of the public comments, we are finalizing the work and time values for CPT code 93623 as proposed.

(43) Intracardiac Echocardiography (ECG) (CPT Code 93662)

The review of CPT code 93662 (*Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation (List separately in addition to code for primary procedure*), was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 10,000 claims in a year that had an increase in volume by 100 percent between the 2012 to 2017. This procedure has since changed from its last review, in its reduced use of fluoroscopy, now replaced with ultrasound that create arrhythmia mapping systems with intracardiac echo images processed to produce 3-dimensional electroanatomical maps. The physician can now visualize better and have more accurate details for more effective catheter ablation for a wide range of arrhythmias. CPT code 93662 currently has a work RVU of 2.80 with 5 minutes of preservice evaluation time, 55 minutes of intraservice time, 10 minutes of immediate postservice time, and 70 minutes of total time.

The survey resulted in a median intraservice time of 25 minutes, a significant shift from the current intraservice time of 55 minutes. The RUC recommended a work RVU of 2.53 and 25 minutes of intraservice time for add-on CPT code 93662. We noted that we do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the surveyed work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we believed that since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs. CPT code 92979 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (ivus) or optical coherence tomography (oct) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (list separately in addition to code for primary procedure)*), with 1.44 work RVUs and 25 minutes of intraservice time, is a good equivalent comparator code in light of the significant physician time reduction from 55 minutes. A similarly proportioned reduction of physician intraservice time from the current 55 minutes to the surveyed 25 minutes, if applied to the current work RVU would result in a value much lower than our reference CPT code 92979's work RVU, so we proposed a work RVU of 1.44 and 25 minutes of intraservice time for add-on CPT code 93662.

This CPT code is a facility only service and has no direct PE inputs.

We received public comments on the service of Intracardiac Echocardiography (ECG) CPT code 93662. The following is a summary of the comments we received and our responses.

Comment: The AMA RUC disagreed with our selection of CPT code 92979 as an equivalent comparator code to CPT code 93662 because of ECG's higher technical nature, and its use of anesthesia which supports a higher intensity and a difference in the nature of the work. As in their AMA RUC recommendation, they referenced their selection of CPT code 34713 (*Percutaneous access and closure of femoral artery for delivery of endograft through a large sheath (12 French or larger), including ultrasound guidance, when performed, unilateral (List separately in addition to code for primary procedure)*) with a work RVU of 2.50 and an intraservice time of 20 minutes. The commenters strongly suggested that CMS accept their comparison code and the 25th percentile work RVU of 2.53 from their recent survey of 42 cardiologists.

Response: We consider CMS' selection of CPT code 92979 to be a more appropriate comparator to value CPT code 93662, than the AMA RUC's selection of comparator CPT code 34713, and believe that the physician time change from the current 55 minutes to 25 minutes indicates a reduction in work RVUs of greater than 0.27. We also do not agree with the AMA RUC that the increase in ECG's work intensity supports the AMA RUC recommended 2.53 work RVUs (90% of the current value). The substantial reduction in physician time (45%) and increase in work intensity, is not reflected in the AMA RUC-recommended reduction of work RVUs. CPT code 92979's intraservice time of 25 minutes and 1.44 work RVUs is a better equivalent that reflects the halving on the physician's current time and we do not believe that the work intensity has substantial change enough to justify the AMA RUC's recommended work value. We note that CPT code 93662's work value is for the professional component (26) that is set in the fee schedule and that CPT code 93622's technical component and global are also add-on codes and are carrier-priced, meaning that if the health care provider performs both components, their final payment will be more than the work RVUs finalized here.

After consideration of the public comments, we are finalizing a work RVU of 1.44 with 25 minutes of intraservice time for CPT code 93662 as proposed.

(44) Ventricular Assist Device (VAD) Interrogation (CPT Code 93750)

The review of CPT code 93750, (*Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report*) was prompted by the Relativity Assessment Workgroup Medicare utilization screen of over 10,000 claims in a year and had had an increased in volume by 100 percent between the 2012 to 2017. CPT code 93750 currently has a work RVU of 0.92 with 30 minutes of intraservice time.

For physician times, the societies' survey for CPT code 93750 yielded 6 minutes preservice time, 10 minutes intraservice time, 7 minutes immediate post-service time, and 23 minutes of total time. The 25th percentile surveyed work RVU was 0.96. The RUC compared the survey code to CPT code 78598 (*Quantitative differential pulmonary perfusion and ventilation (e.g., aerosol or gas), including imaging when performed*) (0.85 work RVU and 5 minutes of preservice time, 10 minutes of intraservice time, 9 minutes of immediate postservice time, and total time of 24 minutes). The RUC recommended crosswalking the work RVU of 0.85 from CPT code 78598 to 93750.

CPT code 93289 (*Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements*), with 0.75 work RVUs and 5 minutes of preservice time, 10 minutes of intraservice time, 8.5 minutes of immediate postservice time, and total time of 23.5 minutes, we noted we believe is a more precise comparator code. CPT code 93289's intraservice times, pre and post times, and total times are almost identical to CPT code 93750's survey times; therefore, we proposed a work RVU of 0.75 and 23 minutes of total time for CPT code 93750.

The PE Subcommittee corrected the equipment times based on the formulas as provided by CMS. In addition, the PE Subcommittee changed the clinical staff type for direct labor item ID CA013 Prepare Room, Equipment and Supplies, from an RN to the RN/LPN/MTA blend and the direct equipment item ID EQ168 light, exam was removed from CPT code 93750. We proposed to accept the RUC-recommended direct PE inputs.

We received public comments on the Ventricular Assist Device (VAD) Interrogation CPT code 93750. The following is a summary of the comments we received and our responses.

Comment: The AMA RUC surveyed CPT code 93750 and initially reviewed their surveyed 25th percentile recommendation of 0.96 work RVUs for this code, finding it to be overestimated, since the current work RVU value is 0.92 for the current 30 minutes of physician time. Instead, they selected CPT code 78598 as a comparator code with a work RVU of 0.85. Commenters disagreed with our selection of CPT code 93289 with a work RVU of 0.75 as inappropriately low, but they noted that they had originally reviewed CPT code

93289 only to abandon this code on the basis that it did not involve device programming.

Response: We disagree with commenters that our selection of comparator CPT code 93289 is inappropriate. The reduction in time from 30 minutes to 23 minutes suggests that the work RVUs should be decreasing, and the survey's 25th percentile reflects an increase. We do not believe the RUC-recommended work RVU appropriately accounts for the substantial reductions in the work times for the procedure. Although we do not imply that the decrease in time as reflected in survey values must equate to a one-to-one or linear decrease in the valuation of work RVUs, we continue to believe that, since the two components of work are time and intensity, significant decreases in time should be appropriately reflected in decreases to work RVUs; and that CPT code 93289 is a more appropriate comparator to CPT code 93750.

After consideration of the public comments, we are finalizing a work RVU of 0.75 with a total time of 23 minutes for CPT code 93750, as proposed.

(45) Spirometry (CPT Codes 94010 and 94060)

CPT code 94010 (*spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation*) and CPT code 94060 (*Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration*) were identified as part of a Relativity Assessment Workgroup (RAW) review of action plans on the status of services that were RUC referrals to develop CPT Assistant articles. These codes were recommended to be surveyed.

We proposed the RUC-recommended work RVU of 0.17 for CPT code 94010 (*spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation*) and the RUC-recommended work RVU of 0.22 for CPT code 94060 (*Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration*). We proposed the RUC-recommended direct PE inputs for this code family without refinements.

We did not receive public comments on this code family, and are finalizing as proposed.

(46) Exercise Test for Bronchospasm (CPT Codes 94619, 94617, 94618, and 94621)

In 2018, the CPT Editorial Panel created CPT code 94617 (*Exercise test for bronchospasm, including pre- and post-spirometry, electrocardiographic recording(s), and pulse oximetry*), and CPT code 94618 (*Pulmonary stress testing (e.g., 6-minute walk test), including measurement of heart rate, oximetry, and oxygen titration, when performed*) from the now deleted CPT code 94620 (*Pulmonary stress testing; simple (e.g., 6-minute walk test, prolonged exercise test for bronchospasm with pre- and post-spirometry and oximetry)*), and revised CPT code 94621 (*Cardiopulmonary exercise testing, including measurements of minute ventilation, co2 production, o2 uptake, and electrocardiographic recordings*) to better describe the specialty's pulmonary exercise test. Shortly after the creation and revision of these codes, the specialty society became aware of some health care providers performing CPT code 94617 without ECG monitoring, so to more accurately account for this work without the ECG monitoring, the CPT Editorial Panel proposed to establish CPT code 94619 with the descriptor, (*Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)*). For the October 2019 RUC meeting, the specialty societies surveyed CPT code 94619, and included a request to reaffirm the values of the rest of the codes in the code family.

For CPT code 94619, the surveyed physician time yielded 5 minutes of preservice time, 9 minutes of intraservice time, followed by 10 minutes of immediate post-service time, for a total time of 24 minutes. This distribution of physician times is of course very similar to the times for CPT code 94617, total time of 26 minutes, except without the task of including an electrocardiographic recording. The RUC recommended the survey's median work RVU of 0.49 for CPT code 94619.

We proposed the RUC's recommendation of a work RVU of 0.49 and a total physician time of 24 minutes for CPT code 94619.

This CPT family of codes that includes CPT code 94619, are CPT codes 94617, 94618, and 94621 and there are no changes to their physician service times, no change to their descriptors, nor their work RVUs, and remain as they currently are. The specialty societies reaffirmed these current valuations and we proposed to accept them without change.

We proposed the RUC-recommended PE changes without refinement.

We did not receive public comments on this provision, and are finalizing as proposed.

(47) Evaluation of Wheezing (CPT Codes 94640, 94667, 94668, and 94669)

At the April 2019 RUC meeting, four PE only CPT codes from the Evaluation of Wheezing code family were reviewed. The codes included CPT codes 94640 (*Pressurized or nonpressurized inhalation treatment for acute airway obstruction for therapeutic purposes and/or for diagnostic purposes such as sputum induction with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device*), 94667 (*Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation*), 94668 (*Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lunch function; subsequent*), and 94669 (*Mechanical chest wall oscillation to facilitate lung function, per session*).

We proposed the RUC-recommended direct PE inputs for the four PE only codes. The RUC did not recommend work RVUs and we proposed to maintain the current work RVU of 0.00 for all four codes.

We did not receive public comments on this code family, and are finalizing as proposed.

(48) Exhaled Nitric Oxide Measurement (CPT Code 95012)

In January 2019, the RAW reviewed services with 2017 Medicare utilization of 10,000 or more that had increased by at least 100 percent from 2012 through 2017. The RUC recommended that CPT code 95012 (*Nitric oxide expired gas determination*) be surveyed for the April 2019 meeting. We proposed the direct PE inputs for CPT code 95012 without refinement. CPT code 95012 is a PE-only code with no work RVU, and we proposed to maintain the current work RVU of 0.00.

We did not receive public comments on this code family and are finalizing as proposed.

(49) Acupuncture Services (CPT Codes 97810, 97811, 97813, and 97814)

The CPT Editorial Panel created two new codes and two new add-on codes in 2004 to describe the appropriate time or additional time and levels of service that can be performed using acupuncture and electroacupuncture,

acupuncture therapy with electrical stimulation. These codes were designated as noncovered services since Medicare did not reimburse for acupuncture services at the time. In January 2020, we issued a decision memo stating that Medicare will cover acupuncture for chronic low back pain under section 1862(a)(1)(A) of the Act (CAG–00452N). This was reflected in the April 2020 PFS Quarterly Update which changed CPT codes 97810 through 97814 to active payment status (CMS Change Request 11661). Because we had never conducted a review of these four acupuncture codes, the CY 2020 payment rate consisted of the work RVUs recommended by the RUC in 2004.

For CY 2021, we proposed to establish work RVUs for these four acupuncture codes based on a pair of crosswalks to two recently reviewed codes in the Dry Needling family. We proposed a work RVU of 0.48 for CPT codes 97810 (*Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*) and 97813 (*Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*) based on a crosswalk to CPT code 20561 (*Needle insertion(s) without injection(s); 3 or more muscles*). We proposed a work RVU of 0.32 for CPT codes 97811 (*Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)*) and 97814 (*Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)*) based on a crosswalk to CPT code 20560 (*Needle insertion(s) without injection(s); 1 or 2 muscle(s)*).

CPT codes 20560 and 20561 are clinically similar services associated with dry needling that were reviewed last year for CY 2020. We finalized work RVUs of 0.32 and 0.48 respectively for these two codes following our review of their associated RUC recommendations, while noting that dry needling services were non-covered by Medicare unless otherwise specified through a national coverage determination (NCD) (84 FR 62722 through 62724). Like the acupuncture codes, CPT codes 20560 and 20561 were updated to active payment status in the April 2020 PFS Quarterly Update to reflect the Medicare coverage of acupuncture for chronic low back pain. We noted that CPT codes 97810 and 97813 share the identical work time values with CPT code 20561, and that CPT codes 97811 and 97814 differ from CPT code 20560 by only 1 minute of work time, 15 minutes as compared to 16 minutes. Although we did not imply that codes with similar work times must equate to a one-to-one or linear relationship in the valuation of work RVUs, we believed that, since the two components of work are time and intensity, clinically related services with similar intensities and work times should, generally speaking, be valued similarly. Due to the similar clinical nature of these services and their nearly identical work times, we believed that it is more accurate to propose crosswalking CPT codes 97810 through 97814 to the work RVUs of the Dry Needling codes, which were finalized last year, as opposed to proposing work RVUs from 2004, which were never reviewed by CMS.

The RUC did not make any recommendations and we did not propose any changes to the direct PE inputs for CPT codes 97810 through 97814.

We received public comments on the codes in the Acupuncture Services family. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed work RVUs assigned to the acupuncture codes and appreciated CMS' recent coverage determination. The commenters stated that it is important for CMS to provide coverage and adequate reimbursement to a broad array of services that provide non-opioid pain management alternatives.

Response: We appreciate the support for our proposals from the commenters.

Comment: Many commenters were supportive of the Medicare decision to provide coverage for acupuncture services but disagreed with the proposed valuation crosswalk to two recently reviewed codes in the Dry Needling family. Commenters stated that the dry needling services were not clinically similar to the acupuncture codes as CMS had claimed in the proposed rule, as the dry needling codes do not reflect the training or expertise required to perform an acupuncture treatment. Commenters stated that acupuncture is more physically and mentally intensive than inserting a dry needle into a tender muscle. Commenters stated that the higher skill and knowledge set that is required to perform acupuncture therapy is evidenced in the licensure requirements to perform these services, whereas there are no standardized training curriculums or accreditation programs for dry needling. Commenters stated that the current acupuncture therapy codes are specifically intended to include pre- and post-service intervention assessment/evaluation, as per the CPT guidelines, which is lacking in the dry needling codes. Many commenters stated that if Medicare rates are reduced for acupuncture services then providers of acupuncture services will not be able to afford to treat Medicare beneficiaries and this would create additional barriers to care.

Response: We appreciate the detailed feedback from the commenters detailing the differences between acupuncture and dry needling services. After reviewing the comments, we agree that there are significant differences between these services and it would not be appropriate to use the proposed crosswalk for valuation. Therefore, we are not finalizing our proposal to establish work RVUs for these four acupuncture codes based crosswalks to CPT codes 20560 and 20561. We are instead finalizing the current CY 2020 work RVUs of 0.60 for CPT code 97810, 0.50 for CPT code 97811, 0.65 for CPT code 97813, and 0.55 for CPT code 97814. As this valuation is based on a RUC review that took place in 2005, we welcome the prospect of an updated formal review or other new information regarding the valuation of these services for potential future rulemaking.

(50) Interim Final Rule With Comment Period for Coding and Payment for Personal Protective Equipment (PPE) (CPT Code 99072)

a. Background

Following the publication of the CY 2021 PFS proposed rule, the CPT Editorial Panel approved the creation of CPT code 99072 (*Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency, as defined by law, due to respiratory-transmitted infectious disease*). During the comment period for the proposed rule, stakeholders contacted CMS and stated that practices have incurred significant costs of maintaining safe offices, particularly in implementing specific infection control measures related to screening patients, purchasing personal protective equipment (PPE), and implementing office redesign measures to ensure social distancing. Stakeholders requested that CMS immediately consider implementation of relative values and payment (outside of budget neutrality) for the newly created CPT code 99072 in recognition of these costs.

Stakeholders submitted recommended direct PE inputs associated with CPT code 99072 designed to capture the additional supplies, materials, and clinical staff time over and above the PE inputs included in an office visit or other nonfacility service(s) when the office visit or other non-facility service(s) are rendered during a public health emergency (PHE). Stakeholders submitted more than 500 invoices associated with PPE supplies and requested that CMS use them to update their pricing, as well as requested that N95 masks should be added to the direct PE supply list. Stakeholders stated that payment for these additional costs should be fully funded and not be subject to budget neutrality, and that CMS could use remaining money from the CARES Act funding to pay physicians for these costs and/or recognize the decreased expenditures during the early months of the pandemic to waive budget neutrality. Stakeholders also stated that CMS should review the utilization assumptions for equipment due to decreased practice capacity during the PHE for COVID–19 and that any modifications to the equipment utilization during the PHE should not be subject to budget neutrality.

b. Interim Final Policy

We appreciate the submission of this additional information regarding CPT code 99072, especially the large number of invoice submissions for use in updating the pricing of PPE supplies. We share in the concerns of the stakeholders regarding the additional costs borne by providers during the public health emergency. After reviewing the information provided by the stakeholders, we are finalizing CPT code 99072 as a bundled service on an interim basis. We believe that use of these additional forms of PPE would be inherent to the furnishing of separately paid services under these practitioner/patient interactions. We agree with the stakeholders that there have been additional costs for providers as part of the PHE for COVID–19; however payment for the services as described under CPT code 99072 are always bundled into payment for other services and payment for them is subsumed by the payment for the services to which they are incident.

In recognition of the increased market-based costs for certain types of PPE, we are finalizing on an interim basis several supply pricing increases using the invoices submitted along with CPT code 99072. We did not previously include the N95 mask in our supply database and we are finalizing on an interim basis its addition under supply code SD344 at the median price of $2.36 based on 94 submitted invoices. We are also finalizing on an interim basis an increase in the price of the surgical mask (SB033) supply to the median price of $0.43 based on 259 submitted invoices and an increase in the price of the surgical mask with face shield (SB034) supply to the median price of $3.40 based on 49 submitted invoices. We are using the median price as opposed to the average price of the submitted invoices as the median was more typical of market-based pricing and avoided the effect of outlier prices. The increased cost associated with these forms of PPE will be reflected in payment for services that include these supply inputs.

We also received additional invoices associated with non-sterile gloves (SB022), nitrile gloves (SB023), patient gowns (SB026), and sterile surgical gowns (SB028). We are not finalizing changes in the prices of these supplies at this time due to concerns that we had regarding the data on the submitted invoices. The non-sterile gloves and nitrile gloves contained median prices which were significantly lower than their CY 2021 prices, $0.05 as compared to $0.25 for the non-sterile gloves and $0.06 as compared to $1.01 for the nitrile gloves. The sterile surgical gowns followed the same pattern with a median invoice price of $3.39 as compared to the CY 2021 price of $5.02. We do not believe that the typical price for these supplies has undergone significant decreases as a result of the PHE and we are not finalizing any price changes at this time pending additional discussion with stakeholders. For the patient gown (SB026) supply, the median price of the 43 submitted invoices was $0.51 and the average price was $0.67. We believe that this additional data supports the current CY 2021 price of $0.58 and we are not finalizing a price change since the invoice data suggested that the current price remains typical during the PHE. We also received a small quantity of invoices associated with other PPE supplies but we did not believe that we had enough data in these cases to determine typical pricing and therefore we are not finalizing any additional price changes to supply items.

As described in section VIII. of this final rule, Regulatory Impact Analysis, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures do not increase or decrease by more than $20 million. We do not have authority to waive the budget neutrality provision for CPT code 99072 unless explicitly stated by statute. In addition, as described in section II.B. of this rule (PE section), we also disagree with the stakeholders that utilization assumptions for equipment should be revisited as part of the public health emergency. While we agree that many services had a reduced volume of Medicare beneficiaries at times during CY 2020, we note that equipment costs under the PFS are amortized across the full useful life of the equipment, which in the vast majority of cases is 5–10 years. We believe that it would distort relativity to apply a temporary decrease in utilization caused by the PHE to the pricing structure of the equipment's full useful life duration. We also note that we do not have statutory authority to exempt any modifications to the equipment utilization assumptions from budget neutrality calculations.

c. Waiver of Proposed Rulemaking Provisions

Under the Administrative Procedure Act (APA), 5 U.S.C. 553(b), an agency is generally required to publish a notice and solicit comment on a proposed rule in the **Federal Register** before issuing a final rule. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of a proposed rule in the **Federal Register** and provide a period of not less than 60 days for public comment. The APA provides for exceptions from the notice and comment requirements, *see* 5 U.S.C. 553(b)(B); in cases in which the APA exceptions apply, section 1871(b)(2)(C) of the Act provides for exceptions from the notice and 60-day comment period requirements of the Act as well. Section 553(b)(B) of Title 5 and section 1871(b)(2)(C) of the Act authorize an agency to dispense with normal rulemaking requirements if the agency for good cause finds that the notice and comment process is impracticable, unnecessary, or contrary to the public interest.

We find that there is good cause to waive the notice and comment requirements under sections 553(b)(B) of the APA and section 1871(b)(2)(C) due to the September 2020 creation of CPT code 99072 which did not allow for its inclusion in the proposed rule. We believe that establishing payment for this service on an interim basis will allow for its provision as a bundled service during the public health emergency. We find that it would be impracticable and contrary to the public interest to undergo notice and comment procedures before finalizing these

payment policies on an interim basis. We also find that delaying implementation of these policies is unnecessary because the impact on other PFS services for 2021 is negligible and the practical alternative for this treatment is no payment under Medicare Part B. In either case, payments for 2022 and beyond would be informed by public comments.

Therefore, we find good cause to waive the notice of proposed rulemaking as provided under section 1871(b)(2)(C) of the Act and section 533(b)(B) of the APA and to issue this interim final rule with an opportunity for public comment. We are providing a 60-day public comment period as specified in the **DATES** section of this document. We are seeking interim final comment on our general approach to CPT code 99072, as well as how to think about services that may not include these specific PPE items but for which there are incurred costs as described by the stakeholders. Additionally, we will consider the market cost for these supply items relative to the changing conditions in the market, as appropriate.

(51) Chronic Care Management Services (CPT Code 99439 and HCPCS Code G2058)

We established payment for HCPCS code G2058 (*Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified healthcare professional, per calendar month*) in the CY 2020 PFS final rule (84 FR 62690). At the January 2020 RUC meeting, specialty societies requested a temporary crosswalk through CY 2021 between the value established by CMS for HCPCS code G2058 and the value of new CPT code 99439 (with a descriptor identical to G2058). The Chronic Care Management code family will be resurveyed during CY 2020 and is expected to be presented for review as part of the 2022 RUC review process.

For CY 2021, we proposed the RUC-recommended work RVU of 0.54 and the RUC-recommended direct PE inputs for CPT code 99439.

We received several public comments all in support of our proposed valuations for Chronic Care Management Services (CPT code 99439 and G2058). After consideration of the comments, we are finalizing as proposed.

(52) External Counterpulsation (HCPCS Code G0166)

In the CY 2020 PFS proposed rule (84 FR 40516), an external stakeholder nominated HCPCS code G0166 as potentially misvalued due to concerns that the PE RVUs for this code did not fully reflect the total resources required to deliver the service and CMS proposed G0166 as potentially misvalued. The RUC reviewed the direct PE inputs for HCPCS code G0166 at the October 2019 RUC meeting.

We proposed the RUC-recommended preservice period, service period and postservice period with refinements. We proposed to replace CA010 (*obtain vital signs*) during the postservice of service period with CA023 (*monitor patient following procedure/service, no multitasking*).

For the equipment items, we proposed to update the price of the ''EECP, external counterpulsation system'' (EQ012) equipment to $101,247.50 based on an average of the five invoices submitted along with the recommendations. We noted that the EQ012 equipment is the only current equipment item in our direct PE database with an equipment utilization rate of 25 percent and the only equipment item with a utilization rate under 50 percent. Although we did not propose to change the equipment utilization rate, we solicited feedback from commenters regarding the utilization rate for the EQ012 equipment to help us understand why it should differ from all other medical equipment.

We also received invoices for a series of additional equipment items: An EECP service contract, an EECP compression equipment package, and an EECP electrical equipment package. We did not propose to establish a price for the EECP service contract, as service contracts are considered to be an administrative expense and a form of indirect PE under our methodology. As for the two equipment packages, there were a number of unusual factors involving these items that created difficulties for our equipment methodology. Both equipment packages had a suggested utilization rate of 25 percent, half of our typical utilization rate of 50 percent, and both had a suggested useful life duration of only 3 months. As we stated in section II.B. of the proposed rule (85 FR 50082–50083), Determination of Practice Expense RVUs, we have concerns that assigning very low useful life durations to this type of equipment would fail to maintain relativity with other equipment on the PFS. We also noted that the equipment cost per minute formula was designed under the assumption that each equipment item would remain in use for a period of several years and depreciate over that span of time. Our current equipment formula is not designed to address cases in which equipment is replaced multiple times per year, and we noted that we believe that applying a multi-year depreciation in these situations would not be reflective of market pricing. Although we agreed that these costs should be reflected in the pricing of HCPCS code G0166, we believed that the very frequent replacement of the items in the two equipment packages makes them a poor fit under our equipment methodology.

Therefore, we proposed to treat the two EECP equipment packages as supplies instead of treating them as equipment. We proposed to establish the EECP compression equipment package (SD341) as a supply with a cost of $645 based on an average of the submitted invoices, and proposed to establish the EECP electrical equipment package (SD342) as a supply with a cost of $500 again based on an average of the submitted invoices. Based on information provided by stakeholders, we proposed a supply quantity of 1/325 for these two items (0.00308) based on the supply being used on average five times per day and replaced every 3 months (5 uses * 5 days * 13 weeks = 325). We noted that we believe that assigning these two items as supplies rather than equipment more accurately captures the unusual circumstances associated with providing this service.

We received public comments on External Counterpulsation. The following is a summary of the comments we received and our responses.

Comment: Several commenters disagreed with CMS's proposal to move 3 minutes of clinical labor time for checking vitals at the end of the session to post-procedure monitoring, stating this is not monitoring in the sense of the CA023 activity code but taking vitals to evaluate the effectiveness of the treatment and the patient's condition.

Response: We disagree with the commenters and continue to believe our proposal to replace CA010 (*obtain vital signs*) during the postservice of the service period with CA023 (*monitor patient following procedure/service, no multitasking*) was appropriate. We understand that the clinical labor taking place is not a monitoring activity, however the CA010 activity code is used to describe clinical labor that takes place before the service occurs, not afterward. We proposed to use the CA023 activity code as the closest proxy available to describe this clinical labor. We note that there is no change in valuation for the service as we proposed the same 3 minutes for the CA023 activity code as the RUC recommended under the CA010 activity code.

Comment: Several commenters disagreed with the proposal to price the

''EECP, external counterpulsation system'' (EQ012) equipment at $101,247.50. Commenters stated that one of the previous invoices used for pricing the EQ012 equipment reflected a discount of $10,000 and was not for the purchase of a new ECP system. Commenters stated that although it was not explicitly listed, it was highly likely that another invoice used for pricing was either the result of a trade-in credit or reflected a refurbished system. Commenters submitted a new invoice for the EQ012 equipment with a listed price of $130,890 and requested that CMS use this invoice for pricing while disregarding the prior invoices.

Response: We disagree with the commenters that the previous invoices used for pricing the EQ012 equipment should be disregarded for pricing. We do not agree that invoices from 2015 and 2017 have no validity; while we prefer to use current invoices wherever possible, we also believe in the importance of using multiple data points as opposed to relying on a single invoice. We also note that the same commenter submitted invoices for pricing the supply packages, which ranged in date from 2012 to 2020. We have no indication that the previous invoices were part of trade-in programs, and our pricing methodology uses the actual market rate for supplies/equipment, which does include discounts. We also do not agree with the commenter that the use of new equipment would be typical in all cases as it is clear that providers of these services can and do purchase used versions of the EQ012 equipment. As a result, we are employing our standard policy for invoice submissions and averaging together the previously submitted invoices with the new invoice submission, which results in a price of $111,128.30 for the EQ012 equipment. We are finalizing this as the new price for the EECP, external counterpulsation system.

Comment: Several commenters supported the current equipment utilization rate of 25 percent for the EQ012 equipment. Commenters stated that this rate reflected 80 minutes (proposed nonfacility time) × 1.57 services per day × 5 days per week × 50 weeks = 31,400 minutes for a total utilization rate of 20.9 percent (31,400 divided by 150,000). Commenters stated that the utilization rate was accurate based on their experience delivering this service and their discussions with other ECP therapy providers in different regions across the country. One commenter disagreed with the proposed equipment utilization rate of 25 percent and requested that CMS review the equipment utilization for this service and explain why it differs from all other medical equipment.

Response: We appreciate the additional information provided by the commenters regarding the utilization rate for the EQ012 equipment. Based on the information supplied by the commenters, we continue to believe that the current equipment utilization rate of 25 percent is the most accurate value for this unique type of equipment.

Comment: Several commenters provided feedback on the proposal to establish the EECP compression equipment package (SD341) and the EECP electrical equipment package (SD342) as disposable supplies. Commenters were supportive of the concept of treating these items as supplies instead of as equipment and provided additional details regarding the supply contents and supply quantities. Commenters stated that the EECP compression equipment package (SD341) supply should contain eight total inputs consisting of cuffs, bladders, hoses, straps, connectors, and specialized treatment pants. Several commenters stated that the total cost for the SD341 supply package summed to $847.00 while other commenters stated the cost of the same supply to be $826.75. For the EECP electrical equipment package (SD342), commenters stated that CMS accurately captured the finger plethysmograph and ECG cable in this package while omitting the Spo2 probe. Commenters stated that the Spo2 probe is a required item needed to perform the pulse oximetry and the price of the SD342 package should be updated to $752.00. Commenters submitted an extensive list of invoices to support these requested prices.

Response: We appreciate the additional information provided by the commenters regarding these supply packages, especially the pricing data contained in the submitted invoices. For the SD341 compression equipment package, we note that the invoices show that the two sets of cuffs are often sold together at a price of $220 instead of separately at $245. This accounts for the difference between the $847.00 and $826.75 prices listed by different commenters, and since the bundling of these cuffs appears to be the typical case, we are finalizing an update in the price of the EECP compression equipment package (SD341) supply at $826.75. For the second supply package, we agree with the commenters and we are finalizing an update in the price of the EECP electrical equipment package (SD342) at $752.00.

Comment: Several commenters provided additional details regarding the quantities for the two supply packages. Commenters stated that the compression package items typically have to be replaced every 13 weeks while the electrical package items typically have to be replaced every 50 weeks. Commenters stated that a provider of these services would be highly unlikely to be able to use the same cuffs, bladders, hoses, and straps in the SD341 supply package for 325 hours as these items would be completely deteriorated by this point and would be likely to lose the structural integrity needed to maintain clinical effectiveness. Commenters stated that a 100 hour life span would be more accurate for the SD341 supply as it reflected the typical wear and tear with inflating the compression items at high pressure (300 mm Hg every heartbeat) and was consistent with the manufacturer's estimated usage. Commenters stated that the electrical package does not experience the same level of stress and wear, and instead those items have a 400 hour life span.

Response: We appreciate the additional information provided by the commenters regarding the quantities for these two supply packages. Given that the intraservice treatment time for HCPCS code G0166 lasts for one hour, we are finalizing an update in the quantity of the SD341 supply pack to 1/100 and an update in the quantity of the SD342 supply pack to 1/400. These updated supply quantities reflect how many times the service can be performed before the supply package needs to be replaced.

Comment: Several commenters disagreed with the proposal of the RUC-recommended clinical labor time of 83 minutes. Commenters stated that the proposed time omitted 8 minutes of required clinical activities consistent with the ECP user manual. Commenters stated that ECP therapy providers must check legs, conduct a patient assessment, auscultate/assess lungs, and review change in baseline. Commenters stated that ECP therapy providers also must perform patient checks immediately following the service such as assess signs related to blood sugar levels (for diabetic patients), assess the patient's lower body for redness, blistering, and/or ulceration, and assist patients from the treatment area following the service. Commenters stated that these are essential safety measures to ensure patients have tolerated the treatment well and these activities must be performed every treatment and must be captured as part of the clinical labor time. Commenters

requested that CMS add 8 minutes to the total time under the CA016 activity code (''Prepare, set-up and start IV, initial positioning and monitoring of patient''), increasing the time for this clinical activity from 6 minutes to 14 minutes.

Response: Although we appreciate the additional information supplied by the commenters, we continue to agree with the RUC's recommendation of 83 minutes of total clinical labor time. The RUC reviewed the same information provided by the commenters and concluded that this additional clinical labor time would not be typical. We also note that the recommended 83 minutes of total clinical labor time already represents an increase over the prior total time of 73 minutes for the service, with additional clinical labor time for preparing and positioning the patient as well as completing post-procedure forms. We believe that the typical clinical labor activities for HCPCS code G0166 are captured in the RUC-recommended clinical labor time.

After considering the comments, we are finalizing the RUC-recommended preservice period, service period, and postservice period clinical labor times for HCPCS code G0166 along with our proposal to replace the CA010 clinical labor time with an equivalent 3 minutes of CA023 clinical labor time. We are also finalizing updates in the price of the EQ012 equipment and the SD341 and SD342 supply packages, along with updates to the supply quantity for the two supply packages.

(53) Molecular Pathology Interpretation (HCPCS Code G0452)

At the October 2018 RUC meeting, the Relativity Assessment Workgroup (RAW) identified HCPCS code G0452 (*Molecular pathology procedure; physician interpretation and report*) as potentially misvalued on a CMS/Other screen. The RUC had never reviewed HCPCS code G0452 and assumptions regarding work and time were based upon a 1995 vignette. In addition, the specialty society noted that the technology available for furnishing the service, as well as the patient population receiving the service, had changed since the code was valued by CMS.

The RUC requested a physician work survey be completed for the October 2019 RUC meeting. It was during the October meeting that the work and PE values for HCPCS code G0452 were reviewed and recommended.

For CY 2021, we proposed the RUC-recommended work RVU of 0.93 and the RUC-recommended direct PE inputs for HCPCS code G0452.

We received several public comments on Molecular Pathology Interpretation (HCPCS code G0452) all in support of our proposal to adopt the RUC's recommendations for the service.

After consideration of the comments, we are finalizing the work RVU and direct PE inputs as proposed.

(54) Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS Codes G2082 and G2083)

In the CY 2020 PFS final rule (84 FR 63102 through 63104), we issued an interim final rule with comment period (IFC) to establish coding and payment for E/M, observation, and the provision of self-administered Esketamine to facilitate beneficiary access to care for treatment-resistant depression as efficiently as possible. We created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020 on an interim final basis. For CY 2020, we established RVUs for these services that reflect the relative resource costs associated with the E/M, observation and provision of the self-administered esketamine product. The HCPCS G-codes are described as follows: HCPCS code G2082 (*Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation*) and HCPCS code G2083 (*Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation*).

In developing the interim final values for these codes, we used a building block methodology that sums the values associated with several codes. For the overall E/M and observation elements of the services, we incorporated the work RVUs, work time and direct PE inputs associated with a level two office/outpatient visit for an established patient, CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 10 minutes are spent face-to-face with the patient and/or family*), which has a work RVU of 0.48 and a total work time of 16 minutes, which is based on a pre-service evaluation time of 2 minutes, an intraservice time of 10 minutes, and a postservice time of 4 minutes.

We also incorporated CPT codes 99415 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; first hour (List separately in addition to code for outpatient Evaluation and Management service)*) and 99416 (*Prolonged clinical staff service (the service beyond the typical service time) during an evaluation and management service in the office or outpatient setting, direct patient contact with physician supervision; each additional 30 minutes (List separately in addition to code for prolonged service)*)) in which neither code has a work RVU, but includes direct PE inputs reflecting the prolonged time for clinical staff under the direct supervision of the billing practitioner.

In addition, to account for the cost of the provision of the self-administered esketamine as a direct PE input, we incorporated the wholesale acquisition cost (WAC) data from the most recent available quarter. For HCPCS code G2082, we used a price of $590.02 for the supply input that describes 56 mg (supply code SH109) and for HCPCS code G2083, we used a price of $885.02 for the supply input describing 84 mg of esketamine (supply code SH110).

We sought comment on the interim final values we established for HCPCS codes G2082 and G2083, including the assigned work RVUs, work times, and direct PE inputs. See the CY 2021 PFS proposed rule (85 FR 50169 through 50172) for a summary of the comments we received and our responses.

After considering the comments we received, we proposed to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that sums the values associated with several codes. For the overall E/M and observation elements of the services, we incorporated the work RVUs, work time and direct PE inputs associated with a level two office/outpatient visit for an established patient, CPT code 99212. We also proposed to include the clinical labor for CPT codes 95076 and 95079 (in lieu of CPT codes 99415 and 99416 as detailed earlier); and to account for the

cost of the provision of the self-administered esketamine as a direct PE input, we proposed to incorporate the wholesale acquisition cost (WAC) data from the most recent available quarter. We solicited comment on this updated payment proposal and valuation of HCPCS code G2082 and G2083.

We received public comments on the Evaluation and Management, Observation and Provision of Self-Administered Esketamine (HCPCS Codes G2082 and G2083). The following is a summary of the comments we received and our responses.

Comment: Overall, commenters were in support of our proposal to refine the values for HCPCS codes G2082 and G2083.

Response: We appreciate the support for our proposal to refine the direct PE inputs of HCPCS codes G2082 and G2083, in part, by using the clinical labor time for CPT codes 95076 and 95079, in lieu of the clinical labor time of CPT codes 99415 and 99416, which increased the clinical labor time from 30 minutes to 150 minutes.

Comment: A commenter stated that administering esketamine may on occasion necessitate a higher level of E/M from the physician, and therefore, encouraged CMS to provide the ability to bill a separate E/M service on those occasions where medical necessity dictates a higher level of service. The commenter also requested that CMS issue a J-code specifically for esketamine treatment and create a HCPCS code that separates the clinical work of the service from the cost of the medication.

Response: HCPCS codes G2082 and G2083 are bundled services that include, as discussed in the CY 2021 PFS proposed rule (85 FR 50169 through 50172), the E/M, observation and the provision of self-administered esketamine. We continue to believe that HCPCS codes G2082 and G2083 should be a bundled services. We do not believe it would be appropriate to create a J-code that could permit esketamine to be billed separately, particularly given that the product is only available through a restricted distribution system under a REMS; patients must be monitored by a health care provider for at least 2 hours after receiving their Spravato dose; the prescriber and patient must both sign a Patient Enrollment Form; and the product will only be administered in a certified medical office where the health care provider can monitor the patient.[24] Additionally, we continue to believe that the building block methodology we used incorporating CPT code 99212 is appropriate for valuing this service. Since HCPCS codes G2082 and G2083 already take into account E/M provided as part of these services, it would be duplicative for a clinician to bill for a separate E/M code along with HCPCS codes G2082 and G2083. We believe the direct PE input refinements made for HCPCS codes G2082 and G2083, which increased the clinical labor time to 150 minutes, are appropriate for the necessary observation associated with esketamine administration. However, other reasonable and necessary E/M services may be furnished and billed for a patient on dates before and after HCPCS codes G2082 and G2083, for example, when the services are furnished in the course of treating and diagnosing treatment-resistant depression. Additionally, the self-administered esketamine is considered a supply item for this bundled service. Therefore, esketamine cannot be billed separately along with HCPCS codes G2082 and G2033 under the PFS.

After consideration of public comments, we are finalizing our proposal to refine the values for HCPCS codes G2082 and G2083 using a building block methodology that sums the values associated with several codes.

(55) Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088)

In the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD). The codes and descriptors we finalized for CY 2020 were:

- HCPCS code G2086: *Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code G2087: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code G2088: *Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

As noted in the CY 2020 PFS final rule (84 FR 62673), if a patient's treatment involves MAT, this bundled payment would not include payment for the medication itself. Billing and payment for medications under Medicare Part B or Part D would remain unchanged.

As discussed in the CY 2021 PFS proposed rule (85 FR 50172), we received requests to expand these bundled payments to be inclusive of other SUDs, not just OUD. We agreed that doing so could expand access to needed care. We proposed to expand these bundled payments to be inclusive of all SUDs. To accomplish this, we proposed to revise the code descriptors for HCPCS codes G2086, G2087, and G2088 by replacing ''opioid use disorder'' with ''a substance use disorder.'' The payment and billing rules would otherwise remain unchanged. We noted that HCPCS codes G2086, G2087, and G2088 were added to the Medicare Telehealth list in the CY 2020 PFS final rule (84 FR 62628). The revised code descriptors are:

- HCPCS code G2086: *Office-based treatment for a substance use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- HCPCS code G2087: *Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- HCPCS code G2088: *Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

In addition, in the CY 2020 PFS final rule we stated that we anticipated that the services described by HCPCS codes G2086, G2087, and G2088 would often be billed by addiction specialty practitioners, but note that these codes are not limited to any particular physician or NPP specialty. We also noted that consultation was not a required condition of payment for these codes, but that consultation with a specialist could be counted toward the minutes required for billing HCPCS codes G2086, G2087, and G2088 (84 FR 62674). Although it is not a requirement for billing the code, we encouraged that practitioners consult with specialists in cases where it is warranted and refer the patient to specialty care as needed.

[24] *https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.*

We noted that while these codes describe treatment for any SUD, information about which specific SUDs are being treated would provide valuable information that can help assess local, state, and national trends and needs. We believe it is important that the diagnosis codes listed on the claim form reflect all SUDs being treated; however, we also noted that we do not wish to add any additional burden on practitioners related to claims submission, and therefore, we solicited information on whether there are sources of data we could explore in order to provide this information. We also solicited information on whether there are differences in the resource costs associated with furnishing services for the various SUDs, and accordingly whether there is a need for more stratified coding to describe these services. We noted that in some instances, the CPT Editorial Panel has created CPT codes to replace G codes created by CMS, and that we welcomed such input on those services.

We received public comments on the proposal to expand these bundled payments to be inclusive of all SUDs. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported this proposal. Some noted that this flexibility would permit practitioners to furnish comprehensive services for individuals with SUDs, the majority of whom have polysubstance use disorder. One commenter noted that every service code can have one or more diagnosis codes connected to it on a claim, therefore, a generic SUD treatment code still permits physicians to specify which SUDs were treated, allowing CMS to track that information without adding additional administration burden. Some commenters also stated they were not aware of any significant variation in resource costs between SUDs. One stakeholder encouraged CMS to work with the medical societies through the CPT Editorial Panel process to examine the different resource costs involved in treating different SUDs to determine the need for more stratified coding, but advised that in the meantime, CMS should finalize the proposal to ensure that more patients have access to these critical services. A few commenters suggested that these codes should account for risk stratification, noting that some patients, such as pregnant or postpartum women have more complex needs and require more frequent services. One commenter stated that expanding the use of these codes to all SUD diagnoses may present opportunity for fraudulent, duplicative coding, were providers to bill the codes for each SUD diagnosis, noting that many patients with SUD use multiple substances and require treatment for more than one substance, therefore, the commenter recommended that CMS limit billing of these codes to once per month per patient.

Response: We thank the commenters for their feedback. After consideration of the comments, we are finalizing our proposal to expand the bundled payments described by HCPCS codes G2086–G2088 to be inclusive of all SUDs. We appreciate the commenter that pointed out that duplicative billing could occur in cases where a beneficiary is being treated for more than one SUD. We agree that HCPCS codes G2086–G2088 should not be billed more than once per month per beneficiary since these codes describe treatment for one or more SUDs. Additionally, we welcome the opportunity to work with the medical societies and CPT Editorial Panel to determine whether there is a need to stratify this coding to reflect variation in service intensity, through future rulemaking.

(56) Initiation of Medication Assisted Treatment (MAT) in the Emergency Department (HCPCS Code G2213)

In the CY 2020 PFS proposed rule (84 FR 40545), we sought comment on the use of medication assisted treatment (MAT) in the emergency department (ED) setting, including initiation of MAT and the potential for either referral or follow-up care, to better understand typical practice patterns to help inform whether we should consider making separate payment for such services in future rulemaking. We noted that the term MAT generally refers to treatment of OUD that includes both an FDA-approved medication for the treatment of OUD and behavioral/psychosocial treatment, but that care provided in the ED typically would include medication for the treatment of OUD and referral or linkage to primary care or a hospital-based bridge clinic for continuation of medication and potentially other services, including counseling and other psychosocial services.

The public comments received in response to the comment solicitation were supportive of us making a proposal, several citing research that indicates improved outcomes for patients who initiate medications for the treatment of OUD in the ED. One commenter noted that by implementing this treatment regimen, practitioners can address a patient's immediate withdrawal symptoms, which allows time to coordinate care and provide a referral to substance use disorder specialists and other community resources who can appropriately carry out long-term treatment. Another commenter cited that the national rate of overdose-related visits seen in EDs nearly doubled between 2005 and 2014 and noted that hospital-based care represents a critical opportunity to initiate treatment and connect patients with OUD to care, noting that patients who receive information about drug treatment in the hospital post-overdose are more likely to seek treatment.[25] The commenter also cited a randomized clinical trial that showed that more patients were engaged in treatment 30 days after buprenorphine was initiated in the ED and coupled with a referral, compared to interventions that did not include buprenorphine.[26] Another study found that ED induction of buprenorphine was more cost-effective than either brief intervention or referral upon discharge.[27] One commenter suggested that CMS institute a G-code to address this coding gap in the short term, while a more permanent solution is pursued to address this site-of-service specification.

We were persuaded by the comments received in response to our comment solicitation that this work is not currently accounted for in the existing code set. To account for the resource costs involved with initiation of medication for the treatment of opioid use disorder in the ED and referral for follow-up care, we proposed to create one add-on G-code to be billed with E/M visit codes used in the ED setting. We discussed that this code would include payment for assessment, referral to ongoing care, follow-up after treatment begins, and arranging access to supportive services, but we note that the drug itself would be paid separately. We proposed the following code:

- HCPCS code GMAT1: *Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive*

[25] Agency for Healthcare Research and Quality, ''Statistical Brief #219: Opioid-Related Inpatient Stays and Emergency Department Visits by State, 2009–2014,'' (2017), *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.pdf*.

[26] Gail D'Onofrio et al., ''Emergency Department—Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence Randomized Clinical Trial,'' *JAMA* 16, no. 313 (2015): 2002–2010, *https://www.ncbi.nlm.nih.gov/pubmed/25919527*.

[27] Susan Busch et al., ''Cost Effectiveness of Emergency Department—Initiated Treatment for Opioid Dependence,'' *Journal of Addiction* 11, no. 112 (2017), *https://www.ncbi.nlm.nih.gov/pubmed/28815789*.

services (List separately in addition to code for primary procedure).

To price this service, we proposed to use a direct crosswalk to the work and direct PE inputs for HCPCS code G0397 (*Alcohol/subs interv >30 min*), which is assigned a work RVU of 1.30. We noted that we believe that the work and PE described by this crosswalk code is similar in nature and magnitude to the services described in HCPCS code GMAT1. We noted that unlike the requirements for reference code, we did not propose a required number of minutes to bill HCPCS code GMAT1. We welcomed comment on the proposal and whether we should consider a different valuation to account for the resource costs involved with these services.

We received public comments on our proposal to create an add-on G-code to be billed with E/M visit codes used in the ED setting. The following is a summary of the comments we received and our responses.

Comment: Commenters were very supportive of finalizing this proposal, noting that payment for this service will encourage hospitals to engage in this evidence-based practice. One commenter sought clarification on which of these elements were mandatory given that ''initiation'' of the service for patients will involve a transition of care to other health care providers and requested that CMS provide guidance on what ''follow-up'' is required of the emergency department provider given that post-initiation care is administered by the practitioner to whom the ED provider would have transitioned the patient care.

Response: We are finalizing payment for this code as proposed. We note that HCPCS code GMAT1 was a placeholder code in the proposed rule. The finalized code is HCPCS code G2213 (*Initiation of medication for the treatment of opioid use disorder in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (List separately in addition to code for primary procedure)*). In response to the request for clarification about which elements are required in order to bill for this code, practitioners should furnish only those activities that are clinically appropriate for the beneficiary that is being treated.

(57) Percutaneous Creation of an Arteriovenous Fistula (AVF) (HCPCS Codes G2170 and G2171)

We received a comment in response to the CY 2020 PFS proposed rule (84 FR 40481), as well as inquiries from stakeholders, requesting that we establish new coding for the percutaneous creation of an arteriovenous fistula (AVF) used for dialysis access.

For CY 2019, based on two new technology applications for arteriovenous fistula creation, we established two new HCPCS codes to describe the two modalities of this service. Specifically, we established HCPCS code C9754 (*Creation of arteriovenous fistula, percutaneous; direct, any site, including all imaging and radiologic supervision and interpretation, when performed and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization, when performed)*) and HCPCS code C9755 (*Creation of arteriovenous fistula, percutaneous using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed*). The HCPCS codes were created for institutional payment systems, and thus do not allow for payment for the physician's work portion of the service. Stakeholders have stated that the lack of proper coding to report the physician work associated with these procedures is problematic, as physicians are either billing an unlisted procedure code, or are billing other CPT codes that do not appropriately reflect the resource cost associated with the physician work portion of the service. Stakeholders stated that separate coding for physician payment will allow billing when the procedures are furnished in either a physician office or an institutional setting, and be paid under the respective payment systems, as appropriate. We have recognized that the lack of appropriate coding for this critical physician's service has become an even greater burden given the PHE for COVID–19. In order to mitigate potential health risks to beneficiaries, physicians and practitioners as a result of having this procedure performed in an institutional setting, we created two HCPCS G codes for percutaneous creation of an arteriovenous fistula (AVF). The codes are contractor priced and effective July 1, 2020. This will allow for more accurate billing and coding of a crucial physician service that could then be performed in both institutional and office settings, thus mitigating unnecessary risk to beneficiaries, physicians and practitioners caused by disease transmission. The HCPCS G codes are described as follows:

- HCPCS G code G2170 (*Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed.*)
- HCPCS G code G2171 (*Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, when performed) and fistulogram(s), angiography, venography, and/or ultrasound, with radiologic supervision and interpretation, when performed.*)

We proposed to maintain contractor pricing for these HCPCS codes for CY 2021, however, we also solicited information from stakeholders on the resource costs involved in furnishing the services described by HCPCS codes G2170 and G2171 to ensure proper payment for these physician's services, for consideration in future rulemaking. We noted that under the OPPS these services are assigned to APC 5193, which for CY 2020 has an assigned payment rate of $15,938.20.

We received public comments on Percutaneous Creation of an Arteriovenous Fistula (AVF) (HCPCS code G2170 and G2171).

The following is a summary of the comments we received and our responses.

Comment: Commenters stated that they were supportive of the creation of the HCPCS codes G2170 and G2171. Many commenters stated that they believe this will increase access for beneficiaries by allowing this service to be performed in outpatient settings. Commenters were also appreciative of the creation of these codes for use during the PHE.

Response: We appreciate the commenters' support of the creation of HCPCS codes G2170 and G2171.

Comment: A few commenters stated that they did not understand the logic of our proposal to contractor price HCPCS codes G2170 and G2171 to avoid disease transmission.

Response: We believe that our statement about reduced risk of disease transmission in connection with our proposal to maintain contractor pricing

for calendar year 2021 for HCPCS codes G2170 and G2171 may have been confusing to some commenters. We created HCPCS codes G2170 and G2171 to facilitate provision of these services outside of institutional facility settings. We stated that expanded access to this service outside of facility settings, especially in light of the PHE for COVID–19, could reduce the potential health risks to beneficiaries, physicians and other health care practitioners that could occur when these services are furnished in higher acuity health care settings. The proposal to contractor price these services was not related to risks of disease transmission.

Comment: Commenters stated that they believe HCPCS codes G2170 and G2171 should be nationally priced for calendar year 2021 and beyond. The commenters stated that they believe contractor pricing creates unnecessary variability and unreliable payment.

Response: CMS routinely contractor prices new HCPCS codes. The services described by G2170 and G2171 are new technology and are just beginning to be performed outside of the facility setting. As such, we anticipate collecting more information for purposes of national pricing. We expect to take these comments into consideration for future rulemaking and we hope to continue a dialogue with stakeholders on these important services.

Comment: A few commenters stated that they are displeased with the publication of a proposed Local Coverage Determination (LCD) that would limit coverage for these services.

Response: We appreciate the concern of some commenters regarding a proposed LCD for HCPCS codes G2170 and G2171. We did not address coverage policies for these services in the proposed rule. Such local coverage policies are not within the scope of the CY 2021 PFS rulemaking process.

Comment: A few commenters responded to our request for information from stakeholders on the resource costs involved in furnishing the services described by HCPCS codes G2170 and G2171 for consideration in future rulemaking. Some commenters submitted invoices for various equipment as well as a breakdown of their estimated supply and clinical staff costs.

Response: We appreciate the information commenters provided on the resource costs involved in furnishing these services. We will take this information into consideration for future rulemaking.

After consideration of these public comments, we are finalizing our proposals for HCPCS codes G2170 and G2171 with contractor pricing as proposed, and will consider addressing national pricing through potential future rulemaking.

(58) Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System (Category III CPT Codes 0446T, 0447T, and 0448T)

Category III CPT codes 0446T, 0447T, and 0448T describe the services related to the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor from subcutaneous pocket, in a subcutaneous pocket via incision. The implantable interstitial glucose sensors are part of systems that can allow real-time glucose monitoring, provides glucose trend information, and signal alerts for detection and prediction of episodes of low blood glucose (hypoglycemia) and high blood glucose (hyperglycemia). The codes that describe the implantation, removal, and removal and implantation of implantable interstitial glucose sensors are currently contractor-priced.

- Category III CPT code 0446T (*Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training*);
- Category III CPT code 0447T (*Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision*); and
- Category III CPT code 0448T (*Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation*).

In the CY 2020 PFS final rule (84 FR 62627), we requested information from stakeholders to ensure proper payment for this important physician's service and welcomed recommendations on appropriate valuation for these services to be considered in future rulemaking.

We proposed to establish national payment amounts for the codes describing the insertion, removal, and removal and insertion of an implantable interstitial glucose sensor, effective January 1, 2021. We proposed a work RVU of 1.14 for Category III CPT code 0446T, a work RVU of 1.34 for Category III CPT code 0447T, and work RVU of 1.91 for Category III CPT code 0448T based on a crosswalk to the work RVUs, work time, and direct PE inputs of CPT codes 11981 (*Insertion, non-biodegradable drug delivery implant*), 11982 (*Removal, non-biodegradable drug delivery implant*), and 11983 (*Removal with reinsertion, non-biodegradable drug delivery implant*), respectively, due to the similar clinical nature of these procedures.

We also proposed to include one supply and one equipment item to the direct PE inputs crosswalked from CPT codes 11981–11983. We added a new ''implantable interstitial glucose sensor'' (supply code SD334) for Category III CPT codes 0446T and 0448T to include the supply costs of the ''implantable interstitial glucose sensor'' (supply code SD334) included in these procedures, which we proposed to price at $1,500.00, based on information we received from stakeholders. We also proposed to include the smart transmitter associated with the use of this implantable interstitial glucose sensor. We proposed to price the smart transmitter involved in furnishing this service by using a similar equipment item finalized in the CY 2019 PFS final rule (83 FR 59624) as a proxy, the ''heart failure patient physiologic monitoring equipment package'' (EQ392); the EQ392 has a price of $1,000.00, and is similarly used for long term remote monitoring of patients. We proposed to use the EQ392 equipment as a proxy for the valuation of the smart transmitter associated with the implantable interstitial glucose sensor, to which we are assigning a time of 25,920 minutes for EQ392 in Category III CPT codes 0446T and 0448T. We explained that this time is derived from 60 minutes per hour times 24 hours per day times 90 days per billing quarter, divided by 1 minute of equipment use out of every 5 minutes of time. We did not include the implantable interstitial glucose sensor or the EQ392 equipment proxy for Category III CPT code 0447T, as it describes only a removal procedure.

We solicited comment on the proposed values for these Category III CPT codes (0446T, 0447T, and 0448T), and we solicited comment on the appropriateness and accuracy of the proposed work RVUs, work times, and direct PE inputs.

We received public comments on the Insertion, Removal, and Removal and Insertion of Implantable Interstitial Glucose Sensor System code family. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the proposed work RVUs for the Category III CPT codes, 1.14 for Category III CPT code 0446T, 1.34 for Category III CPT code 0447T, and 1.91 for Category III CPT code 0448T.

Response: We appreciate the support for the proposed work RVUs for these Category III CPT codes (0446T, 0447T, and 0448T).

Comment: Several commenters stated that they agreed with the inclusion of

the ''implantable interstitial glucose sensor'' supply (SD334) for Category III CPT codes 0446T and 0448T, which should include the supply costs of the implantable interstitial glucose sensor at the proposed price of $1,500.00. However, the commenters stated that the cost of the smart transmitter equipment (EQ392) associated with the use of the implantable interstitial glucose sensor should be included only for Category III CPT code 0446T and not be included as part of the cost of Category III CPT code 0448T. A commenter stated that the 90-day implantable sensor will be implanted for the first time and linked to the transmitter device in the first procedure, Category III CPT code 0446T. The commenter stated that there is no need to report the cost of the transmitter with Category III CPT 0448T as the sensor will be removed and replaced, but the patient will not receive a new smart transmitter during this visit.

Response: We appreciate the additional information supplied by the commenter regarding the use of the smart transmitter equipment in Category III CPT codes 0446T and 0448T. Given that there is no need to report the cost of the transmitter with Category III CPT 0448T because the sensor will be removed and replaced, but the patient will not receive a new smart transmitter during this visit, we are finalizing the removal of the heart failure patient physiologic monitoring equipment package (EQ392) from Category III CPT code 0448T.

After consideration of public comments, we are finalizing the work RVUs as proposed for Category III CPT codes 0446T, 0447T, and 0448T, and finalizing the direct PE inputs as proposed except that we are removing the equipment package (EQ392) from the Category III CPT code 0448T in response to comments as explained above.

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TABLE 28: CY 2021 Work RVUs for New, Revised, and Potentially Misvalued Codes

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	0.00	1.14	1.14	Yes
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision	0.00	1.34	1.34	Yes
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	0.00	1.91	1.91	Yes
10004	Fine needle aspiration biopsy, without imaging guidance; each additional	0.80	0.80	0.80	No
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	1.46	1.46	1.46	No
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion	1.00	1.00	1.00	No
10007	Fine needle aspiration biopsy, including fluoroscopic guidance; first lesion	1.81	1.81	1.81	No
10008	Fine needle aspiration biopsy, including fluoroscopic guidance; each additional lesion	1.18	1.18	1.18	No
10009	Fine needle aspiration biopsy, including CT guidance; first lesion	2.26	2.26	2.26	No
10010	Fine needle aspiration biopsy, including CT guidance; each additional lesion	1.65	1.65	1.65	No
10011	Fine needle aspiration biopsy, including MR guidance; first lesion	C	C	C	No
10012	Fine needle aspiration biopsy, including MR guidance; each additional lesion	C	C	C	No
10021	Fine needle aspiration biopsy, without imaging guidance; first lesion	1.03	1.03	1.03	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
11960	Insertion of tissue expander(s) for other than breast, including subsequent expansion	11.49	11.49	11.49	No
11970	Replacement of tissue expander with permanent implant	8.01	7.49	7.49	No
11971	Removal of tissue expander without insertion of implant	3.41	6.50	7.02	No
19307	Mastectomy, modified radical, including axillary lymph nodes, with or without pectoralis minor muscle, but excluding pectoralis major muscle	18.23	17.99	17.99	No
19316	Mastopexy	11.09	11.09	11.09	No
19318	Breast reduction	16.03	16.03	16.03	No
19325	Breast augmentation with implant	8.64	8.12	8.12	No
19328	Removal of intact breast implant	6.48	6.92	7.44	No
19330	Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)	8.54	9.00	9.00	No
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)	13.99	10.48	10.48	No
19342	Insertion or replacement of implant on separate day from mastectomy	12.63	10.48	10.48	No
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)	18.50	14.84	14.84	No
19370	Revision of peri-implant capsule, breast, including capsulotomy, capsulorrhaphy, and/or partial capsulectomy	9.17	9.17	9.17	No
19371	Peri-implant capsulectomy, breast, complete, including removal of all intra-capsular contents	10.62	9.98	9.98	No
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in	10.41	11.17	11.17	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	implant-based reconstruction)				
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	20.72	19.60	19.60	No
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	20.72	19.60	19.60	No
28820	Amputation, toe; metatarsophalangeal joint	5.82	3.51	3.51	No
28825	Amputation, toe; interphalangeal joint	5.37	3.41	3.41	No
29822	Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])	7.60	7.03	7.03	No
29823	Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies])	8.36	7.98	7.98	No
30468	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s)	NEW	2.80	2.80	No
32408	Core needle biopsy, lung or mediastinum, percutaneous, including imaging guidance, when performed	NEW	3.18	3.18	No
33741	Transcatheter atrial septostomy (TAS) for	NEW	14.00	14.00	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	congenital cardiac anomalies to create effective atrial flow, including all imaging guidance by the proceduralist, when performed, any method (e.g., Rashkind, Sang-Park, balloon, cutting balloon, blade)				
33745	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (e.g., atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); initial intracardiac shunt	NEW	20.00	20.00	No
33746	Transcatheter intracardiac shunt (TIS) creation by stent placement for congenital cardiac anomalies to establish effective intracardiac flow, all imaging guidance by the proceduralist when performed, left and right heart diagnostic cardiac catherization for congenital cardiac anomalies, and target zone angioplasty, when performed (e.g., atrial septum, Fontan fenestration, right ventricular outflow tract, Mustard/Senning/Warden baffles); each additional intracardiac shunt location	NEW	8.00	8.00	No
33990	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, arterial access only	7.90	6.75	6.75	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
33991	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; left heart, both arterial and venous access, with transseptal puncture	11.63	8.84	8.84	No
33992	Removal of percutaneous left heart ventricular assist device, arterial or arterial and venous cannula(s), separate and distinct session from insertion	3.75	3.55	3.55	No
33993	Repositioning of percutaneous right or left heart ventricular assist device, with imaging guidance, at separate and distinct session from insertion	3.26	3.10	3.10	No
33995	Insertion of ventricular assist device, percutaneous, including radiological supervision and interpretation; right heart, venous access only	NEW	6.75	6.75	No
33997	Removal of percutaneous right heart ventricular assist device, venous cannula, separate and distinct session from insertion	NEW	3.00	3.00	No
43239	Esophagogastroduodenoscopy, flexible, transoral; with biopsy, single or multiple	2.39	2.39	2.39	No
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique	4.57	4.57	4.57	No
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance	NEW	17.73	17.73	No
57282	Colpopexy, vaginal; extra-peritoneal approach (sacrospinous, iliococcygeus)	7.97	11.63	11.63	No
57283	Colpopexy, vaginal; intra-peritoneal approach (uterosacral, levator myorrhaphy)	11.66	11.66	11.66	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
57425	Laparoscopy, surgical, colpopexy (suspension of vaginal apex)	17.03	17.03	17.03	No
57465	Computer-aided mapping of cervix uteri during colposcopy, including optical dynamic spectral imaging and algorithmic quantification of the acetowhitening effect	NEW	0.81	0.81	No
67028	Intravitreal injection of a pharmacologic agent (separate procedure)	1.44	1.44	1.44	No
69705	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); unilateral	NEW	3.00	3.00	No
69706	Nasopharyngoscopy, surgical, with dilation of eustachian tube (i.e., balloon dilation); bilateral	NEW	4.27	4.27	No
70030	Radiologic examination, eye, for detection of foreign body	0.17	0.18	0.18	No
70450	Computed tomography, head or brain; without contrast material	0.85	0.85	0.85	No
70460	Computed tomography, head or brain; with contrast material	1.13	1.13	1.13	No
70470	Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections	1.27	1.27	1.27	No
71250	Computed tomography, thorax, diagnostic; without contrast material	1.16	1.08	1.08	No
71260	Computed tomography, thorax, diagnostic; with contrast material(s)	1.24	1.16	1.16	No
71270	Computed tomography, thorax, diagnostic; without contrast material, followed by contrast material(s) and further sections	1.38	1.25	1.25	No
71271	Computed tomography, thorax, low dose for lung cancer screening, without contrast material(s)	NEW	1.08	1.08	No
74300	Cholangiography and/or pancreatography; intraoperative, radiological supervision and interpretation	0.36	0.27	0.27	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
74328	Endoscopic catheterization of the biliary ductal system, radiological supervision and interpretation	0.70	0.47	0.47	No
74329	Endoscopic catheterization of the pancreatic ductal system, radiological supervision and interpretation	0.70	0.47	0.47	No
74330	Combined endoscopic catheterization of the biliary and pancreatic ductal systems, radiological supervision and interpretation	0.90	0.56	0.56	No
75820	Venography, extremity, unilateral, radiological supervision and interpretation	0.70	1.05	1.05	No
75822	Venography, extremity, bilateral, radiological supervision and interpretation	1.06	1.48	1.48	No
75984	Change of percutaneous tube or drainage catheter with contrast monitoring (e.g., genitourinary system, abscess), radiological supervision and interpretation	0.72	0.83	0.83	No
76145	Medical physics dose evaluation for radiation exposure that exceeds institutional review threshold, including report	NEW	0.00	0.00	No
76513	Ophthalmic ultrasound, diagnostic; anterior segment ultrasound, immersion (water bath) B-scan or high resolution biomicroscopy, unilateral or bilateral	0.66	0.53	0.60	No
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day	0.00	0.00	0.00	No
77520	Proton treatment delivery; simple, without compensation	C	C	C	No
77522	Proton treatment delivery; simple, with compensation	C	C	C	No
77523	Proton treatment delivery; intermediate	C	C	C	No
77525	Proton treatment delivery; complex	C	C	C	No
90460	Immunization administration through 18	0.17	0.18	0.17	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	years of age via any route of administration, with counseling by physician or other qualified health care professional; first or only component of each vaccine or toxoid administered				
90461	Immunization administration through 18 years of age via any route of administration, with counseling by physician or other qualified health care professional; each additional vaccine or toxoid component administered	0.15	0.09	0.15	No
90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)	0.17	0.18	0.17	No
90472	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); each additional vaccine (single or combination vaccine/toxoid)	0.15	0.09	0.15	No
90473	Immunization administration by intranasal or oral route; 1 vaccine (single or combination vaccine/toxoid)	0.17	0.18	0.17	No
90474	Immunization administration by intranasal or oral route; each additional vaccine (single or combination vaccine/toxoid)	0.15	0.09	0.15	No
91200	Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report	0.27	0.21	0.21	No
92227	Imaging of retina for detection or monitoring of disease; with remote clinical staff review and report, unilateral or bilateral	0.00	0.00	0.00	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
92228	Imaging of retina for detection or monitoring of disease; with remote physician or other qualified health care professional interpretation and report, unilateral or bilateral	0.37	0.32	0.32	No
92229	Imaging of retina for detection or monitoring of disease; with point-of-care automated analysis with diagnostic report; unilateral or bilateral	NEW	0.00	C	No
92517	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP)	NEW	0.80	0.80	No
92518	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; ocular (oVEMP)	NEW	0.80	0.80	No
92519	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report; cervical (cVEMP) and ocular (oVEMP)	NEW	1.20	1.20	No
92584	Electrocochleography	0.00	1.00	1.00	No
92650	Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis	NEW	N	N	No
92651	Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report	NEW	1.00	1.00	No
92652	Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report	NEW	1.50	1.50	No
92653	Auditory evoked potentials; neurodiagnostic, with interpretation and report	NEW	1.05	1.05	No
93000	Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report	0.17	0.17	0.17	No
93005	Electrocardiogram, routine ECG with at least 12 leads; tracing only,	0.00	0.00	0.00	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	without interpretation and report				
93010	Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only	0.17	0.17	0.17	No
93224	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation by a physician or other qualified health care professional	0.52	0.39	0.39	No
93225	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; recording (includes connection, recording, and disconnection)	0.00	0.00	0.00	No
93226	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; scanning analysis with report	0.00	0.00	0.00	No
93227	External electrocardiographic recording up to 48 hours by continuous rhythm recording and storage; review and interpretation by a physician or other qualified health care professional	0.52	0.39	0.39	No
93241	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	NEW	0.50	C	No
93242	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage;	NEW	0.00	0.00	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	recording (includes connection and initial recording)				
93243	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; scanning analysis with report	NEW	0.00	C	No
93244	External electrocardiographic recording for more than 48 hours up to 7 days by continuous rhythm recording and storage; review and interpretation	NEW	0.50	0.50	No
93245	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; includes recording, scanning analysis with report, review and interpretation	NEW	0.55	C	No
93246	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; recording (includes connection and initial recording)	NEW	0.00	0.00	No
93247	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; scanning analysis with report	NEW	0.00	C	No
93248	External electrocardiographic recording for more than 7 days up to 15 days by continuous rhythm recording and storage; review and interpretation	NEW	0.55	0.55	No
93306	Echocardiography, transthoracic, real-time with image documentation (2D), includes M-mode recording, when performed, complete, with	1.50	1.46	1.46	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	spectral Doppler echocardiography, and with color flow Doppler echocardiography				
93623	Programmed stimulation and pacing after intravenous drug infusion	2.85	0.98	0.98	No
93662	Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation	2.80	1.44	1.44	No
93750	Interrogation of ventricular assist device (VAD), in person, with physician or other qualified health care professional analysis of device parameters (e.g., drivelines, alarms, power surges), review of device function (e.g., flow and volume status, septum status, recovery), with programming, if performed, and report	0.92	0.75	0.75	No
94010	Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation	0.17	0.17	0.17	No
94060	Bronchodilation responsiveness, spirometry as in 94010, pre- and post-bronchodilator administration	0.27	0.22	0.22	No
94617	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; with electrocardiographic recording(s)	0.70	0.70	0.70	No
94618	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without electrocardiographic recording(s)	0.48	0.48	0.48	No
94619	Exercise test for bronchospasm, including pre- and post-spirometry and pulse oximetry; without	NEW	0.49	0.49	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	electrocardiographic recording(s)				
94621	Cardiopulmonary exercise testing, including measurements of minute ventilation, CO2 production, O2 uptake, and electrocardiographic recordings	1.42	1.42	1.42	No
94640	Pressurized or nonpressurized inhalation treatment for acute airway obstruction for therapeutic purposes and/or for diagnostic purposes such as sputum induction with an aerosol generator, nebulizer, metered dose inhaler or intermittent positive pressure breathing (IPPB) device	0.00	0.00	0.00	No
94667	Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; initial demonstration and/or evaluation	0.00	0.00	0.00	No
94668	Manipulation chest wall, such as cupping, percussing, and vibration to facilitate lung function; subsequent	0.00	0.00	0.00	No
94669	Mechanical chest wall oscillation to facilitate lung function, per session	0.00	0.00	0.00	No
95012	Nitric oxide expired gas determination	0.00	0.00	0.00	No
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.60	0.48	0.60	No
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)	0.50	0.32	0.50	No
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient	0.65	0.48	0.65	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)	0.55	0.32	0.55	No
99072	Additional supplies, materials, and clinical staff time over and above those usually included in an office visit or other non-facility service(s), when performed during a Public Health Emergency as defined by law, due to respiratory-transmitted infectious disease.	NEW	0.00	B	No
99202	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 15-29 minutes of total time is spent on the date of the encounter	0.93	0.93	0.93	Yes
99203	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 30-44 minutes of total time is spent on the date of the encounter	1.42	1.60	1.60	Yes
99204	Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 45-59 minutes of total time is spent on the date of the encounter	2.43	2.60	2.60	No
99205	Office or other outpatient visit for the evaluation and management of a new	3.17	3.50	3.50	Yes

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 60-74 minutes of total time is spent on the date of the encounter				
99211	Office or other outpatient visit for the evaluation and management of an established patient, that may not require the presence of a physician or other qualified health care professional. Usually, the presenting problem(s) are minimal	0.18	0.18	0.18	No
99212	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using time for code selection, 10-19 minutes of total time is spent on the date of the encounter	0.48	0.70	0.70	Yes
99213	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using time for code selection, 20-29 minutes of total time is spent on the date of the encounter	0.97	1.30	1.30	No
99214	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using time for code selection, 30-39 minutes of total time is spent on the date of the encounter	1.50	1.92	1.92	Yes

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
99215	Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using time for code selection, 40-54 minutes of total time is spent on the date of the encounter	2.11	2.80	2.80	No
99417	Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each 15 minutes	NEW	0.61	I	No
99439	Chronic care management services, with the following required elements: * multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, * chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, * comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month	NEW	0.54	0.54	No
G0166	External counterpulsation, per treatment session	0.00	0.00	0.00	No
G0452	Molecular pathology procedure; physician interpretation and report	0.37	0.93	0.93	No
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of	0.48	0.70	0.70	Yes

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation				
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	0.48	0.70	0.70	Yes
G2170	Percutaneous arteriovenous fistula creation (AVF), direct, any site, by tissue approximation using thermal resistance energy, and secondary procedures to redirect blood flow (e.g., transluminal balloon angioplasty, coil embolization) when performed, and includes all imaging and radiologic guidance, supervision and interpretation, when performed	NEW	0.00	0.00	No
G2171	Percutaneous arteriovenous fistula creation (AVF), direct, any site, using magnetic-guided arterial and venous catheters and radiofrequency energy, including flow-directing procedures (e.g., vascular coil embolization with radiologic supervision and interpretation, wen performed) and fistulogram(s), angiography, enography, and/or ultrasound, with radiologic supervision and interpretation, when performed	NEW	0.00	0.00	No
G2211	Visit complexity inherent to evaluation and	NEW	0.33	0.33	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)				
G2212	Prolonged office or other outpatient evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services) "(Do not report G2212 on the same date of service as 99354, 99355, 99358, 99359, 99415, 99416). (Do not report G2212 for any time unit less than 15 minutes))	NEW	-	0.61	No
G2213	Initiation of medication assisted treatment in the emergency department setting, including assessment, referral to ongoing care, and arranging access to supportive services (List separately in addition to code for primary procedure)	NEW	1.30	1.30	No
G2214	Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of	NEW	0.77	0.77	No

HCPCS	Descriptor	CY 2020 Work RVU	Proposed CY 2021 Work RVU	Final CY 2021 Work RVU	CMS Work Time Refinement
	behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional				
G2215	Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	0.00	0.00	No
G2216	Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	NEW	0.00	0.00	No
G2250	Remote assessment of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment.	NEW	0.18	0.18	No
G2251	Brief communication technology-based service, e.g. virtual check-in, by a qualified health care professional who cannot report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to a service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of clinical discussion	NEW	0.25	0.25	No

TABLE 29: CY 2021 Direct PE Refinements

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
10005	Fna bx w/us gdn 1st les	EF015	mayo stand	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10005	Fna bx w/us gdn 1st les	EF023	table, exam	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.02
10005	Fna bx w/us gdn 1st les	EQ250	ultrasound unit, portable	NF		37	35	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.30
10007	Fna bx w/fluor gdn 1st les	ED050	Technologist PACS workstation	NF		49	47	E18: Refined equipment time to conform to established policies for PACS Workstations	-0.04
10007	Fna bx w/fluor gdn 1st les	EF015	mayo stand	NF		44	42	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10007	Fna bx w/fluor gdn 1st les	EL014	room, radiographic-fluoroscopic	NF		44	34	E2: Refined equipment time to conform to established policies for highly technical equipment	-22.75
10009	Fna bx w/ct gdn 1st les	EF015	mayo stand	NF		52	50	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
10021	Fna bx w/o img gdn 1st les	EF015	mayo stand	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	0.00
10021	Fna bx w/o img gdn 1st les	EF023	table, exam	NF		29	26	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-0.03
28820	Amputation of toe	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-3.70
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.48
28820	Amputation of toe	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.81

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Complete pre-procedure phone calls and prescription	7	3	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.48
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent	20	7	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-4.81
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Schedule space and equipment in facility	8	5	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-1.11
28825	Partial amputation of toe	L037D	RN/LPN/MTA	F	Coordinate pre-surgery services (including test results)	20	10	L8: Standard preservice clinical labor time for procedures with 0/10 day global periods	-3.70
28825	Partial amputation of toe	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	5	2	L1: Refined time to standard for this clinical labor task	-1.11
28825	Partial amputation of toe	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	5	2	L1: Refined time to standard for this clinical labor task	-1.11
67028	Injection eye drug	L038A	COMT/COT/RN/CST	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-0.76
71271	Ct thorax lung cancer scr c-	L037D	RN/LPN/MTA	NF	Coordinate post-procedure services	6	4	G1: See preamble text	-0.74
71271	Ct thorax lung cancer scr c-	L046A	CT Technologist	NF	Provide education/o	3	2	L1: Refined time to standard for this clinical labor task	-0.46

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
					btain consent				
76513	Oph us dx ant sgm us uni/bi	L038A	COMT/COT/RN/CST	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	2	G1: See preamble text	-0.38
77401	Radiation treatment delivery	ER119	Lead Room	NF		19	0	G1: See preamble text	-0.87
77401	Radiation treatment delivery	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	5	3	L1: Refined time to standard for this clinical labor task	-0.74
92229	Img rta detc/mntr ds poc aly	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	3	2	L3: Refined clinical labor time to conform with identical labor activity in other codes in the family	-0.37
93241	Ext ecg>48hr<7 d rec scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	36	31	G1: See preamble text	-1.85
93241	Ext ecg>48hr<7 d rec scan a/r	SB022	gloves, non-sterile	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-0.25

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93243	Ext ecg>48hr<7d scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	24	19	G1: See preamble text	-1.85
93245	Ext ecg>7d<15d rec scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	36	31	G1: See preamble text	-1.85
93245	Ext ecg>7d<15d rec scan a/r	SB022	gloves, non-sterile	NF		2	1	S5: Refined supply quantity to conform with other codes in the family	-0.25
93247	Ext ecg>7d<15d scan a/r	L037A	Electrodiagnostic Technologist	NF	Perform procedure/service---NOT directly related to physician work time	24	19	G1: See preamble text	-1.85
99202	Office o/p new sf 15-29 min	ED021	computer, desktop, w-monitor	NF		34	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.22
99203	Office o/p new low 30-44 min	ED021	computer, desktop, w-monitor	NF		43	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.28

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
99204	Office o/p new mod 45-59 min	ED021	computer, desktop, w-monitor	NF		54	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.35
99205	Office o/p new hi 60-74 min	ED021	computer, desktop, w-monitor	NF		67	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.43
99211	Office o/p est minimal prob	ED021	computer, desktop, w-monitor	NF		17	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.11
99212	Office o/p est sf 10-19 min	ED021	computer, desktop, w-monitor	NF		28	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.18
99213	Office o/p est low 20-29 min	ED021	computer, desktop, w-monitor	NF		36	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.23
99214	Office o/p est mod 30-39 min	ED021	computer, desktop, w-monitor	NF		51	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.33
99215	Office o/p est hi 40-54 min	ED021	computer, desktop, w-monitor	NF		62	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.40
99417	Prolng off/op e/m ea 15 min	ED021	computer, desktop, w-monitor	NF		15	0	G6: Indirect Practice Expense input and/or not individually allocable to	-0.10

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								a particular patient for a particular service	
G0166	Extrnl counterpulse, per tx	EQ012	EECP, external counterpulsation system	NF		83	80	E1: Refined equipment time to conform to established policies for non-highly technical equipment	-2.53
G0166	Extrnl counterpulse, per tx	L037D	RN/LPN/MTA	NF	Obtain vital signs	3	0	G1: See preamble text	-1.11
G0166	Extrnl counterpulse, per tx	L037D	RN/LPN/MTA	NF	Monitor patient following procedure/service, no multitasking	0	3	L1: Refined time to standard for this clinical labor task	1.11
G0166	Extrnl counterpulse, per tx	SD341	EECP compression equipment package	NF		0	0.01	G1: See preamble text	8.27
G0166	Extrnl counterpulse, per tx	SD342	EECP electrical equipment package	NF		0	0.003	G1: See preamble text	1.88
G2212	Prolong outpt/office vis	ED021	computer, desktop, w-monitor	NF		15	0	G6: Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	-0.10

TABLE 30: CY 2021 Direct PE Refinements – Equipment Refinements Conforming to Changes in Clinical Labor Time

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
28820	Amputation of toe	EF014	light, surgical	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28820	Amputation of toe	EF015	mayo stand	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28820	Amputation of toe	EF031	table, power	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
28820	Amputation of toe	EQ110	electrocautery-hyfrecator, up to 45 watts	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28820	Amputation of toe	EQ138	instrument pack, medium ($1500 and up)	NF		67	61	E15: Refined equipment time to conform to changes in clinical labor time	-0.04

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
28820	Amputation of toe	EQ235	suction machine (Gomco)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28820	Amputation of toe	EQ240	tourniquet system (Zimmer1200)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.18
28825	Partial amputation of toe	EF014	light, surgical	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28825	Partial amputation of toe	EF015	mayo stand	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
28825	Partial amputation of toe	EF031	table, power	NF		58	52	E15: Refined equipment time to conform to changes in clinical labor time	-0.10
28825	Partial amputation of toe	EQ110	electrocauter y-hyfrecator, up to 45 watts	NF		56	50	E15: Refined equipment time to conform to	-0.01

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								changes in clinical labor time	
28825	Partial amputation of toe	EQ138	instrument pack, medium ($1500 and up)	NF		67	61	E15: Refined equipment time to conform to changes in clinical labor time	-0.04
28825	Partial amputation of toe	EQ235	suction machine (Gomco)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
28825	Partial amputation of toe	EQ240	tourniquet system (Zimmer1200)	NF		56	50	E15: Refined equipment time to conform to changes in clinical labor time	-0.18
67028	Injection eye drug	ED043	refrigerator, vaccine, temperature monitor w-alarm, security mounting w-sensors, NIST certificates	NF		19	17	E15: Refined equipment time to conform to changes in clinical labor time	-0.01
67028	Injection eye drug	EL005	lane, exam (oph)	NF		19	17	E15: Refined equipment time to conform to changes in	-0.25

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
								clinical labor time	
71271	Ct thorax lung cancer scr c-	ED050	Technologist PACS workstation	NF		35	34	E15: Refined equipment time to conform to changes in clinical labor time	-0.02
92229	Img rta detc/mntr ds poc aly	ED061	camera, retinal, for remote imaging	NF		14	13	E15: Refined equipment time to conform to changes in clinical labor time	-0.06
92229	Img rta detc/mntr ds poc aly	EF030	table, motorized (for instruments-equipment)	NF		14	13	E15: Refined equipment time to conform to changes in clinical labor time	0.00
93241	Ext ecg>48hr<7d rec scan a/r	ED021	computer, desktop, w-monitor	NF		100	95	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
93243	Ext ecg>48hr<7d scan a/r	ED021	computer, desktop, w-monitor	NF		100	95	E15: Refined equipment time to conform to changes in clinical labor time	-0.03

HCPCS code	HCPCS code description	Input Code	Input code description	Nonfacility (NF) / Facility (F)	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change (in dollars)
93245	Ext ecg>7d<15d rec scan a/r	ED021	computer, desktop, w-monitor	NF		128	123	E15: Refined equipment time to conform to changes in clinical labor time	-0.03
93247	Ext ecg>7d<15d scan a/r	ED021	computer, desktop, w-monitor	NF		128	123	E15: Refined equipment time to conform to changes in clinical labor time	-0.03

TABLE 31: CY 2021 Invoices Received for Existing Direct PE Inputs

CPT/ HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
67028, 92352, 92353	phenylephrine 2.5% ophth (Mydfrin)	SH056	$3.77	$5.46	45%	2	3,080,085
76510, 76512, 76513, 76529	ultrasonic biometry, B-scan	EQ247	$14,655.63	$26,647.50	82%	2	204,408
77401	Superficial radiation therapy system	ER045	$201,875.00	$204,999.67	2%	3	206,144
91200	Fibroscan with printer	ER101	$130,425.22	$125,096.21	-4%	6	30,527
G0166	EECP, external counterpulsation system	EQ012	$120,954.23	$111,128.30	-8%	2	88,907
G2082	Esketamine (56 mg vial)	SH109	$590.02	$616.93	5%	1	0
G2083	Esketamine (84 mg vial)	SH110	$885.02	$928.38	5%	1	0
34 codes	electrosurgical generator, gastrocautery	EQ113	$11,375.00	$36,180.00	218%	4	-
90 codes	endoscope disinfector, rigid or fiberoptic, w-cart	ES005	$36,556.97	$27,500.00	-25%	3	-
254 codes	scope video system (monitor, processor, digital capture, cart, printer, LED light)	ES031	$36,306.00	$70,673.38	95%	37	-
363 codes	suction machine (Gomco)	EQ235	$779.61	$3,195.85	310%	4	-
373 codes	mask, surgical	SB033	$0.15	$0.43	181%	259	-
851 codes	mask, surgical, with face shield	SB034	$1.24	$3.40	174%	49	-

TABLE 32: CY 2021 New Invoices

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
30468	Absorabable nasal implant and delivery device	SA133	1,995.00	1	9
32408	Coaxial Biopsy Set	SC108	49.00	1	1,324
32408	Pleural Plug kit	SA132	315.00	1	1,324
37238, 37239	venous stent system	SD340	1,750.00	10	6,592
57465	computer aided spectral imaging system (colposcopy)	ER117	32,000.00	1	79
57465	digital imaging speculum	SD337	5.80	1	79
67028	povidone soln (Betadine), single-use dropper	SJ094	2.31	1	3,080,085
67028	needle, 32g	SC109	0.59	3	3,080,085
69705, 69706	kit, eustachian tube procedure	SA134	2,010.00	7	74
69705, 69706	eustachian tube balloon	SD338	83.01	8	74
76145	Radiation Dosimetry Kit	EQ401	17,182.50	2	7,178
76513	Ophthalmic Ultrasound Biomicroscope (UBM Probe)	ER118	10,995.00	1	14,581
76513	ClearScan ultrasound water-filled condom probe cover	SB055	10.50	1	14,581
77401	Lead Room	ER119	17,236.00	1	206,144
77401	Lead Blocking Shield Kit	ER120	3,348.06	1	206,144
77520, 77522, 77523, 77525	Proton Treatment Vault	ER115	19,001,914.00	1	77,768
77520, 77522, 77523, 77525	Proton Treatment Delivery System	ER116	30,400,000.00	1	77,768
92227, 92228, 92229	camera, retinal, for remote imaging	ED061	14,156.68	3	2,391
92517, 92518, 92519	VEMP module	ED062	2,000.00	1	254
92584	ECochG electrode	SD335	24.21	1	10,213
92650	AABR-automated auditory brainstem response screening system	EQ396	20,000.00	1	0
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	-	0	229,813
94619, 94617, 94010, 94060	PFT System with PC and printer	EQ397	37,527.15	1	1,688,997
95012	sensor, filter, mouthpiece, nitric oxide	SD336	10.33	10	126,914
95012	monitoring system, nitric oxide	EQ398	1,500.00	4	126,914
99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215	Portable stand-on scale	EF048	1,343.85	1	204,303,328

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
G0166	EECP compression equipment package	SD341	826.75	17	88,907
G0166	EECP electrical equipment package	SD342	752.00	1	88,907
G0452	Sequence data analytics (alignment/variant calling) and reporting software	ED063	28,800.00	1	0
	3C patch system	SD343	625.00	2	104
	Mask, N95	SD344	2.36	94	0

TABLE 33: CY 2021 No PE Refinements

HCPCS	Description
10004	Fna bx w/o img gdn ea addl
10006	Fna bx w/us gdn ea addl
10008	Fna bx w/fluor gdn ea addl
10010	Fna bx w/ct gdn ea addl
10011	Fna bx w/mr gdn 1st les
10012	Fna bx w/mr gdn ea addl
11960	Insert tissue expander(s)
11970	Rplcmt tiss xpndr perm implt
11971	Rmvl tis xpndr wo insj implt
19307	Mast mod rad
19316	Suspension of breast
19318	Breast reduction
19325	Breast augmentation w/implt
19328	Rmvl intact breast implant
19330	Rmvl ruptured breast implant
19340	Insj breast implt sm d mast
19342	Insj/rplcmt brst implt sep d
19357	Tiss xpndr plmt brst rcnstj
19370	Revj peri-implt capsule brst
19371	Peri-implt capslc brst compl
19380	Revj reconstructed breast
27130	Total hip arthroplasty
27447	Total knee arthroplasty
29822	Sho arthrs srg lmtd dbrdmt
29823	Sho arthrs srg xtnsv dbrdmt
30468	Rpr nsl vlv collapse w/implt
32408	Core ndl bx lng/med perq
33741	Tas congenital car anomal
33745	Tis crtj cgen car anomal 1st
33746	Tis crtj cgen car anomal ea
33990	Insj perq vad l hrt arterial
33991	Insj perq vad l hrt artl&ven
33992	Rmvl perq left heart vad
33993	Reposg perq r/l hrt vad
33995	Insj perq vad r hrt venous
33997	Rmvl perq right heart vad
43239	Egd biopsy single/multiple
45385	Colonoscopy w/lesion removal
55880	Abltj mal prst8 tiss hifu
57282	Colpopexy extraperitoneal
57283	Colpopexy intraperitoneal
57425	Laparoscopy surg colpopexy
57465	Cam cervix uteri drg colp
69705	Nps surg dilat eust tube uni
69706	Nps surg dilat eust tube bi
70030	X-ray eye for foreign body
70450	Ct head/brain w/o dye
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
71250	Ct thorax dx c-
71260	Ct thorax dx c+
71270	Ct thorax dx c-/c+
75820	Vein x-ray arm/leg
75822	Vein x-ray arms/legs
75984	Xray control catheter change
76145	Med physic dos eval rad exps
77520	Proton trmt simple w/o comp
77522	Proton trmt simple w/comp
77523	Proton trmt intermediate
77525	Proton treatment complex
91200	Liver elastography
92227	Img rta detcj/mntr ds staff
92228	Img rta detc/mntr ds phy/qhp
92517	Vemp test i&r cervical
92518	Vemp test i&r ocular
92519	Vemp tst i&r cervical&ocular
92584	Electrocochleography
92650	Aep scr auditory potential
92651	Aep hearing status deter i&r
92652	Aep thrshld est mlt freq i&r
92653	Aep neurodiagnostic i&r
93000	Electrocardiogram complete
93005	Electrocardiogram tracing
93010	Electrocardiogram report
93224	Ecg monit/reprt up to 48 hrs
93225	Ecg monit/reprt up to 48 hrs
93226	Ecg monit/reprt up to 48 hrs
93227	Ecg monit/reprt up to 48 hrs
93242	Ext ecg>48hr<7d recording
93244	Ext ecg>48hr<7d rev&interpj
93246	Ext ecg>7d<15d recording
93248	Ext ecg>7d<15d rev&interpj
93306	Tte w/doppler complete
93750	Interrogation vad in person
94010	Breathing capacity test
94060	Evaluation of wheezing
94617	Exercise tst brncspsm w/ecg
94618	Pulmonary stress testing
94619	Exercise tst brncspsm wo ecg
94621	Cardiopulm exercise testing
94640	Airway inhalation treatment
94667	Chest wall manipulation
94668	Chest wall manipulation
94669	Mechanical chest wall oscill
95012	Exhaled nitric oxide meas
99439	Chrnc care mgmt svc ea addl
G0452	Molecular pathology interpr

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I. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 PFS final rule (84 FR 62630 through 62677), we implemented coverage requirements and established new codes describing the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. We are monitoring Medicare enrollment by OTPs and utilization of the new benefit to ensure that Medicare beneficiaries have appropriate access to care. For CY 2021, we proposed several refinements and also provided clarification of certain issues that stakeholders have brought to our attention.

2. Definition of OUD Treatment Services

In the CY 2020 PFS final rule (84 FR 62631 through 62635), we finalized a definition of ''OUD treatment services'' that reflects the statutory definition in section 1861(jjj)(1)(A) of the Act, which defines covered OUD treatment services to include oral, injected, and implanted opioid agonist and antagonist treatment medications approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act (FFDCA) for use in the treatment of OUD. There are three drugs currently approved by FDA for the treatment of opioid dependence: Buprenorphine; methadone; and naltrexone. In the CY 2020 PFS final rule, we noted that we had received comments supporting the proposed definition of OUD treatment services but also requesting that CMS include naloxone to treat opioid overdose in that definition as a medication used in treatment of OUD. Although we did not finalize including naloxone in the definition of OUD treatment services in that final rule, we indicated that as we continue to work on refining this new Medicare benefit, we would consider including additional drugs in the definition of OUD treatment services under our discretionary authority in section 1861(jjj)(1)(F) of the Act to include other items and services the Secretary determines are appropriate. As explained in the CY 2021 PFS proposed rule (85 FR 50203), we determined, after further consideration, that it would be appropriate to propose to extend the definition of OUD treatment services to include opioid antagonist medications, such as naloxone, that are approved by FDA under section 505 of the FFDCA for emergency treatment of opioid overdose.

Naloxone is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.[28] [29] Naloxone should be given to a person who shows signs of an opioid overdose or when an overdose is suspected. FDA-approved naloxone products for overdose reversal are effective in reversing opioid overdose, including fentanyl-involved opioid overdoses, although overdoses involving potent (for example, fentanyl) or large quantities of opioids may require higher-than-normal doses of naloxone or repeated administration to reverse overdose.[30]

Naloxone attaches to opioid receptors and reverses and blocks the effects of other opioids.[31] FDA has approved injectable naloxone, intranasal naloxone, and naloxone auto-injector as emergency treatments for opioid overdose. The nasal spray is a prefilled, needle-free device that requires no assembly and can deliver a single dose into each nostril with two sprays. The auto-injector is injected into the outer thigh to deliver naloxone to the muscle (intramuscular). Both the nasal spray and naloxone auto-injector are packaged in a carton containing two doses to allow for repeat dosing if needed.[32] [33] These forms of naloxone can easily be administered by persons who do not have medical training and they may be prescribed to a patient who is receiving medication-assisted treatment (MAT) for OUD, especially if the patient is considered to be at risk for opioid overdose.[34] However, it is important to understand how to administer naloxone properly. A doctor or pharmacist can show patients, their family members, or caregivers how to administer naloxone.[35] We expect that a treating practitioner that is prescribing naloxone will also educate the patient, as appropriate, on how to administer the specific form of naloxone prescribed.

The U.S. Surgeon General Jerome M. Adams, M.D., M.P.H. has released a public health advisory stating that, ''Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities. Therefore, increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.'' [36]

In the CY 2021 PFS proposed rule, we proposed to add naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and to allow OTPs to be paid under Medicare for dispensing naloxone to Medicare beneficiaries who are receiving other OUD treatment services from the OTP. Under the proposal, beneficiaries receiving OUD treatment services from the OTP would be able to receive naloxone from the OTP under the OUD treatment services benefit, to the extent it is medically reasonable and necessary as part of their OUD treatment. We noted that naloxone is already covered under Medicare Part D. In 2017, 72.5 percent of all Medicare beneficiaries were enrolled in Medicare Part D plans.[37] However, as we explained in the proposed rule, we believe allowing beneficiaries to access this important emergency treatment at the OTP may help to decrease barriers to access because there currently are no copayments for services furnished by OTPs and beneficiaries would not need to visit a separate provider to access naloxone.

Accordingly, to align with efforts to end the opioid epidemic, under the discretionary authority in section

[28] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.*

[29] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209862lbl.pdf.*

[30] *https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf.*

[31] *https://www.drugabuse.gov/publications/drugfacts/naloxone.*

[32] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/208411lbl.pdf.*

[33] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/209862lbl.pdf.*

[34] *https://www.samhsa.gov/medication-assisted-treatment/treatment/naloxone.*

[35] *https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/naloxone.*

[36] *https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html.*

[37] *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.*

1861(jjj)(1)(F) of the Act, we proposed to amend the definition of OUD treatment services at § 410.67(b) by adding § 410.67(b)(8) to include opioid antagonist medications that are approved by FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose. We proposed to amend the definition of OUD treatment services under the discretionary authority in section 1861(jjj)(1)(F) of the Act rather than the authority under section 1861(jjj)(1)(A) of the Act because section 1861(jjj)(1)(A) of the Act pertains to opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by FDA under section 505 of the FFDCA for use in the treatment of opioid use disorder. As we explained in the CY 2021 PFS proposed rule, naloxone is not one of the three drugs currently approved by FDA for the treatment of opioid dependence (buprenorphine, methadone, and naltrexone);[38] and, as a result, we do not believe naloxone fits the criteria of section 1861(jjj)(1)(A) of the Act. We sought comment on our proposal to expand the definition of OUD treatment services.

Additionally, we noted that we agree with the public health advisory quoted previously that community education related to overdose prevention is needed to address the opioid crisis. We believe that prevention and community education efforts would increase awareness of treatment options and could play a role in decreasing opioid overdose deaths. We solicited comments on whether the definition of OUD treatment services should be further revised to include overdose education. Additionally, we also solicited comments on whether payment for providing overdose education to the beneficiary and/or the beneficiary's family or partner should be considered to be included in the current weekly bundled payments for episodes of care or whether we should consider establishing an add-on payment for education related to overdose prevention when such services are furnished by OTPs. We specifically sought information related to what inputs we might consider in developing the payment rate for such a service, such as payment amounts for similar services under the PFS, if we were to include this type of education as part of the proposed new add-on codes for naloxone discussed later in this section (HCPCS codes GOTP1 and GOTP2), For example, in order to establish a payment rate for education related to overdose prevention for the beneficiary and/or the beneficiary's family or partner, we could consider a crosswalk to the Medicare payment rate for CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument).* The current non-facility payment rate under the PFS for CPT code 96161 is $2.53.

a. Adjustment to the Bundled Payments for OUD Treatment Services

Consistent with the proposal to expand the definition of OUD treatment services to include opioid antagonist medications indicated for the emergency treatment of known or suspected opioid overdose, we noted that we believed it would be appropriate to propose changes to the payment rates for the bundled payments to reflect the costs of these medications. Therefore, we proposed to adjust the bundled payment rates through the use of add-on codes to account for instances in which OTPs provide Medicare beneficiaries with naloxone. We explained that we believe beneficiaries receiving naloxone will need a supply at the start of treatment and would only require refills later if the supply is used in an emergency. As a result, we noted that we would not expect naloxone to be provided weekly to all patients, but only on an as-needed basis. Accordingly, we noted that we believed that making payment for naloxone through the use of an add-on code would be the most accurate approach to pricing rather than including the costs of these medications as part of the bundled payment rates for all episodes of care.

We proposed to adopt the following add-on G codes:

- *HCPCS code GOTP1:* Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.
- *HCPCS code GOTP2:* Take-home supply of auto-injector naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.

We proposed to adopt an approach similar to the pricing methodology that was used to price the drug component of the bundled payments in the CY 2020 PFS final rule to determine the payment rate for these proposed new add-on codes for naloxone. In the CY 2020 PFS proposed rule (84 FR 40530), we explained that payment structures that are closely tailored to the provider's actual acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. Therefore, we noted that we believe it would be appropriate to use a methodology similar to the one we adopted in the CY 2020 PFS final rule (84 FR 62650 through 62657), for purposes of determining the payment rate for the drug component of the bundled payments to determine the payment rates for the add on codes for naloxone because this methodology would provide the best estimate of an OTP's cost in dispensing naloxone.

In the CY 2020 PFS final rule, we adopted a policy under which we apply the methodology set forth in section 1847A of the Act to determine the payment amount for the drug component of the bundled payment for an episode of care that includes implantable or injectable medications, except that the payment amount shall be 100 percent of the average sales price (ASP), if ASP is used. For oral medications, the payment for the drug component is based on 100 percent of ASP, if ASP data are available. However, if ASP is not available, the payment amount for methadone will be based on the TRICARE rate and the payment amount for oral buprenorphine is calculated using the national average drug acquisition cost (NADAC).

We received public comments on the proposed adjustment to the bundled payments for OUD treatment services to account for instances in which OTPs provide Medicare beneficiaries with naloxone. The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly supportive of extending the definition of OUD treatment services to include opioid antagonist medications, such as naloxone.

Response: We thank commenters for their support of extending the definition of OUD treatment services to include opioid antagonist medications, such as naloxone. Because we continue to believe that the availability of emergency treatment medications is an important component of treatment for OUD, we are finalizing our proposal to amend the definition of OUD treatment service in § 410.67 to add paragraph (b)(8) to include opioid antagonist medications approved by the FDA under section 505 of the FFDCA for emergency treatment of known or suspected opioid overdose.

[38] *https://www.fda.gov/drugs/information-drug-class/information-about-medication-assisted-treatment-mat.*

Comment: Overall, commenters were in support of revising the definition of OUD treatment services to include overdose education. Several commenters indicated that overdose education should be included in the currently established bundled payment. Some other commenters suggested creating a separate add-on code and payment for providing overdose prevention education. Some commenters supported including community education for naloxone as an add-on service, but disagreed with the example provided in the proposed rule (85 FR 50203 and 50204) of using the CY 2020 Medicare payment rate for CPT code 96161 of $2.53 to determine the additional payment amount. Rather, a commenter stated that CPT code 96161 is not commensurate with the cost of the service nor reflective of the required staff involvement and overhead cost and recommended a payment rate of $20 at 15-minute increments. While another commenter thought the clinical activities are more aligned with 98960 (*Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face with the patient (could include caregiver/family) each 30 minutes; individual patient*). Another commenter indicated that overdose education was proposed for Medicare Part D plans for contract year 2021 as part of Medication Therapy Management (MTM) and Drug Management Programs (DMP). However, no additional payment was proposed for these services when delivered in Medicare Part D. Another commenter stated that all patients receiving treatment at an OTP as well as their families should receive overdose education and urged CMS to include this payment in the add-on payments for intake activities and periodic assessments, and in the bundled payment for the initial month of substance use disorder treatment. One commenter stated that the availability of naloxone and other medications that can rapidly reverse an opioid overdose, along with education on its proper use, will save lives. The commenter also recommended that, whether reimbursement for overdose education is included as part of the bundled payment or billed as an add-on service, CMS include guardrails on what services OTPs are permitted to code as education to prevent waste and abuse, including specific requirements regarding the quality of services.

Response: After consideration of comments, we are revising the definition of OUD treatment services to include overdose education. We continue to agree with the U.S. Surgeon General's public health advisory discussed above that community education related to overdose prevention is needed to address the opioid crisis. Overdose education includes educating patients and caregivers on how to recognize respiratory depression, the signs and symptoms of a possible opioid overdose, how to administer naloxone in the event of an overdose, and the importance of calling 911 or getting emergency medical help right away, even if naloxone is administered.[39] Providing naloxone and teaching people to use it is an effective means of preventing deaths among people who misuse opioids. With brief training, most adults can learn to administer life-saving naloxone.[40] We are modifying the proposed provision at § 410.67(b)(8) to include a reference to overdose education that is furnished in conjunction with opioid antagonist medications. After considering the commenters' recommendations regarding the payment rate for this type of education, which ranged from a payment rate of $20 for each 15 minutes of education, to no separate payment for this education, we have determined that it would be appropriate to use a crosswalk to the CY 2020 Medicare payment rate for CPT code 96161 *(Administration of caregiver-focused health risk assessment instrument (e.g., depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument),* which is assigned a non-facility payment rate under the PFS of $2.53. We believe this reference code describes a similar level of service intensity and amount of clinical staff time involved in furnishing overdose education. We believe establishing a separate add-on code for overdose education to be billed in 15-minute increments is unnecessary and may result in overpayment for this service. As noted in the CY 2017 PFS final rule (81 FR 80331), we recognize that practitioners' interactions with caregivers or family members are an integral part of treatment for some patients. Overdose education and naloxone distribution programs have reduced opioid-related overdose for over 20 years.[41] Therefore, as naloxone and overdose education complement one another, we are finalizing add-on codes for naloxone that consist of both a drug component and a non-drug component that would account for overdose education furnished by the OTP. Therefore, the overdose education add-on will be included each time naloxone is furnished by the OTP. We will consider for future rulemaking whether separate coding is needed to allow payment for overdose education when it is furnished separate from the OTP furnishing the patient with naloxone.

Comment: Several commenters were in support of creating a new code for auto-injector naloxone and nasal naloxone. One commenter stated that the generic version of the auto-injector naloxone is currently not available in the marketplace.

Response: We thank the commenters for their support for creating new codes for the auto-injector naloxone and nasal naloxone. After consideration of the comments, we are finalizing our proposal to establish an add-on code for nasal naloxone that is dispensed in conjunction with an episode of care for treatment of OUD. We believe establishing an add-on code for nasal naloxone to allow OTPs to receive payment when they dispense this medication will allow beneficiaries access to this important emergency treatment at OTPs and may help decrease barriers to access because there are currently no copayments for services furnished by OTPs and beneficiaries would not need to visit a separate provider to access naloxone. We note that both the brand and authorized generic formulation of the auto-injector naloxone have been discontinued with obsolete dates effective September 4, 2020.[42] Therefore, we are not finalizing our proposal to create an add-on code for auto-injector naloxone.

After consideration of comments, we are extending the definition of OUD treatment services to include short acting opioid antagonist medications, such as naloxone. We are further revising the definition of OUD treatment services to include overdose education furnished in conjunction with providing an opioid antagonist medication. We are also finalizing our proposal to create a code for nasal naloxone: HCPCS code G2215 (*Take-home supply of nasal naloxone (provision of the services by a*

[39] *https://www.fda.gov/media/140360/download#:~:text=%E2%80%A2%20Naloxone%20is%20an%20FDA-approved%20medicine%20used%20to,Signs%20of%20an%20opioid%20overdose%20include%20breathing%20problems%2C.*

[40] *https://www.samhsa.gov/homelessness-programs-resources/hpr-resources/useful-resources-opioid-overdose-prevention.*

[41] *https://www.japha.org/article/S1544-3191(17)30002-X/fulltext.*

[42] *https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=209862.*

Medicare-enrolled Opioid Treatment Program)); List separately in addition to code for primary procedure.), which will include both a drug component and a non-drug component for overdose education. The payment for the non-drug component of this code will be determined using a crosswalk to the Medicare payment rate for CPT code 96161 of $2.53.

Drug Pricing for Nasal Naloxone

Consistent with the approach that we adopted for pricing the drug component of the weekly bundled payments, we proposed to price the add-on code describing the take home supply of nasal naloxone, using the same methodology we previously adopted for pricing the drug component of episodes of care that include implantable or injectable medications. Accordingly, the payment methodology would be based upon the methodology set forth in section 1847A of the Act, except that payment amounts determined based on ASP and wholesale acquisition cost (WAC) would not include any add-on percentages. In the CY 2021 PFS proposed rule (85 FR 50204), we acknowledged that nasal naloxone is not an oral, implantable or injectable medication; however, ASP data are available. We explained that, as noted in the CY 2020 PFS final rule (84 FR 62653), we believe using ASP provides a transparent and public benchmark for manufacturers' pricing as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions as noted in section 1847A(c)(2) of the Act) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. Therefore, we believe ASP to be the most market-based approach to set drug prices. We sought public comment on our proposal to use ASP+0 to price the add-on payment for nasal naloxone and other potential sources of pricing data for nasal naloxone either generally or specifically with respect to acquisition by OTPs.

We received public comments on the proposed drug pricing for nasal naloxone. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed the proposed ASP + 0 payment for nasal naloxone and asserted that if payment for nasal naloxone is below cost, OTPs would not be able to offer this medication to Medicare beneficiaries. A commenter indicated that this product is made by one manufacturer that does not offer volume discounts. Commenters generally recommended including an add-on payment similar to other drugs. A couple of commenters stated that the cost for OTPs to purchase nasal naloxone is $125. Accordingly, they recommended a payment of cost + 6 percent for nasal naloxone ($125 + 6 percent). A commenter indicated the cost + 6 percent payment rate would avoid imposing a financial loss on OTPs for providing naloxone and take into account OTP overhead costs (for example, training, security), thereby encouraging OTPs to provide this critical medication. A few commenters were in support of the proposed ASP + 0 payment for nasal naloxone. One commenter agreed that setting the payment rate for nasal naloxone at ASP is a reasonable approach.

Response: After review of the comments, we are finalizing our proposal to apply the payment methodology set forth in section 1847A of the Act to determine the payment for the nasal naloxone. However, as proposed, payment amounts for nasal naloxone, determined based on ASP and wholesale acquisition cost (WAC) will not include any add-on percentages. The use of ASP provides a transparent and public benchmark for the acquisition cost of a drug as it reflects the manufacturers' actual sales prices to all purchasers (with limited exceptions) and is the only pricing methodology that includes off-invoice rebates and discounts as described in section 1847A(c)(3) of the Act. We believe this approach is most consistent with the approach we adopted in the CY 2020 PFS final rule for pricing the drug component of an episode of care that includes implantable or injectable medications. For the reasons discussed in the CY 2020 PFS final rule (84 FR 62652 and 62653), we continue to believe that limiting the payment amount to 100 percent of the volume-weighted ASP for a HCPCS code instead of 106 percent of the volume-weighted ASP for a HCPCS code will incentivize the use of the most clinically appropriate drug for a given patient. We understand that many OTPs purchase medications directly from drug manufacturers, thereby limiting the markup from distribution channels. We continue to believe that the selection of drugs purchased by most OTPs is quite limited, which theoretically limits the utility of third-parties, such as wholesalers, and their associated costs and increases the purchase volume for OTPs and accompanying manufacturer discounts. We believe that this situation could lend itself to an OTP drug channel for purchasing at discounted rates either directly or through the use of buying groups as is the standard in the pharmacy industry today. We believe that our proposed approach of paying for nasal naloxone based on ASP offers the most appropriate balance between ensuring OTPs receive appropriate reimbursement for their drug acquisition costs, while also preserving the incentive to use the most clinically appropriate drug for the treatment of individual beneficiaries.

We are interested in continuing to obtain feedback regarding access concerns related to naloxone payment. We will monitor utilization of these codes in the claims data to determine whether CMS should consider proposing changes in the future to the payment policies finalized in this rule.

Drug Pricing for Auto-Injector Naloxone

We proposed to price the add-on code describing the take-home supply of auto-injector naloxone, using the lowest pricing available (the lower of ASP + 0, WAC + 0, or NADAC). Currently, there is no ASP or NADAC reported or calculated for auto-injector naloxone. Accordingly, we proposed to use WAC + 0 to determine the pricing for the add-on payment for auto-injector naloxone. We explained that we believe 100 percent of WAC is a closer estimate of the actual acquisition cost for OTPs compared to WAC with an add-on percentage because, as defined in section 1847A(c)(6)(B) of the Act, WAC does not include prompt pay discounts, rebates or reductions in price. Thus, there should be no need to pay an add-on percentage to ensure OTPs are reimbursed for their acquisition costs for auto-injector naloxone. However, we also noted that in the future, using the lowest pricing available for auto-injector naloxone may be most appropriate, because if ASP and/or NADAC pricing were to become available for auto-injector naloxone, they would be more reflective of actual costs than a list price.

We noted that auto-injector naloxone was available in both a generic and brand name version. We explained that we had considered comparing the Medicare Part D utilization for each formulation to determine the frequency with which the generic and brand name versions might dispensed by OTPs. However, because the generic auto-injector naloxone was rather new to the marketplace [43], we acknowledged that there were limited utilization data available for the generic product. Based on historical information reflecting a

[43] *https://kaleo.com/in-the-news/authorized-generic-for-evzio-naloxone-hcl-injection-to-be-available-at-a-reduced-list-price-of-178/.*

trend of increased generic utilization uptake,[44] we explained that we believed that in most cases where the auto-injector naloxone would be prescribed and dispensed by OTPs to beneficiaries, it would be the generic formulation of the product. Therefore, we noted that we believed using the price for the generic formulation would be a reasonable approach to pricing the proposed add-on code for auto-injector naloxone and would ensure that beneficiaries who need this drug as part of their treatment for OUD would have access to it and that OTPs would receive a reasonable payment for dispensing the drug. Accordingly, we proposed to use the price of the generic formulation, determined as WAC + 0, to pay for auto-injector naloxone when the drug is provided by an OTP as part of an episode of care. We sought comment on our proposed pricing methodology to pay for auto-injector naloxone and other potential sources of pricing data for auto-injector naloxone either generally or specifically with respect to acquisition by OTPs.

We received public comments on the proposed drug pricing for auto-injector naloxone. The following is a summary of the comments we received and our response.

Comment: One commenter pointed out that generic auto-injector naloxone is not currently available in the marketplace and stated that the brand name auto-injector naloxone costs about $4,000. The commenter stated that the proposed payment rate for auto-injector naloxone is inadequate and should be revised to accurately reflect the true acquisition cost of the drug. Another commenter recommended a payment rate of cost plus 6 percent for auto-injector naloxone. Some other commenters also recommended including an add-on of plus 6 percent to the payment rate, similar to other drugs.

Response: As previously discussed, both the brand name auto-injector (Evzio) and authorized generic naloxone auto-injector were recently discontinued with obsolete dates effective September 4, 2020. Because auto-injector naloxone is no longer available in the marketplace, we are not finalizing the proposed code and pricing for auto-injector naloxone.

Frequency Limit

In the CY 2021 PFS proposed rule (85 FR 50205), we noted that Medicare Part D allows prescription drug plans to place quantity limits (QL) on most drugs, including on naloxone. While most Medicare Part D plans do not limit the amount of naloxone a beneficiary is able to receive in a given month, when they do, they most frequently allow a plan enrollee a maximum of 4 units per 30 days (2 boxes of 2 units). In the current contract year (2020) only 22 percent of Medicare Part D formularies apply a QL to naloxone (115/535 formularies), while for the 2021 contract year only 19 percent of Medicare Part D formularies plan to apply a QL to this product (106/564 formularies). However, a review of Medicare Part D claims data shows that beneficiaries who use naloxone most frequently use only one box (2 units) within a 30-day period even though nearly all plans would have permitted additional doses. We also noted that under TRICARE, auto-injector naloxone is covered for a maximum quantity of one carton at retail network pharmacies for up to a 30-day supply.[45] We explained our belief that it would be appropriate to apply a similar limit on the frequency of the add-on payment for naloxone dispensed by OTPs. We stated that applying a frequency limit would assist in enhancing patient safety and discourage misuse, waste and abuse. Furthermore, we noted that such a limitation was reasonable because there are other services that OTPs should already be performing, and which are already included in the weekly bundled payments for episodes of care, such as counseling and individual and group therapy, that should limit the need for this emergency treatment. However, we noted that we do not want to limit access to naloxone when it is a medically reasonable and necessary part of the treatment for OUD. Therefore, we proposed to limit Medicare payment to OTPs for naloxone to one add-on code (HCPCS code GOTP1 or GOTP2) every 30 days to the extent that it is medically reasonable and necessary. We sought comment on whether this proposed limit was reasonable and whether special circumstances may arise under which more frequent payment would be medically reasonable and necessary and the types of circumstances that should qualify for more frequent payment. However, we noted that we also expect OTPs and their treating practitioners will use their clinical judgment as to whether there may be cases in which a referral to a higher level of care may be needed for some beneficiaries in order to reduce the risk of overdose and the need for more frequent emergency treatment. We proposed to add § 410.67(d)(4)(i)(E) to describe payment for a take-home supply of opioid antagonist medications that are approved by FDA under section 505 of the FFDCA for the emergency treatment of known or suspected opioid overdose.

We invited public comments on the proposed pricing for nasal naloxone and auto-injector naloxone. We also sought comment on the proposal to limit payment for the proposed add-on codes for take-home supplies of these medications to once every 30 days to the extent that it is medically reasonable and necessary.

We received public comments on the proposed frequency limit. The following is a summary of the comments we received and our responses.

Comment: Several commenters did not support imposing frequency limits on the provision of naloxone to once per month and stated that clinicians should determine medical necessity, noting that naloxone is a life-saving drug and patient access should not be limited. One commenter recommended that exceptions be allowed for patients with a recent (within the last 30 days) overdose. Other commenters supported the proposed frequency limit and found it reasonable.

Response: After consideration of the comments, we are finalizing a frequency limit on Medicare payments to OTPs for naloxone to one add-on code (HCPCS code G2215 or G2216) every 30 days. However, we agree with commenters that access to naloxone should not be limited when it is a medically reasonable and necessary part of the treatment for OUD. Therefore, we will allow exceptions to this limit in the case where the beneficiary overdoses and uses the initial supply of naloxone dispensed by the OTP to the extent that it is medically reasonable and necessary to furnish additional naloxone. We note that section 1862(a)(1)(A) of the Act requires that in order for payment to made for most Part A and Part B services furnished to Medicare beneficiaries, those services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the malfunctioning of a malformed body member. If an additional supply of naloxone is needed within 30 days of the original supply being provided, OTPs must document in the medical record the reason for the exception. Additionally, CMS will monitor utilization of these codes in the claims data and will refer cases of disproportionate use for further review.

Additionally, we sought comment on whether we should consider creating a

[44] In 2015, approximately 87 percent of prescriptions filled under Part D were for generic drugs, compared with 61 percent in 2007. *http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf.*

[45] *https://www.express-scripts.com/static/formularySearch/2.9.6/#/formularySearch/drugSearch.*

code and establishing an add-on payment for injectable naloxone. We noted that all three forms of naloxone (injectable, auto-injector, and nasal spray) are FDA-approved and may be considered as options for community distribution.

It is important to understand how to administer naloxone properly, therefore, we defer to the clinical judgment of practitioners in the OTP as to which formulation of naloxone would be the most appropriate to dispense to a patient. Brief education on how to administer naloxone using a syringe can be obtained from the provider of the naloxone kit or from *http://prescribetoprevent.org/*.[46] Additionally, we note that in this final rule, we are including overdose education in the non-drug component of the payment rate for both of the new add-on codes for naloxone (HCPCS codes G2215 and G2216), and expect that when OTPs provide beneficiaries with a supply of naloxone, they will also inform them about how to use the medication they are being given.

We stated in the CY 2021 PFS proposed rule (85 FR 50205) that if we were to establish an add-on payment for injectable naloxone, we would consider using the same methodology we adopted for pricing the drug component of an episode of care that includes implantable or injectable medications, as described in § 410.67(d)(2)(i)(A).

We received public comments in response to our request for input on whether we should create a code and establish an add-on payment for injectable naloxone. The following is a summary of the comments we received and our responses.

Comment: Commenters supported the creation of coding and payment for injectable naloxone. Some commenters stated that ensuring payment for all three forms of FDA-approved naloxone would allow providers to select the most appropriate form of naloxone for the particular Medicare beneficiary and provide options in the case of drug shortages. The commenters also noted that traditionally, injectable naloxone is the least expensive form, but can be more difficult to administer in an overdose emergency. Another commenter stated that they believe formulations of naloxone that are intended for use by medical professionals (that is, injectable naloxone) are also valuable in the prevention and treatment of opioid overdose. The commenter stated that given that it is highly probable that OTP providers will be in a position to provide care to a beneficiary who has overdosed, the availability of injectable naloxone at these facilities can facilitate timely opioid overdose reversal. Some commenters stated that the payment rate for injectable naloxone must be adequate and another stated that they believe payment should align with payment for other Medicare Part B medications (that is, ASP plus 6 percent).

Response: We agree with the commenters that providing for Medicare payment to OTPs for all available forms of FDA-approved naloxone will allow practitioners in OTPs to select the most appropriate form of naloxone for the beneficiary, provide options in the case of drug shortages, and expand access to treatment for opioid overdoses. Although we acknowledge that individuals experiencing an opioid overdose will not be able to use injectable naloxone to treat an overdose themselves,[47] self-administration of naloxone is not necessarily a goal of overdose death prevention training. A safer, more reliable approach may be to prescribe naloxone to at-risk patients and train and also equip members of their household and social networks in overdose prevention and response.[48]

After consideration of the comments received, we are finalizing a second new add-on code to cover the cost of providing patients with a supply of injectable naloxone. We recognize the importance of making injectable naloxone available to Medicare beneficiaries. Additionally, creating a new add-on code for injectable and nasal naloxone will provide options in the case of drug shortages or in the event a drug is no longer available in the market, as occurred with auto-injector naloxone.

The add-on code for injectable naloxone is HCPCS code G2216 (*Take-home supply of injectable naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.*), which will include both a drug component and a non-drug component. As stated in previous rulemaking (84 FR 62650), we use the typical maintenance dose to calculate the drug component for the OTP benefit. According to the package insert,[49] [50] an initial dose of 0.4 mg to 2 mg of injectable naloxone may be administered through intravenous, intramuscular, or subcutaneous routes. If needed, it may be repeated at two- to three-minute intervals up to a total dose of 10mg. Because the information we have is not based upon a typical dose, we are contractor pricing this code for CY 2021. This will provide beneficiaries access to injectable naloxone under the OTP benefit and will also allow us the opportunity to obtain more information to better understand the typical dosage of injectable naloxone, in order to potentially establish national pricing for injectable naloxone through future rulemaking. The payment for the non-drug component of this code will be determined using a crosswalk to the Medicare payment rate for CPT code 96161 of $2.53, as discussed previously in conjunction with the new code for nasal naloxone (HCPCS G2215).

Table 34 details the new add-on codes for nasal naloxone and injectable naloxone, and the accompanying payment amounts, which reflect the cost of the drug plus an additional $ 2.53 for overdose education, as discussed previously in this section.

[46] *https://store.samhsa.gov/sites/default/files/d7/priv/sma18-4742.pdf.*

[47] *https://www.samhsa.gov/medication-assisted-treatment/medications-counseling-related-conditions/opioid-overdose.*

[48] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4019939/.*

[49] *http://labeling.pfizer.com/ShowLabeling.aspx?id=4541.*

[50] *https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f0932877-1f3b-4d5e-82d2-dd6c53db4730&type=display.*

TABLE 34: OTP Code Descriptors and Payment Amounts*

HCPCS	Descriptor	Total Payment
G2215	Take-home supply of nasal naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	$92.13
G2216	Take-home supply of injectable naloxone (provision of the services by a Medicare-enrolled Opioid Treatment Program); List separately in addition to code for primary procedure.	Contractor-priced

* Nasal naloxone drug costs are calculated using ASP data plus a payment of $2.53 for overdose education. HCPCS code G2216 will be contractor-priced and will also include a payment of $2.53 for overdose education.

Duplicative Payment

Section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Medicare Part B or Part D for items and services furnished by an OTP. In the CY 2021 PFS proposed rule (85 FR 50206), we noted that under the proposal, OTPs would be able to provide naloxone to Medicare beneficiaries and bill for it as an add-on to the bundled payment for the episode of care. Consistent with § 410.67(e), the beneficiary's copayment amount would remain zero. We also noted that naloxone may also be appropriately available to beneficiaries through other Medicare benefits, including, for example, Medicare Part D, under which the beneficiary would be responsible for the applicable cost sharing. As discussed in the CY 2020 PFS final rule (84 FR 62664) and codified at § 410.67(d)(5), we define duplicative payment to involve only those circumstances where medications that are delivered, administered or dispensed to a beneficiary are paid as part of the OTP bundled payment, and where the delivery, administration or dispensing of the same medication (that is, same drug, dosage and formulation) is also separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Because we proposed to pay for naloxone as an add-on to the weekly bundled payment, any payment to an OTP for naloxone would be duplicative if the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service. Consistent with § 410.67(d)(5), CMS would recoup any duplicative payment made to an OTP for naloxone.

Additionally, we noted that we understand some OTPs negotiate arrangements whereby community pharmacies supply MAT-related medications to OTPs. However, we reiterated that, as stated in the CY 2020 PFS final rule, if the OTP provides reasonable and necessary MAT-related medications as part of an episode of care, we would expect the OTP to take measures to ensure that there is no claim for payment for these drugs other than as part of the OTP bundled payment. Thus, naloxone billed by an OTP as an add-on to the bundled payment should not be reported to or paid under a Medicare Part D plan. We noted that we expect OTPs will take reasonable steps to prevent duplicative payment for naloxone furnished under their care by ensuring it is not reported or billed under a different Medicare benefit. We also noted that we intend to monitor for duplicative payments, and would take appropriate action as needed when and if such duplicative payments are identified.

We received public comments on the discussion of duplicative payment for naloxone. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed recoupment of duplicative payments made to OTPs for naloxone. One commenter noted that OTPs do not have the capacity to be aware of or prevent other providers from prescribing naloxone through Medicare Part D. A commenter recommended that CMS inform health plans if a member is receiving services from an OTP, but acknowledged this may be difficult due to privacy laws. A commenter stated that CMS should either establish a means of coordination or recoup payment from Medicare Part D plans and other healthcare providers if naloxone is provided outside of the OTP. Another commenter stated that if the proposal to establish an add-on payment for naloxone is finalized, CMS will need to provide instructions to guard against duplicative payment.

Response: As we are finalizing the proposal to pay for naloxone as an add-on to the weekly bundled payment, we reiterate that consistent with § 410.67(d)(5), any payment to an OTP for naloxone would be duplicative if a claim for the same medication is separately paid under Medicare Part B or Part D for the same beneficiary on the same date of service, and CMS would recoup any duplicative payment made to an OTP for naloxone. Section 1834(w)(1) of the Act, added by section 2005(c) of the SUPPORT Act, requires the Secretary to ensure, as determined appropriate by the Secretary, that no duplicative payments are made under Medicare Part B or Part D for items and services furnished by an OTP. Therefore, for purposes of implementing section 1834(w)(1) of the Act, payment for medications delivered, administered or dispensed to the beneficiary as part of the OTP bundled payment is considered duplicative if delivery, administration or dispensing of the same medication was also separately paid under Medicare Part B or D. CMS would recoup any duplicative payment made to an OTP for naloxone because OTPs will be in the best position to know whether naloxone that is included as part of the beneficiary's treatment plan is being furnished by the OTP or by another provider or supplier given that the OTP is responsible for managing the beneficiary's overall OUD treatment. OTPs should make a good faith effort to ensure that no duplicative payments are made for naloxone, for example, by inquiring whether the beneficiary has already received a supply of naloxone through Medicare Part B or D. Please see the CY 2020 PFS final rule (84 FR 62663 and 62664) for a more detailed discussion of our policy on duplicative payments.

3. WAC Pricing

Section 1834(w) of the Act gives the Secretary significant discretion to establish bundled payment rates for OUD treatment services. In the CY 2020 PFS final rule, we finalized a payment methodology for the drug component of

the bundled payment rates for OUD treatment services, under which we use the payment methodology set forth in section 1847A of the Act (which bases most payment on ASP) to set the payment rates for implantable and injectable drugs and limited the payment amount for these drugs to 100 percent of the volume-weighted ASP for a drug category or code, if ASP is used. We codified this payment methodology at § 410.67(d)(2)(i)(A).

Section 1847A of the Act provides for the use of other payment methodologies in certain circumstances, including payment based on WAC or average manufacturer price (AMP). In the CY 2020 PFS final rule, we limited payments to OTPs for injectable and implantable drugs to 100 percent of ASP, but did not otherwise diverge from the payment methodology that would apply under section 1847A of the Act. In the CY 2021 PFS proposed rule (85 FR 50206), we noted our belief that it was necessary to amend the OTP drug pricing methodology in order to limit WAC-based payments to 100 percent of WAC. As discussed previously, we proposed to use WAC pricing to determine the payment rate for the add-on code for the auto-injector naloxone. Although none of the drugs that are currently included in the drug component of an episode of care is currently paid based on WAC, we also noted that it is possible that we may use WAC to determine the payment for the drug component of an episode of care in the future, and we wanted to establish, in advance, the methodology that would apply for purposes of determining the payment rate.

As authorized under section 1847A of the Act, some Medicare Part B drugs are paid based on WAC. For example, for single source drugs, payment is 106 percent of the lesser of WAC or ASP (section 1847A(b)(4) of the Act), and in cases where ASP is unavailable during the first quarter of sales (section 1847A(c)(4) of the Act), 103 percent of WAC is used. Additionally, there are some instances where drugs lack ASP data for reasons other than being new, for example, in cases where the manufacturer had no sales in a reporting quarter. In those situations, the Medicare payment method varies, but in some cases, the payment may be 106 percent of the WAC.[51] As we stated in the CY 2020 PFS final rule (84 FR 62651), payment structures that are closely tailored to the provider's actual acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. The WAC is defined in section 1847A(c)(6)(B) as the manufacturer's list price for a drug to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price. A drug's WAC is ultimately controlled by the manufacturer. Unlike ASP, a drug's WAC does not incorporate prompt-pay or other discounts. If discounts are available on drugs reimbursed by Medicare at 106 percent of WAC, then Medicare is paying more for drugs than it otherwise would under the ASP-based formula.[52] Therefore, consistent with our existing policy to set the payment amount at 100 percent of the ASP, if ASP is used to determine the payment for the drug component of an episode of care, we proposed that when WAC-based pricing is used, the payment amount shall be WAC + 0. We proposed to amend the provision at § 410.67(d)(2)(i)(A) to reflect this limitation.

We solicited comments on this proposed alternative pricing methodology when the payment for an implantable or injectable medication included in the drug component of an episode of care is determined using the methodology set forth in section 1847A of the Act, and ASP pricing data are not available.

We received public comments on the WAC pricing proposal. The following is a summary of the comments we received and our responses.

Comment: A commenter expressed concern with CMS establishing payment rates for medications that deviate from the standard methodology under Medicare Part B of paying for drugs at the current rate of ASP plus 6 percent. The commenter also stated that they were concerned that limiting payment to Wholesale Acquisition Cost (WAC) when ASP is not available would limit OTPs' ability to treat Medicare beneficiaries effectively. Another commenter supported the use of WAC + 0 and stated, in reference to auto-injector naloxone, that any payments above WAC would likely only serve to encourage price increases in the market more broadly.

Response: We thank the commenters for their feedback on our proposal that when the payment for an implantable or injectable medication included in the drug component of an episode of care is determined using the methodology set forth in section 1847A of the Act, and ASP pricing data are not available, and WAC-based pricing is used, the payment amount shall be WAC + 0. We continue to believe that payment structures that are closely tailored to the provider's acquisition cost reduce the likelihood that a drug will be chosen primarily for a reason that is unrelated to the clinical care of the patient, such as the drug's profit margin for a provider. Because WAC does not include prompt pay discounts, rebates or price reductions, we believe WAC could be a much higher than acquisition cost. However, we continue to believe that 100 percent of WAC is a closer estimate of the actual acquisition cost for OTPs compared to WAC with an add-on percentage. Therefore, we are finalizing our proposal that when WAC-based pricing is used, the payment amount shall be WAC + 0. We are also finalizing the proposed amendment to the provision at § 410.67(d)(2)(i)(A) to reflect this pricing methodology.

4. Billing and Payment Policies

a. Institutional Claim Forms

As discussed in the CY 2021 PFS proposed rule (85 FR 50207), we have received several requests to allow OTPs to bill on an institutional claim form. We were informed by representatives from the state of New York that all OTPs in New York state bill on institutional claim forms, not just those that are part of a hospital system. Given the public health need related to the opioid epidemic, we explained that we were exploring claims processing flexibilities requested by some OTPs that would allow them to bill services on institutional claims. See also section III.B. of this final rule, OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions, for a discussion related to OTP enrollment as it relates to institutional claims. As we explained in the CY 2021 PFS proposed rule, there would be no differences in coverage or payment between services billed on the institutional claim form versus the professional claim form. We noted that the National Uniform Billing Committee (NUBC) approved a new Type Of Bill (087x) for Freestanding Non-residential Opioid Treatment Program provider billing, as well as a new condition code (89) for Opioid Treatment Program/Indicates claim for opioid treatment program services, to be used on hospital based OTP claims (TOB 013x and 085x). We sought information on the reasons this claims-processing flexibility is necessary for OTPs, and stated that we would address any changes to provider billing policies

[51] *http://www.medpac.gov/-blog-/requiring-reporting-of-sales-price-data/2019/06/14/payment-for-part-b-drugs.*

[52] *http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf.*

in subsequent claims processing instructions.

We received public comments on allowing OTPs to bill on an institutional claim form. The following is a summary of the comments we received and our response.

Comment: Several commenters expressed support for allowing this flexibility. One commenter noted that they anticipate there will be a significant increase in OTP enrollment as a result of this flexibility, especially in states that have a significant number of hospital-based OTPs. Another commenter noted that allowing OTPs to submit claims on the institutional claim form (837i) will help to facilitate the processing of crossover claims between Medicare and Medicaid.

Response: We are continuing to explore how best to implement these flexibilities. We will provide notice of any relevant changes through claims processing instructions.

b. Periodic Assessments

In the CY 2020 PFS final rule (84 FR 62634), we stated that we understood that intake activities and periodic assessments are integral services for the establishment and maintenance of OUD treatment for a beneficiary at an OTP, and therefore, we believed it was reasonable to include these services in the definition of OUD treatment services. Accordingly, we finalized a definition of OUD treatment services in § 410.67(b) that reflected the required intake activities and periodic assessments. We stated it was our understanding that these services are furnished much less frequently than the other services included in the weekly bundled payments; therefore, we created add-on G codes to describe these services, which would allow us to make more targeted payments for these services. We noted that the add-on code describing intake activities should only be billed for new patients (that is, patients starting treatment at the OTP). We agreed with the commenters that the level 4 office/outpatient E/M visits for new and established patients are a good approximation of the services provided at intake and during periodic assessments at OTPs based on the expected acuity of patients with OUD receiving services at OTPs, who are likely to have multiple co-morbidities and present with problems that are of moderate to high severity and require medical decision making of moderate complexity. The finalized add-on codes are HCPCS code G2076 (*Intake activities; including initial medical examination that is a complete, fully documented physical evaluation and initial assessment conducted by a program physician or a primary care physician, or an authorized health care professional under the supervision of a program physician or qualified personnel that includes preparation of a treatment plan that includes the patient's short-term goals and the tasks the patient must perform to complete the short-term goals; the patient's requirements for education, vocational rehabilitation, and employment; and the medical, psycho-social, economic, legal, or other supportive services that a patient needs, conducted by qualified personnel*) and HCPCS code G2077 (*Periodic assessment; assessing periodically by qualified personnel to determine the most appropriate combination of services and treatment*). The medical services described by these add-on codes can be furnished by a program physician, a primary care physician or an authorized healthcare professional under the supervision of a program physician or qualified personnel such as nurse practitioners (NPs) and physician assistants (PAs). The other assessments, including psychosocial assessments can be furnished by practitioners who are eligible to do so under state law and their scope of licensure. We noted that to bill for the add-on code, the services need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record (84 FR 62647).

As we explained in the CY 2021 PFS proposed rule (85 FR 50207), we have received inquiries from stakeholders related to what activities would qualify to bill the add-on code for periodic assessments, HCPCS code G2077. In the CY 2020 PFS final rule (84 FR 62647), we noted that the add-on code describing periodic assessments can be billed for each periodic assessment performed for patients that require multiple assessments during an episode of care, such as patients who are pregnant or postpartum. We noted that in order to bill for the add-on code, the services would need to be medically reasonable and necessary and that OTPs should document the rationale for billing the add-on code in the patient's medical record. Based on our understanding of the typical resources costs involved in furnishing periodic assessments, we priced HCPCS code G2077 based on a crosswalk to a level 4 office/outpatient E/M visit. Consistent with our understanding of the expected acuity of patients with OUD receiving services at OTPs, including the likelihood of the patient having multiple co-morbidities and presenting with problems that are of moderate to high severity and requiring medical decision making of moderate complexity, as well as the associated payment rate assigned to this code, we explained that we believe it is important for the clinician to be able to visually assess the patient as part of any periodic assessment. Therefore, for CY 2021, we proposed that in order to bill for HCPCS code G2077, a face-to-face medical exam or biopsychosocial assessment would need to have been performed. Accordingly, we proposed to amend the definition of periodic assessment in § 410.67(b)(7) to provide that the definition is limited to a face-to-face encounter.

Additionally, we noted that in the May 8th COVID–19 IFC, CMS revised § 410.67(b)(7) on an interim final basis to allow periodic assessments to be furnished during the PHE for COVID–19 via two-way interactive audio-video communication technology and, in cases where beneficiaries do not have access to two-way audio-video communication technology, to permit the periodic assessments to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology, provided all other applicable requirements are met. We explained our belief that allowing periodic assessments to be furnished via two-way interactive audio-video communication technology beyond the conclusion of the PHE for COVID–19 would help to expand access to care for patients who may have a difficult time getting to the OTP in person. Therefore, in the proposed rule, we proposed to revise § 410.67(b)(7) to allow periodic assessments to be furnished via two-way interactive audio-video communication technology, provided all other applicable requirements are met. We noted that we are currently permitting the use of audio-only telephone calls to furnish these services during the PHE for COVID–19, because we believe it is important to maintain access to these services while the public is following infection control guidelines to stay at home and practice social distancing, and not all beneficiaries receiving OUD treatment services from OTPs may have access to interactive audio-video communication technology. However, we did not believe this flexibility would be needed in order to ensure access after the PHE for COVID–19 ends. Therefore, we did not propose to extend the flexibility to use audio-only telephone services to furnish periodic assessments once the PHE for COVID–19 has ended.

We noted that we would consider payment for any periodic assessment-related services furnished via audio-only telephone calls to be included in the bundled payment for a weekly episode of care, but that audio-only telephone services would not qualify for billing HCPCS code G2077 after the end of the PHE for COVID–19. We sought input from the public on whether we should consider continuing to make add-on payments for audio-only periodic assessments furnished by OTPs after the conclusion of the PHE for COVID–19, and if so, whether the payment rate for audio-only services should reflect any differences in resource costs.

We received public comments on the proposals related to periodic assessments. The following is a summary of the comments we received and our responses.

Comment: Commenters supported our proposal to allow OTPs to utilize two-way interactive audio-video communication to satisfy the proposed requirement that periodic assessments include a face-to-face encounter. Several commenters requested that CMS allow audio only communication to continue to be used for periodic assessments beyond the PHE for beneficiaries who do not have video capabilities, noting that many individuals who receive treatment at OTPs do not have access to devices with audio-video capability and beneficiaries in rural areas may not have broadband internet access.

Response: While we believe it is important to allow the flexibility to furnish periodic assessments via audio-only telephone calls during the PHE for COVID–19, we continue to have concerns about continuing this flexibility after the end of the PHE. For example, we are concerned that the effectiveness and/or quality of the care furnished during these interactions may be lower when practitioners cannot observe visual cues while furnishing these assessments. Therefore, after consideration of the comments, we are finalizing our proposal that in order to bill for HCPCS code G2077, a face-to-face medical exam or biopsychosocial assessment would need to have been performed. Additionally, we are finalizing our proposal to revise § 410.67(b)(7) to provide that periodic assessments must be furnished during a face-to-face encounter, but may be furnished via two-way interactive audio-video communication technology, as clinically appropriate, provided all other applicable requirements are met. We plan to analyze differences in utilization in the claims data during and after the PHE for COVID–19, and are interested in feedback related to differences in frequency, effectiveness, and quality of care furnished by OTPs when services are furnished via audio-only communication in order to help assess whether we should consider making any changes to our current policies regarding the use of communication technology in future rulemaking.

c. Date of Service

In the CY 2020 PFS final rule (84 FR 62641), we defined an episode of care as a 1-week (contiguous 7-day) period at § 410.67(b). We have received inquiries related to the date of service used on claims for the weekly bundles and add-on codes, particularly related to an approach that many providers informed us they use, which is to establish a ''standard billing cycle'' in which episodes of care for all patients at that OTP begin on the same day of the week. We do not believe that the definition of an episode of care that was finalized for CY 2020 precludes the use of a ''standard billing cycle.'' Therefore, OTPs may choose to apply a standard billing cycle by setting a particular day of the week to begin all episodes of care. In this case, the date of service would be the first day of the OTP's billing cycle. If a beneficiary starts treatment at the OTP on a day that is in the middle of the OTP's standard weekly billing cycle, the OTP may still bill the applicable code for that episode of care provided that the threshold to bill for the code has been met. Alternatively, OTPs may choose to adopt weekly billing cycles that vary across patients. Under this approach, the initial date of service will depend upon the day of the week when the patient was first admitted to the program or when Medicare billing began. Therefore, under this approach of adopting weekly billing cycles that vary across patients, when a patient is beginning treatment or re-starting treatment after a break in treatment, the date of service would reflect the first day the patient was seen and the date of service for subsequent consecutive episodes of care would be the first day after the previous 7-day period ends. For the codes describing add-on services (HCPCS codes G2076–G2080), the date of service should reflect the date that service was furnished; however, if the OTP has chosen to apply a standard weekly billing cycle, the date of service for codes describing add-on services may be the same as the first day in the weekly billing cycle.

In the CY 2021 PFS proposed rule (50208), we noted that this approach is consistent with earlier guidance that was issued in the OTP Billing and Payment Fact sheet that is posted on the CMS OTP web page (*https://www.cms.gov/files/document/otp-billing-and-payment-fact-sheet.pdf*).

We received public comments on the discussion of the date of service used on claims in the proposed rule. The following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for the flexibility to use either a ''standard billing cycle'' or a weekly billing cycle that varies across patients.

Response: We intend to continue to offer this flexibility to OTPs. Additionally, we note that the current policies regarding the date of services for add-on codes will apply to the new add-on codes we are adopting in this final rule for nasal naloxone and injectable naloxone.

d. Coding

In the CY 2021 PFS proposed rule (85 FR 50208), we explained that we recognize the importance of allowing OTPs to become accustomed to billing Medicare using the coding that was established in the CY 2020 PFS final rule; however, we remain interested in refining the code set through future rulemaking, including stratifying the coding and associated payment amounts to account for significant differences in resource costs among patients, especially in relation to amounts of expected counseling. In the CY 2020 PFS final rule (84 FR 62645), we finalized an add-on code to describe an adjustment to the bundled payment when additional counseling or therapy services are furnished, HCPCS code G2080. This add-on code may be billed when counseling or therapy services are furnished that substantially exceed the amount specified in the patient's individualized treatment plan. We stated that we have received feedback from stakeholders noting a range of OTP attendance patterns that represent a continuum of care and service intensity, noting significant differences in services received during the induction phase versus the maintenance phase. We also understand that patients' needs for service may fluctuate over time, depending on a variety of factors and circumstances. We sought comments on how we might better account for differences in resource costs among patients over the course of treatment. We noted that we would consider the comments received in developing any proposed refinements to our coding policies in future rulemaking.

We received public comments on the discussion of billing and payment policies in the proposed rule. The

following is a summary of the comments we received and our responses.

Comment: Commenters expressed support for CMS' retaining the coding framework that was established in the CY 2020 rulemaking. A few commenters stated that CMS should maintain the current bundle structure because it has proven to be successful and viable during the first year of the new Medicare Part B benefit for OUD treatment services furnished by OTPs, and therefore there is no need to overly tinker with a functioning reimbursement structure. Another commenter stated that the current bundled payment methodology, with the ability to bill for additional counseling via add-on codes has worked remarkably well due to its simplicity. They stated that the current bundled payments reflect the costs associated with treating a patient with average needs and that while some patients require greater services and some require less, it usually balances out from a reimbursement-to-costs standpoint. They also stated that they have found that Medicare beneficiaries generally are a more health care service intensive population than non-Medicare patients, and therefore many OTPs are working to increase counseling resources to meet the unique needs of the Medicare population. They also stated that changing the current bundled payment methodology would undermine the progress OTPs have made in this area and therefore recommended that CMS maintain the current bundled payment structure.

Response: We are pleased to hear that the coding and payment policies that we established in CY 2020 PFS final rule have been effective and well received. We plan to retain the current coding structure for 2021, and will continue to consider any refinements to that structure for future rulemaking.

5. Annual Updates

In the CY 2020 PFS final rule (84 FR 62667 through 62669), we finalized a policy under which the payment for the drug component of episodes of care will be determined using the most recent data available at the time of ratesetting for the applicable calendar year. The payment for the non-drug component of the bundled payment for OUD treatment services will be updated annually based upon the Medicare Economic Index. The current payment rates, as finalized in the CY 2020 PFS final rule, both with and without locality adjustments, can be found on the CMS OTP web page under Billing and Payment at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program/billing-payment.* The list of the payment rates for OUD treatment services furnished by OTPs, with the annual update applied for CY 2021, is available in the file called CY 2021 PFS final rule OTP Payment Rates on the CMS website under downloads for the CY 2021 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices?DLSort=2&DLEntries=10&DLPage=1&DLSortDir=descending.*

Comment: Commenters stated that using the Medicare Economic Index (MEI), which focuses more narrowly on physician practices, to update the payment rates for the non-drug component of the bundled payments does not ensure that Medicare payment rates for OTPs keep pace with growing practice costs. The commenters stated that OTPs' cost structures are more similar to HOPDs than they are to physician offices, in that they employ interdisciplinary teams, including medical directors, doctors, counselors, nurses, pharmacists, laboratory technicians, social workers, and case managers, to provide care to patients. They also noted that like hospitals, OTPs serve patients 7 days per week and go through extensive accreditation and certification process and are subject to thorough inspections by deferral regulators. OTPs are also required to employ diversion control systems to ensure treatment medication is being used properly, while physicians in the office setting who prescribe buprenorphine are not subject to those requirements. Commenters stated that given these similarities between OTPs and HOPDs, the IPPS market basket update would be a more accurate measure of annual price growth in the OTP setting for the non-drug component of the OTP bundled payment rates, noting that TRICARE increases its payments to OTPs by the IPPS update factor annually.

Response: We did not propose any changes for CY 2021 to the annual update process that was established in the CY 2020 PFS final rule (84 FR 62667), however, we will consider this feedback for future rulemaking.

J. Technical Correction to the Definition of Public Health Emergency

In the March 31st COVID–19 IFC (85 FR 19285), we amended 42 CFR part 400 by adding the definition of ''Public Health Emergency.'' We made an inadvertent typographical error in the regulations at § 400.200 by referring to the authority for the Public Health Emergency (PHE) as the ''Public Health Security Act'' rather than the ''Public Health *Service* Act.'' We are correcting this error in this final rule and amending § 400.200 by revising the definition. Public Health Emergency (PHE) now means the Public Health Emergency determined to exist nationwide as of January 27, 2020, by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals. This revised definition has an applicability date of March 1, 2020, which is the same applicability date as the March 31st COVID–19 IFC.

III. Summary of the Proposals for Other Part B Provisions, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

A. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions, and Comment Solicitation on Payment for Specimen Collection for COVID–19 Clinical Diagnostic Laboratory Tests

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS), with certain exceptions, under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) The amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a multi-factor productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. In the June 23, 2016 **Federal Register** (81 FR 41036), we published a final rule entitled Medicare Clinical Diagnostic Laboratory Tests

Payment System (CLFS final rule), that implemented section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016 through June 30, 2016. The first data reporting period occurred from January 1, 2017 through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of Civil Monetary Penalties (CMPs) for failure to report applicable information with respect to the initial data reporting period. This announcement is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850; 83 FR 35855 through 35862). First, we excluded Medicare Advantage (MA) plan payments under Part C from the denominator of the Medicare revenues threshold calculation, in an effort to broaden the types of laboratories qualifying as an applicable laboratory. Specifically, excluding MA plan payments could allow additional laboratories of all types serving a significant population of beneficiaries enrolled in Medicare Part C to meet the majority of Medicare revenues threshold and potentially qualify as an applicable laboratory (if they also meet the low expenditure threshold) and report data to CMS during the data reporting period. Because MA plan payments are now excluded from the total Medicare revenues calculation, the denominator amount (total Medicare revenues) would decrease. If the denominator amount decreases, the likelihood increases that a laboratory would qualify as an applicable laboratory. This is because the laboratory's PFS and CLFS revenues are being compared to a lower total Medicare payment amount (than what they would have been compared to if MA plan payments remained in the denominator). Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period, and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction cannot be more than 10 percent per year, and for the next 3 years (CY 2021 through CY 2023), the reduction cannot be more than 15 percent per year. Under section 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs occurred from January 1, 2019 through June 30, 2019, and the next data reporting period was scheduled to take place from January 1, 2020 through March 31, 2020, with the next update to the Medicare payment rates for these tests based on that reported applicable information scheduled to take effect as of January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. As defined in § 414.502, an ADLT is a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory, and cannot be sold for use by a laboratory other than the single laboratory that designed the test or a successor owner. Also, an ADLT must meet either Criterion (A), which implements section 1834A(d)(5)(A) of the Act, or Criterion (B), which implements section 1834A(d)(5)(B) of the Act, as follows:

- *Criterion (A):* The test is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins; when combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition(s) or respond to a particular therapy(ies); provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and may include other assays; or:
- *Criterion (B):* The test is cleared or approved by the FDA.

Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101) and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-regulations.*

3. Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Section 105(a) of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, enacted on December 20, 2019), and section 3718 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L. 116–136, enacted on March 27, 2020), made revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs under section 1834A of the Act. Additionally, the CARES Act made

revisions to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 105(a)(1) of the FCAA amended the data reporting requirements in section 1834A(a) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by 1 year, so that data reporting would be required during the period of January 1, 2021 through March 31, 2021; the 3-year data reporting cycle for CDLTs that are not ADLTs would resume after that data reporting period. Section 105(a)(1) of the FCAA also specified that the data collection period that applies to the data reporting period of January 1, 2021 through March 30, 2021 would be the period of January 1, 2019 through June 30, 2019, which is the same data collection period that would have applied absent the amendments. In addition, section 105(a)(2) of the FCAA amended section 1834A(b)(3) of the Act regarding the phase-in of payment reductions to provide that payments may not be reduced by more than 10 percent as compared to the amount established for the preceding year through CY 2020, and for CYs 2021 through 2023, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year. These statutory changes were consistent with our regulations implementing the private payor rate-based CLFS (81 FR 41036;§ 414.507(d)).

Subsequently, section 3718 of the CARES Act further amended the data reporting requirements for CDLTs that are not ADLTs and the phase-in of payment reductions under the CLFS. Specifically, section 3718(a) of the CARES Act amended section 1834A(a)(1)(B) of the Act to delay the next data reporting period for CDLTs that are not ADLTs by one additional year, to require data reporting during the period of January 1, 2022 through March 31, 2022. As amended by the CARES Act, section 1834A(a)(1)(B) of the Act now provides that in the case of reporting with respect to CDLTs that are not ADLTs, the Secretary shall revise the reporting period under subparagraph (A) such that-(i) no reporting is required during the period beginning January 1, 2020, and ending December 31, 2021; (ii) reporting is required during the period beginning January 1, 2022, and ending March 31, 2022; and (iii) reporting is required every 3 years after the period described in clause (ii).

The CARES Act did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (January 1, 2022 through March 31, 2022) will be based on the data collection period of January 1, 2019 through June 30, 2019. In § 414.502, the current definition of data collection period is defined as the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period. Additionally, in § 414.502 the data reporting period is defined as the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. Unless we revised our current definitions of data collection period and data reporting period, the definitions would have been incorrect with regard to the data collection period that applies to the next data reporting period. Therefore, we proposed to revise the definitions of data collection period and data reporting period in § 414.502 to reflect that the data collection period will be January 1, 2019 through June 30, 2019 for the data reporting period of January 1, 2022 through March 31, 2022.

Section 3718(b) of the CARES Act further amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2024. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2021 is 0 percent, meaning that the payment amount determined for a CDLT for CY 2021 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2020. Section 3718(b) of the CARES Act further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent will apply for CYs 2022 through 2024, instead of CYs 2021 through 2023.

4. Conforming Regulatory Changes

In accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we proposed to make conforming changes to the data reporting and payment requirements at part 414, subpart G. Specifically, we proposed to revise § 414.502 to update the definitions of both the data collection period and data reporting period, specifying that for the data reporting period of January 1, 2022 through March 31, 2022, the data collection period is January 1, 2019 through June 30, 2019. We also proposed to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2022. In addition, we proposed conforming changes to our requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, we proposed to revise § 414.507(d) to indicate that for CY 2021, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2020, and for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We received public comments on the revised data reporting requirements and phase-in of payment reductions for the CLFS. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for the proposed conforming regulatory changes to the data reporting and payment requirements.

Response: We appreciate the commenters' support for these changes that reflect the recent statutory revisions required by section 105(a) of the FCAA and section 3718 of the CARES Act.

Comment: One commenter suggested that CMS delay implementation of the phase-in of payment reductions under the CLFS.

Response: We note that the phase-in of payment reductions to the CLFS payment amounts is statutory; therefore, we are unable to delay implementation. Additionally, we note that there will be a 0.0% payment reduction for CY 2021 and, for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

In consideration of these public comments and in accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we are finalizing the proposed conforming changes to the data reporting and payment requirements at part 414, subpart G.

5. Response to the Comment Solicitation on Payment for Specimen Collection for COVID–19 Clinical Diagnostic Laboratory Tests

In the ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment period (March 31st COVID–19 IFC), which displayed and became effective on March 31, 2020 and

appeared in the April 6, 2020 **Federal Register** (85 FR 19230), we established that Medicare will pay a nominal specimen collection fee and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients (85 FR 19256 through 19258). This policy provides independent laboratories with additional resources to provide COVID–19 testing and helps with efforts to limit patients' exposure to the general population and alleviate patients' unease with leaving the home. To identify specimen collection for COVID–19 testing specifically, we established two new level II HCPCS codes: Code G2023 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2) (Coronavirus disease [COVID–19]), any specimen source*); and code G2024 (*specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS–Cov–2) (Coronavirus disease [COVID19]), from an individual in a SNF or by a laboratory on behalf of a HHA, any specimen source*), for independent laboratories to use when billing Medicare for the nominal specimen collection fee for COVID–19 testing for the duration of the PHE for COVID–19.

We indicated in the March 31st COVID–19 IFC that this specimen collection fee policy was established for the duration of the PHE for COVID–19 (85 FR 19256). In the CY 2021 PFS proposed rule, we requested comments on whether we should delete HCPCS codes G2023 and G2024 once the PHE for COVID–19 ends (85 FR 50211). We noted that comments received may inform a future proposal. Specifically, we sought public input on why these codes, and their corresponding payment amounts, which are higher than the nominal specimen collection fees for other conditions, would be necessary or useful outside of the context of the PHE for COVID–19. We stated that we were particularly interested in why separate, increased payment for specimen collection specifically for COVID–19 tests, in contrast to other tests, may be needed following the end of the PHE.

We received public comments on the specimen collection fees for COVID–19 clinical diagnostic laboratory tests. The following is a summary of the comments we received and our response.

Comment: Several commenters expressed support for permanently extending payment for specimen collection for COVID–19 tests after the PHE, as commenters expect the COVID–19 virus to be present into CY 2021, thus making it appropriate for CMS to continue to pay for specimen collection. Commenters recommended that CMS expand and permanently authorize the specimen collection fees under HCPCS codes G2023 and G2024 to apply to all CDLTs to compensate for the supplies, equipment, and sterilization protocols required for safe and uncontaminated specimen collection and handling in the presence of COVID–19. Commenters noted that COVID–19 will continue to spread and may become an ongoing and/or seasonal infectious disease event, and because of this possibility, they expect that the heightened safety precautions, the need for personal protective equipment, and the requirement for special training for specimen collection will persist beyond the immediate PHE.

Commenters also recommended that CMS confirm that HCPCS code G2023 applies to any site where clinical laboratory personnel collect specimens, and not solely to homebound and nonhospital inpatients. Some commenters requested that CMS confirm that when a laboratory receives a health care professional's order for COVID–19 test specimen collection in a beneficiary's home, the laboratory may consider this order to be a determination by the health care professional that the beneficiary is homebound, and therefore, the laboratory is eligible for the increased specimen collection fee represented by HCPCS code G2023.

Response: We appreciate the comments regarding the nominal specimen collection fees and associated travel allowance to independent laboratories for the collection of specimens for COVID–19 clinical diagnostic laboratory testing. We plan to take this feedback into consideration for possible future rulemaking or guidance.

B. OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions

1. Modifications to OTP Enrollment Process

a. Background

Under 42 CFR 424.510, a provider or supplier must complete, sign, and submit to its assigned Medicare Administrative Contractor (MAC) the Form CMS–855 (OMB Control No. 0938–0685) application to enroll in the Medicare program and obtain Medicare billing privileges. The Form CMS–855, which can be submitted via paper or electronically through the internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process (SORN: 09–70–0532, Provider Enrollment, Chain, and Ownership System), captures information about the provider or supplier that CMS or its MACs reviews and verifies to determine whether the provider or supplier meets all Medicare requirements. (The specific Form CMS–855 application (of which there are several variations) to be completed will depend upon the type of provider or supplier submitting said application.) This process of enrollment helps ensure that: (1) All prospective providers and suppliers are carefully screened and reviewed; and (2) unqualified providers and suppliers are kept out of the Medicare program, which helps protect the Trust Funds and Medicare beneficiaries. Indeed, without this process, billions of taxpayer dollars might be paid to fraudulent or otherwise non-compliant parties.

b. Completion of Form CMS–855

Existing § 424.67 outlines a number of enrollment requirements for OTPs. One requirement, addressed in § 424.67(b)(1), is that OTPs must complete the Form CMS–855B application (Medicare Enrollment Application: Clinics/Group Practices and Certain Other Suppliers; OMB #: 0938–0685) to enroll in Medicare. The reference to the Form CMS–855B in § 424.67(b)(1) was predicated in part on the assumption that OTPs would generally submit the CMS–1500 claim form (Health Insurance Claim Form; OMB Control No.: 0938–1197) to receive payment for their services. However, as mentioned previously in section II.I.4. of the CY 2021 PFS proposed rule (85 FR 50074), we have received requests to allow OTPs to bill for services on an institutional claim form (specifically, the 837I). To do so, these OTPs would have to enroll in Medicare via the Form CMS–855A (Medicare Enrollment Application for Institutional Providers (OMB #: 0938–0685)). To account for circumstances where an OTP wishes to pursue Form CMS–855A enrollment for the reason stated above, we proposed the following revisions to § 424.67:

- Current § 424.67(b)(1) states that a newly enrolling OTP must fully complete and submit the Form CMS–855B application (or its successor application). We proposed to revise this paragraph to state that the newly enrolling OTP must fully complete and submit, as applicable, the Form CMS–855A or Form CMS–855B application (or their successor applications).
- Existing § 424.67(b)(1)(ii) requires the OTP to certify compliance with the requirements and standards described in paragraphs § 424.67(b) and (d) via the Form CMS–855B and/or the applicable

supplement or attachment thereto. We proposed to revise this paragraph such that the OTP must certify compliance with the above-referenced requirements and standards via the Form CMS–855A or Form CMS–855B (as applicable) and/or the applicable supplement or attachment thereto.

• Existing § 424.67(b)(5) requires the OTP to report on the Form CMS–855B and/or any applicable supplement all OTP staff who meet the definition of ''managing employee'' in § 424.502. We proposed to change this to state that the OTP must report on the Form CMS–855A or Form CMS–855B (as applicable) and/or any applicable supplement all OTP staff who meet this definition.

We believed these revisions would accomplish two objectives. First, they would permit OTPs to submit a Form CMS–855A in lieu of a Form CMS–855B based on their preferred method of billing. Second, they would confirm that the requirements of § 424.67 apply to all OTPs regardless of whether they complete the Form CMS–855A or the Form CMS–855B.

c. Screening Activities Associated With Risk Designation

Section 424.518 outlines provider enrollment screening categories and requirements based on our assessment of the degree of risk of fraud, waste, and abuse posed by a particular category of provider or supplier. In general, the higher the level of risk that a certain provider or supplier type presents, the greater the degree of scrutiny with which we will screen and review enrollment applications submitted by providers or suppliers within that category. There are three levels of screening addressed in § 424.518: Limited; moderate; and high. Irrespective of which level a provider or supplier type falls within, the MAC performs certain minimum screening functions upon receipt of an initial enrollment application, a revalidation application, or an application to add a new practice location. These include:

• Verification that the provider or supplier meets all applicable federal regulations and state requirements for their provider or supplier type.

• State license verifications.

• Database reviews on a pre- and post-enrollment basis to ensure that providers and suppliers continue to meet the enrollment criteria for their provider or supplier type.

Providers and suppliers at the moderate and high categorical risk levels must also undergo a site visit. Moreover, for those in the high categorical risk level, the MAC performs two additional functions under § 424.518(c)(2). First, the MAC requires the submission of a set of fingerprints for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. Second, it conducts a fingerprint-based criminal history record check of the Federal Bureau of Investigation's (FBI) Integrated Automated Fingerprint Identification System on all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. These additional verification activities are intended to correspond to the heightened risk involved with such provider or supplier types.

For newly enrolling OTPs, those that have been fully and continuously certified by the Substance Abuse and Mental Health Services Administration (SAMHSA) since October 23, 2018 fall within the moderate level of categorical screening. OTPs that have not been so certified since the aforementioned date are subject to the high screening level. As discussed in the CY 2021 PFS proposed rule (85 FR 50074), we recognize that certain providers and suppliers have already enrolled as OTPs via the Form CMS–855B—and, accordingly, undergone a site visit and, if applicable, fingerprinting—but would seek to newly enroll via the Form CMS–855A should our proposals be finalized. (Said enrollment would be considered ''new'' for purposes of enrollment because the OTP would be enrolling via a different variation of the Form CMS–855.) While not seeking to minimize the importance of the enhanced screening activities associated with the moderate and high categorical levels, we do not wish to unduly burden currently enrolled OTPs that would pursue Form CMS–855A enrollment as an OTP. More specifically, we noted that we did not believe such OTPs should have to undergo another site visit and, if applicable, fingerprinting when they previously did so as an OTP via their original Form CMS–855B enrollment. This, in our view, would constitute an unnecessary expenditure of CMS, MAC, and OTP resources. We add that the same would hold true if, in the future, an OTP that is enrolled via the Form CMS–855A under revised § 424.67(b) decides to change to a Form CMS–855B enrollment. In both cases, we believe a duplication of effort should be avoided to the extent consistent with safeguarding the integrity of the Medicare program.

Existing § 424.67(b)(3) states that an enrolling OTP must successfully complete the assigned categorical risk level screening required under, as applicable, § 424.518(b) and (c) (which outline the screening requirements for newly enrolling parties in, respectively, the moderate and high categorical levels). Given the foregoing discussion, we proposed several changes to § 424.67(b)(3). First, we proposed to redesignate existing § 424.67(b)(3) as new § 424.67(b)(3)(i), though with an exception to its requirements. Second, and to address this exception, we proposed to add paragraph (b)(3)(ii) to state that currently enrolled OTPs that are changing their OTP enrollment from a Form CMS–855B to a Form CMS–855A, or vice versa, must successfully complete the limited level of categorical screening under § 424.518(a) if the OTP has already completed, as applicable, the moderate or high level of categorical screening under § 424.518(b) or (c), respectively. Third, we proposed to redesignate existing § 424.518(a)(1)(xii) through (xvii) as § 424.518(a)(1)(xiii) through (xviii). Fourth, proposed new § 424.518(a)(1)(xii) would add OTPs that fall within the purview of new paragraph (b)(3)(ii) to the provider and supplier types subject to limited risk categorical screening.

d. Additional OTP Enrollment Clarifications Regarding the Form CMS–855A

We proposed three additional clarifications related to our previously mentioned OTP enrollment provisions. To incorporate these into § 424.67, we proposed to redesignate existing paragraphs (c), (d), (e), and (f) as paragraphs (d), (e), (f), and (g), respectively. The three clarifications would be included in new paragraph (c).

With the redesignation of existing paragraph (d) as paragraph (e), we also proposed to change the reference to:

• Paragraph (d) in existing paragraph (b)(1)(ii) to paragraph (e).

• Paragraph (d)(1) in existing paragraph (d)(2)(i) to paragraph (e)(1) in redesignated paragraph (e)(2)(i).

(1) Single Enrollment

We proposed in new § 424.67(c)(1) that an OTP may only be enrolled as such via the Form CMS–855A or the Form CMS–855B but not both. The OTP, in other words, must opt for either Form CMS–855A enrollment or Form CMS–855B enrollment. This is to help ensure that the OTP does not bill twice for the same service via separate claim vehicles (specifically, the CMS–1500 and the 837I).

(2) Effective Date of Billing

Section 424.520(d) outlines the effective date of billing privileges for newly enrolling OTPs (and certain other provider and supplier types). This date is the later of: (1) The date of the OTP's filing of a Medicare enrollment application that was subsequently approved by a Medicare contractor; or (2) the date that the OTP first began furnishing services at a new practice location. In a similar vein, § 424.521(a) states that OTPs (and certain other provider and supplier types) may retrospectively bill for services when the OTP has met all program requirements (including state licensure requirements), and services were provided at the enrolled practice location for up to—

- 30 days prior to their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- 90 days prior to their effective date if a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act) precluded enrollment in advance of providing services to Medicare beneficiaries.

In light of proposed § 424.67(c)(1) (and as further explained in the collection of information section of this proposed rule), we anticipate that a number of OTPs would end their existing enrollment and apply as a new OTP via, as applicable, the Form CMS–855A or Form CMS–855B. Given this, we believe it is important to clarify for stakeholders the new enrollment's effective date of billing. Accordingly, at § 424.67, we proposed in new paragraph (c)(2) that if a Form CMS–855B-enrolled OTP changes to a Form CMS–855A enrollment, or vice versa, the effective date of billing that was established for the OTP's prior enrollment under §§ 424.520(d) and 424.521(a) would be applied to the OTP's new enrollment. This would allow OTPs that have been unable to bill for furnished services via their preferred claim form (and have consequently chosen to delay the submission of these claims for services) to do so retroactive to the effective billing date of its prior enrollment. To illustrate, suppose an OTP initially enrolled via the Form CMS–855B in 2020. The effective date of billing was April 1, 2020. Wishing to submit an 837I claim form for the services it has provided since April 1, 2020, the OTP elects to end its Form CMS–855B enrollment and enroll via the Form CMS–855A pursuant to revised § 424.67. It successfully does the latter in March 2021. Under § 424.67(c)(2), the billing effective date of the Form CMS–855A enrollment would be retroactive to April 1, 2020. However, we noted in the proposed rule that the time limits for filing claims found in § 424.44 would continue to apply. Specifically, all Medicare Part A and Part B claims must be filed within 1 calendar year after the date of service unless one of a very limited number of exceptions applies. Switching from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, is not grounds for an exception.

We recognized that not every OTP that seeks to change its enrollment will have chosen to withhold submission of all of its claims under its prior enrollment. (Using our example in the previous paragraph, the OTP may have submitted some claims via the CMS–1500 while planning to eventually submit the remaining ones via the 837I.) Irrespective of this, CMS has long had operational safeguards in place to prevent double-billing for the same service. Said protections would be used in the scenario described in proposed § 424.67(c)(2) so that claims submitted under the prior enrollment could not be resubmitted under the new one.

(3) Application Fee

As stated in § 424.514, prospective and revalidating institutional providers that are submitting a Medicare enrollment application generally must pay the applicable application fee in accordance with § 424.514. (For CY 2020, the fee amount is $595.) The term ''institutional provider'' is defined in § 424.502 as any provider or supplier that submits a paper Medicare enrollment application using the Form CMS–855A, Form CMS–855B (not including physician and NPP organizations, which are exempt from the fee requirement if they are enrolling as a physician or NPP organization), Form CMS–855S, Form CMS–20134, or an associated internet-based PECOS enrollment application.

As stated previously, OTPs currently complete the Form CMS–855B to enroll in Medicare. They are considered ''institutional providers'' (as defined in § 424.502) and must pay an application fee, a requirement addressed in existing § 424.67(b)(2). Since the existing OTPs referenced in new paragraph (c)(2) would be enrolling as new providers via the Form CMS–855A or Form CMS–855B (as applicable), we stated our belief in the proposed rule that they would fall within the scope of both (1) the aforementioned definition of ''institutional provider'' and (2) § 424.514(a)(1); as described therein, § 424.514(a)(1) applies to prospective institutional providers that are submitting an initial application. To clarify this issue for the OTP community, we proposed to add language to § 424.67(b)(2) stating that compliance with the application fee requirements in § 424.514 would also apply to those OTPs enrolling under the circumstances described in § 424.67(c)(2).

We emphasized that the flexibilities described in this section III.B. are complementary to those in section II.I. (''Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs))'' regarding OTP billing via the 837I. Our OTP enrollment revisions are intended to facilitate greater flexibility for OTPs.

We received the following public comment on our OTP provider enrollment proposals:

Comment: Several commenters supported our proposal to permit an OTP to enroll via the Form CMS–855B or the Form CMS–855A. One commenter also questioned whether this applies to a Medicare OTP Part B provider sharing the same clinical space as a Medicare Part A provider.

Response: We appreciate the commenters' support. However, we emphasize that an OTP may only enroll as such via the Form-855B or the Form-855A, not both. In the situation the OTP appears to describe, the OTP operating in the clinical space in question would have to elect which of the two available enrollment mechanisms to pursue.

Based on the comments received, we are finalizing our provisions pertaining to OTP enrollment as proposed.

C. Payment for Principal Care Management (PCM) Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. RHC and FQHC Payment Methodologies

RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which time one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners (NPs), physician assistants (PA), certified nurse midwives (CNMs), clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient. A Transitional Care Management (TCM) service can also be an RHC or FQHC

visit. In addition, a Diabetes Self-Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT program may also count as an FQHC visit. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per visit payment.

RHCs are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). In general, the A/B Medicare Administrative Contractor (MAC) calculates the AIR for the year for each RHC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services. The AIR is subject to a payment limit, except for certain provider-based RHCs that have an exception to the payment limit.

FQHCs were paid under the same AIR methodology until October 1, 2014 when, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Affordable Care Act), they began to transition to an FQHC PPS system in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF).

b. Care Management Services in RHCs and FQHCs

In the CY 2018 PFS final rule with comment period (82 FR53180), we finalized revisions to the payment methodology for Chronic Care Management (CCM) services furnished by RHCs and FQHCs and established requirements for general Behavioral Health Integration (BHI) and psychiatric Collaborative Care Management (CoCM) services furnished in RHCs and FQHCs, beginning on January 1, 2019. Specifically, we revised § 405.2464(c) to permit RHCs and FQHCs to bill for care management services (HCPCS codes G0511 and G0512).

HCPCS code, G0511, is a General Care Management code for use by RHCs or FQHCs when at least 20 minutes of qualified CCM or general BHI services are furnished to a patient in a calendar month.

The payment amount for HCPCS code G0511 is set at the average of the 3 national non-facility PFS payment rates for the CCM and general BHI codes and updated annually based on the PFS amounts. The 3 codes are CPT 99490 (*20 minutes or more of CCM services*), CPT 99487 (*60 minutes or more of complex CCM services*), and CPT 99484 (*20 minutes or more of BHI services*).

In the CY 2019 PFS final rule with comment period (83 FR 59687), we added CPT code 99491 (*30 minutes or more of CCM furnished by a physician or other qualified health care professional*) as a general care management service and included it in the calculation of HCPCS code G0511. Beginning January 1, 2019, the payment for HCPCS code G0511 is set at the average of the national non-facility PFS payment rates for CPT codes 99490, 99487, 99484, and 99491 and is updated annually based on the PFS amounts. Additional information on CCM requirements is available on the CMS Care Management web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Care-Management.html*, and on the CMS RHC and FQHC web pages at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html* and *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html*.

2. Requirements for PCM Services in RHCs and FQHCs

In the CY 2020 PFS final rule with comment (84 FR 62692), we established a separate payment for PCM services. PCM services include comprehensive care management services for a single high-risk disease or complex condition, typically expected to last at least 3 months and may have led to a recent hospitalization, and/or placed the patient at significant risk of death. Beginning January 1, 2020, practitioners billing under the PFS can bill for PCM services using HCPCS codes G2064 or G2065.

HCPCS code G2064 is for at least 30 minutes of PCM services furnished by physicians or NPPs during a calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan; the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization; the condition requires development or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen; and/or the management of the condition is unusually complex due to comorbidities.

HCPCS code G2065 is for at least 30 minutes of PCM services furnished by clinical staff under the direct supervision of a physician or NPP with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan; the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization; the condition requires development or revision of disease-specific care plan; the condition requires frequent adjustments in the medication regimen; and/or the management of the condition is unusually complex due to comorbidities.

In the CY 2021 PFS proposed rule (85 FR 50214), we stated that a national stakeholder organization representing rural health clinics requested that RHCs be allowed to furnish and bill for PCM services. We agreed that there can be significant resources involved in care management for a single high-risk disease or complex chronic condition, and that the requirements for the new PCM codes are similar to the requirements for the care management services described by HCPCS code G0511. We explained that these are services that do not currently meet the requirements for an RHC or FQHC billable visit, and they provide an array of care management services that are not generally included in the RHC AIR or the FQHC PPS. Therefore, we proposed to add HCPCS codes G2064 and G2065 to G0511 as a comprehensive care management service for RHCs and FQHCs starting January 1, 2021. The payment rate for HCPCS G0511 is set at the average of the national non-facility PFS payment rate for the RHC and FQHC care management and general behavioral health codes (CPT codes 99490, 99487, 99484, and 99491), and we proposed that these 2 new codes be added to the calculation of the G0511 payment rate.

3. Other Options Considered

In the CY 2021 PFS proposed rule (85 FR 50214), we stated that we also considered creating a separate G code for PCM services. We did not propose this approach because PCM and CCM are similar services and grouping them together is consistent with an integrated approach to care with reduced reporting

requirements. As we stated in the CY 2018 PFS final rule, if a new care management code is proposed and subsequently finalized for practitioners billing under the PFS, we would review the new code to determine if it should be included in the calculation of the RHC and FQHC General Care Management Code. The determination of whether a new care management code should be added to the codes used to determine the payment rate is based on the applicability of the service in RHCs and FQHCs, and may result in either an increase or decrease in the payment amount for HCPCS code G0511.

4. Implementation

In the CY 2021 PFS proposed rule (85 FR 50214), we explained that if this proposal is finalized as proposed, RHCs and FQHCs that furnish PCM services would also be able to bill the services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2021. The payment rate for HCPCS code G0511 would continue to be the average of the national non-facility PFS payment rates for the RHC/FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491). HCPCS G2064 and G2065 would be added to G0511 to calculate a new average for the national non-facility PFS payment rate. The payment rate for HCPCS code G0511 would be updated annually based on the PFS amounts for these codes.

We received approximately 27 public comments on the proposed requirements for PCM services in RHCs and FQHCs from a mix of stakeholders, including individuals, associations, advocate groups, and provider groups. The following is a summary of the comments we received and our responses.

Comment: All commenters supported the proposal to add the PCM HCPCS codes to the general care management HCPCS code (G0511) for care management services furnished in RHCs and FQHCs. One commenter recommended we create two new G codes for PCM services furnished in RHCs and FQHCs. A few commenters suggested that CMS waive the coinsurance for PCM services.

Response: Per the comment that recommended that we create two new G codes, we considered creating new G codes for PCM services as we stated in the CY 2021 PFS proposed rule (85 FR 50214); however, we explained that since the requirements for PCM services are similar to the requirements for care management services furnished in an RHC and FQHC, grouping them together is consistent with an integrated approach to care with reduced reporting requirements.

Regarding the comment suggesting that CMS waive the coinsurance for PCM services, we remind commenters that we have no authority to waive coinsurance for care management services. Coinsurance for care management services is 20 percent of lesser of submitted charges or the payment rate for general care management HCPCS code.

Comment: We received several public comments that were out-of-scope for this rule. Commenters requested that CMS expand certain flexibilities provided during the PHE for COVID–19, including the addition of services to the Medicare Telehealth Services List. In addition, several commenters requested that CMS create a separate G code for remote physiologic monitoring (RPM) services and add RPM treatment management services (RPMTMS) to the general care management services.

Response: We appreciate the feedback from commenters, and will continue to monitor Medicare telehealth services during the PHE for COVID–19. RHCs are paid an AIR when a medically-necessary, face-to-face visit is furnished by an RHC practitioner. FQHCs are paid the lesser of their charges or the FQHC PPS rate when a medically-necessary, face-to-face visit is furnished by an FQHC practitioner. Both the RHC AIR and the FQHC PPS rate include all services and supplies furnished incident to the visit. Services such as RPM are not separately billable because they are already included in the RHC AIR or FQHC PPS payment. We may consider analyzing the RPMTMS services and how they would impact the payment for general care management services in future rulemaking; however, we note that we did not specifically make any proposals associated with these subjects in the CY 2021 PFS proposed rule.

In consideration of these public comments, we are finalizing the proposal to add the PCM HCPCS codes, G2064 and G2065, to the general care management code, G0511, as a comprehensive care management service for RHCs and FQHCs, starting January 1, 2021 as proposed. We are also finalizing that when RHCs and FQHCs furnish PCM services, they will also be able to bill the services using HCPCS code G0511, either alone or with other payable services on an RHC or FQHC claim for dates of service on or after January 1, 2021. The payment rate for HCPCS code G0511 will be the average of the national non-facility PFS payment rates for the RHC/FQHC care management and general behavioral health codes (CPT codes 99484, 99487, 99490, and 99491) with the addition of HCPCS G2064 and G2065. That is, the PCM services will be added to G0511 to calculate a new average for the national non-facility PFS payment rate. The payment rate for HCPCS code G0511 will be updated annually based on the PFS amounts for these codes.

D. Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Rebasing and Revising of the FQHC Market Basket

1. Background

Section 10501(i)(3)(A) of the Affordable Care Act added section 1834(o) of the Act to establish a payment system for the costs of FQHC services under Medicare Part B based on prospectively set rates. In the Prospective Payment System (PPS) for FQHC final rule published in the May 2, 2014 **Federal Register** (79 FR 25436), we implemented a methodology and payment rates for the FQHC PPS. Beginning on October 1, 2014, FQHCs began to transition to the FQHC PPS based on their cost reporting periods, and as of January 1, 2016, all FQHCs have been paid under the FQHC PPS.

Section 1834(o)(2)(B)(ii) of the Act requires that the payment for the first year after the implementation year be increased by the percentage increase in the Medicare Economic Index (MEI). Therefore, in CY 2016, the FQHC PPS base payment rate was increased by the MEI. The MEI is based on 2006 data from the American Medical Association (AMA) for self-employed physicians and was used in the PFS sustainable growth rate (SGR) formula to determine the CF for physician service payments. (See the CY 2014 PFS final rule (78 FR 74264) for a complete discussion of the 2006-based MEI.) Section 1834(o)(2)(B)(ii) of the Act also requires that beginning in CY 2017, the FQHC PPS base payment rate will be increased by the percentage increase in a market basket of FQHC goods and services, or if such an index is not available, by the percentage increase in the MEI.

Beginning with CY 2017, FQHC PPS payments were updated using a 2013-based market basket reflecting the operating and capital cost structures for freestanding FQHC facilities (hereafter referred to as the FQHC market basket). A complete discussion of the 2013-based FQHC market basket can be found in the CY 2017 PFS final rule (81 FR 80393 through 80403).

In the CY 2021 PFS proposed rule (85 FR 50214 through 50223), we proposed

to rebase and revise the 2013-based FQHC market basket to reflect a 2017 base year. The proposed 2017-based FQHC market basket is primarily based on Medicare cost report data for FQHCs for 2017, which are for cost reporting periods beginning on and after October 1, 2016, and prior to September 31, 2017. We proposed to use data from cost reports beginning in FY 2017 because these data are the latest available complete data for purposes of calculating cost weights for the market basket at the time of rulemaking.

In the following discussion, we provide an overview of the proposed FQHC market basket, describe the proposed methodologies for developing the 2017-based FQHC market basket, and provide information on the proposed price proxies. We then describe any comments received, responses to these comments, and our final decision for this final rule.

2. Overview of the 2017-Based FQHC Market Basket

Similar to the 2013-based FQHC market basket, the proposed 2017-based FQHC market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix (that is, intensity) of goods and services purchased over time are not measured. The index itself is constructed using three steps. First, a base period is selected (we proposed to use 2017 as the base period) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called ''cost weights'' or ''expenditure weights.'' Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe. As noted above, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to furnish FQHC services. The effects on total expenditures resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a FQHC hiring more nurse practitioners to accommodate the needs of patients would increase the volume of goods and services purchased by the FQHC, but would not be factored into the price change measured by a fixed-weight FQHC market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect a recent mix of goods and services that FQHCs purchase (FQHC inputs) to furnish inpatient care.

3. Development of the 2017-Based FQHC Market Basket Cost Categories and Weights

We solicited public comments on the proposed methodology for deriving the 2017-based FQHC market basket.

a. Use of Medicare Cost Report Data

We proposed a 2017-based FQHC market basket that consists of eleven major cost categories and a residual derived from the 2017 Medicare cost reports (CMS Form 224–14, OMB Control Number 0938–1298) for FQHCs, hereafter referred to as the 2014 Medicare Cost Report form. The eleven cost categories are FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Medical Supplies, Pharmaceuticals, Fixed Capital and Moveable Capital. The residual category reflects all remaining costs not captured in the 11 cost categories such as non-medical supplies and utilities for example. We noted that for the 2013-based FQHC market basket, we estimated six cost categories from the Medicare cost reports (CMS Form 222–92, OMB Control Number 0938–0107), hereafter referred to as the 1992 Medicare cost report form: FQHC Practitioner Compensation, Clinical Staff Compensation, Non-Health Staff Compensation, Pharmaceuticals, Fixed Capital and Moveable Capital.

The resulting 2017-based FQHC market basket cost weights reflect Medicare allowable costs. We proposed to define Medicare allowable costs for freestanding FQHC facilities as the total expenses reported on: Worksheet A, columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, column 1, lines 23 through 36; and Worksheet S3 Part II, columns 1 and 2, lines 2 through 14. We noted that we continue to exclude Professional Liability Insurance (PLI) costs from the total Medicare allowable costs because FQHCs that receive section 330 grant funds also are eligible to apply for medical malpractice coverage under Federally Supported Health Centers Assistance Act (FSHCAA) of 1992 (Pub. L. 102–501) and FSHCAA of 1995 (Pub. L. 104–73 amending section 224 of the Public Health Service Act).

The following is a summary of how we proposed to derive the eleven major cost category weights. Prior to estimating any costs, we remove any providers that did not report any total gross patient revenues as reported on the FQHC cost report Worksheet F–1, line 1, column 4.

(1) FQHC Practitioner Wages and Salaries Costs

A FQHC practitioner is defined as one of the following occupations: Physicians; nurse practitioners (NPs); physician assistants (PAs); certified-nurse midwife (CNMs); clinical psychologist (CPs); and clinical social workers (CSWs). We proposed to derive FQHC Practitioner Wages and Salaries costs as the sum of direct care costs salaries as reported on Worksheet A, column 1, lines 23, 25, 26, 29, 30, and 31. These lines represent the wages and salaries costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. For the 2013-based FQHC market basket, we estimated FQHC Practitioner Total Compensation costs based on a similar methodology using cost data reported on Worksheet A of the 1992 Medicare cost report form (81 FR 80394) for specific details on the prior methodology.

(2) FQHC Practitioner Employee Benefits Costs

Effective with the implementation of the 2014 Medicare cost report form, we began collecting Employee Benefits and Contract Labor data on Worksheet S–3, part II and proposed to derive FQHC Practitioner Employee Benefits costs using data obtained from that worksheet. Approximately 66 percent of FQHCs included in the sample of FQHCs reporting Salary costs also reported data on Worksheet S–3, part II for 2017. We continue to encourage all providers to report these data on the

Medicare cost report. Therefore, we proposed to calculate FQHC Practitioner Employee Benefits costs using Worksheet S–3, part II data. Specifically, we proposed to use data from Worksheet S–3, part II, column 2, lines 2, 3, 4, 7, 8, and 9 to derive FQHC Practitioner Employee Benefits costs. These lines represent the employee benefits costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. Our analysis of the Worksheet S–3, part II data submitted by these FQHCs indicates that we had a large enough sample to enable us to produce a reasonable Employee Benefits cost weight.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate FQHC Practitioner Employee Benefits costs, and instead computed FQHC Practitioner Total Compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. Anytime direct costs can be obtained for a cost category directly from the Medicare Cost Reports we consider that to be a technical improvement to the market basket weight methodology as it allows the index to reflect the relative shares specific to the provider type. Therefore, as discussed in the CY 2021 PFS proposed rule, we noted that we believe the proposed method of separately estimating FQHC Practitioner Employee Benefits is a technical improvement over the 2013-based FQHC market basket.

(3) FQHC Practitioner Contract Labor Costs

FQHC Practitioner Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described below. Approximately 60 percent of FQHCs reported contract labor costs on Worksheet S–3, part II, which we noted that we believe is an adequate sample size to enable us to produce a reasonable FQHC Practitioner Contract Labor cost weight. Therefore, we proposed to derive the FQHC Practitioner Contract Labor costs for the proposed 2017-based FQHC market basket from data reported on Worksheet S–3, part II, column 1, lines 2, 3, 4, 7, 8, and 9. These lines represent the contract labor costs for physicians, PAs, NPs, CNMs, CPs, and CSWs. We would also add in the costs for physician services under agreement as reported on Worksheet A, column 2, line 24 to derive the total FQHC Practitioner Contract Labor cost weight in the 2017-based FQHC market basket.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate FQHC Practitioner Contract Labor costs and instead computed FQHC Practitioner Total Compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. As noted previously, anytime direct costs can be obtained for a cost category directly from the Medicare Cost Reports we consider that to be a technical improvement to the market basket weight methodology as it allows the index to reflect the relative shares specific to the provider type. Therefore, we noted that we believe the proposed method of separately estimating FQHC Practitioner Contract Labor is a technical improvement over the 2013-based FQHC market basket.

(4) Clinical Staff Wages and Salaries Costs

Clinical Compensation includes any health-related clinical staff who does not fall under the definition of a FQHC Practitioner described in paragraph. We proposed to derive Clinical Staff Wages and Salaries costs as the sum of direct care costs salaries as reported on Worksheet A, column 1, lines 27, 28, 32, 33, 34, 35, and 36. These lines represent the wages and salaries costs for visiting registered nurses (RNs), visiting licensed practical nurses (LPNs), laboratory technicians, registered dietician/Certified DSMT/MNT educators, physical therapists (PTs), occupational therapists (OTs), and other allied health personnel.

- For the 2013-based FQHC market basket, we estimated a clinical staff total compensation cost based on a similar methodology using cost data reported on Worksheet A of Medicare Cost Report Form CMS–222–92, (see 81 FR 80394 for specific details on the prior methodology).

(5) Clinical Staff Employee Benefits Costs

Effective with the implementation of the 2014 Medicare cost report form, we began collecting employee benefits and contract labor data on Worksheet S–3, part II and proposed to derive clinical staff employee benefits costs using data obtained from that worksheet. Approximately 64 percent of FQHCs included in the sample of FQHCs reporting salary expenses also reported data on Worksheet S–3, part II for 2017. We noted that we continue to encourage all providers to report these data on the Medicare cost report. Therefore, we proposed to calculate clinical staff employee benefits costs using Worksheet S–3, part II, column 2, lines 5, 6, 10, 11, 12, 13, and 14. These lines represent the employee benefits costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel.

- For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate clinical staff employee benefits costs and instead computed clinical staff total compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. We noted that we believe the proposed method of separately estimating clinical staff employee benefits is a technical improvement over the 2013-based FQHC market basket.

(6) Clinical Staff Contract Labor Costs

We proposed to derive the clinical staff contract labor costs for the proposed 2017-based FQHC market basket from data reported on Worksheet S–3, part II, column 1, lines 5, 6, 10, 11, 12, 13, and 14 to derive clinical staff contract labor costs. These lines represent the contract labor costs for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel.

For the 2013-based FQHC market basket, we did not have data at the level of detail to separately estimate clinical staff contract labor costs and instead computed clinical staff total compensation costs, which reflected costs for wages and salaries, employee benefits, and contract labor together. We noted that we believe the proposed method of separately estimating FQHC clinical staff contract labor is a technical improvement over the 2013-based FQHC market basket.

(7) Non-Health Staff Compensation Costs

Non-Health Staff Compensation includes wage and salary costs for personnel in general service cost centers including: Employee Benefits department; Administrative & General; Plant Operation & Maintenance; Janitorial; Medical Records; Pharmacy; Transportation; and Other General Services. Specifically, non-health staff compensation costs are derived as the sum of compensation costs as reported on Worksheet A, column 1 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Additionally, we add a portion of employee benefit costs reported on Worksheet A, line 3, column 2 accounting for the non-health staff. We

estimate the ratio of non-health staff related wages and salaries as a percentage of total wages and salaries. We then apply the percentage of non-health staff related wages and salary costs to the total employee benefits costs (Worksheet A, line 3, column 2) for each FQHC. We noted that we believe this is a reasonable estimate of non-health staff employee benefits. We proposed to only use the costs from column 1 for most of the general service cost centers other than employee benefits since we believe that there are noncompensation costs reported in column 2 (such as maintenance and janitorial supplies). The remaining other costs for the general service categories are reflected in the remaining proposed cost categories as explained in more detail below.

(8) Pharmaceuticals Costs

We proposed to calculate pharmaceuticals costs using the non-salary costs for the pharmacy cost center reported on Worksheet A, column 2, line 9. We proposed to exclude the costs for drugs charged to patients as reported on Worksheet A, line 67 since these drugs are not included in the Medicare allowable costs for the FQHC PPS and are separately reimbursed. For the 2013-based FQHC market basket we were not able to exclude non-reimbursable drug costs (such as drugs charged to patient costs) from the pharmacy cost weight as the 1992 Medicare cost report form did not capture these costs separately. We noted that we believe our proposed methodology is a technical improvement as it is more consistent with the FQHC PPS reimbursement.

(9) Medical Supplies

We proposed to calculate medical supplies costs using the non-salary costs for the medical supplies cost center reported on Worksheet A, column 2, line 10. The medical supplies cost weight for the 2013-based FQHC market basket was derived based on the relative share of the medical supply costs in the MEI since these costs were not separately reported on the 1992 Medicare cost report form (81 FR 80395 through 80396). Since these costs are now directly reported by FQHC providers we noted that we believe that the proposed method is a technical improvement to the method used in the 2013-based FQHC market basket.

(10) Fixed Capital

We proposed that fixed capital costs be equal to costs reported on Worksheet A, line 1, column 2 of the Medicare Cost Report. A similar methodology was used for the 2013-based FQHC market basket.

(11) Moveable Capital Costs

We proposed that moveable capital costs be equal to the capital costs as reported on Worksheet A, line 2, column 2. A similar methodology was used for the 2013-based FQHC market basket.

Comment: Several commenters expressed support, as well as some concerns with the proposed use of the Medicare cost reports. Specifically, the commenters supported the proposed use of the Medicare cost report data to derive eleven major cost categories in the 2017-based FQHC market basket—an increase from 6 cost categories used in the 2013-based FQHC market basket. They stated this calculation will give a broader base to more accurately compute the increasing costs of providing FQHC services.

The commenters also agreed with the proposed lines included in the calculation of the Medicare Allowable total expenses (Worksheet A, columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, column 1, lines 23 through 36; and Worksheet S3 Part II, columns 1 and 2, lines 2 through 14). However, they disagreed with the use of columns 1 and 2 from Worksheet A to capture a health center's expenses because they reflect their internal accounting records in accordance with generally accepted accounting principles (GAAP). The commenters noted that the net expenses as listed in Worksheet A, column 7 of the Medicare cost report most accurately reflects Medicare allowable cost for a community health center as these reflect the reclassification entries which are common on the Medicare cost report, particularly for expenses related to compensation and drugs. They also noted that CMS must factor in the reclassification and adjustment entries that are recorded on health center Medicare cost reports to accurately calculate a 2017-based market basket that reflects the change in Medicare allowable costs. Furthermore, the commenters noted that the costs that are used to calculate the costs per visits in Worksheet B reflect the reclassifications and adjustments and so the 2017-based FQHC market basket should be calculated using the same cost information.

Response: Using the data from the net cost column (column 7) presents unique challenges because a detailed breakdown of the net expenses is not provided on the FQHC cost report, particularly for employee benefits, which is why we proposed to utilize the data from Worksheet A column 1 and 2 to estimate salary and all other costs. Specifically, the FQHC cost report does not have a detailed step down of the net expenses allocated to each General Service cost center like other provider cost reports such as the hospice cost report (CMS Form 1984–14). This means that for some categories, particularly Employee Benefits cost center, we must make assumptions on how the total employee benefit costs are allocated across cost centers. On the other hand, Worksheet B on the hospice cost report gives a detailed allocation of General Service cost centers' net expenses (including employee benefits) across the patient-care cost centers.

Based on the commenters' concerns, we reviewed the FQHC Medicare cost report data and found that a large percentage of providers had reclassifications and adjustments and these had an impact on the distribution of total expenses among the major cost weight categories, particularly pharmaceuticals and FQHC practitioner salaries. Therefore, based on public comments, for this final rule we are revising our methodology from the proposed rule to reflect the use of net expenses as reported on Worksheet A, column 7 rather than the proposed Worksheet A, column 1 and column 2 to derive the FQHC cost share weights. Below we provide the revised detailed methodology for the major market basket cost weights in response to public comment.

In response to public comments to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining Medicare allowable costs for freestanding FQHC facilities as the total expenses reported on: Worksheet A, column 7, for lines 1 through 7, lines 9 through 12, and lines 23 through 36. These are the same cost centers that were used in the proposed market basket for which the commenters agreed was appropriate.

(1–3) FQHC Practitioner Compensation (Wages & Salaries, Benefits, and Contract Labor)

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining the FQHC Practitioner Compensation as the sum of net expenses (that is, costs after reclassifications and adjustments) as reported on Worksheet A, column 7, lines 23, 25, 26, 29, 30, and 31. These lines represent the total net costs for physicians, PAs, NPs, CNMs, CPs, and CSWs—the same lines that were used for the proposed methodology for which the commenters agreed was appropriate. Using this finalized methodology, we derive a 2017-based FQHC market

basket FQHC Practitioner Compensation cost weight of 28.4 percent compared to the proposed rule with 30.0 percent.

To further divide the FQHC Practitioner Compensation costs into FQHC Practitioner Wages and Salaries, Benefits, and Contract Labor costs, we are using the shares derived for each of these costs using the proposed methodologies for each FQHC provider as described in sections III.D.3.a.1, D.3.a.2 and D.3.a.3 of this final rule. Specifically, for each line included in the FQHC Practitioner category, the FQHC Practitioner Wages and Salaries costs is equal to the FQHC Practitioner Compensation costs as described above multiplied by the FQHC Practitioner Wages and Salaries costs (described in section III.D.3.a.1 of this final rule) as a percent of FQHC Practitioner Compensation costs. This revised methodology reflects the net expenses (Worksheet A, column 7) to address the commenters' concerns while also using the Medicare cost report data to reflect the split among the types of compensation costs: Wages and salaries, employee benefits, and contract labor.

Therefore, for this final rule, in response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, the FQHC Practitioner Wages and Salaries cost weight is 19.4 percent, and accounts for 68 percent of the FQHC Practitioner Compensation cost weight. The FQHC Practitioner Employee Benefit cost weight is 4.5 percent, and accounts for 16 percent of the FQHC Practitioner Compensation cost weight. The FQHC Practitioner Contract Labor cost weight is 4.6 percent, and accounts for 16 percent of the FQHC Practitioner Compensation cost weight.

(4–6) Clinical Staff Compensation (Wages & Salaries, Benefits, and Contract Labor)

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining Clinical Staff Compensation costs as the sum of net expenses (that is, costs after reclassifications and adjustments) as reported on Worksheet A, column 7, lines 27, 28, 32, 33, 34, 35, and 36. These lines represent the net expenses for visiting RNs, visiting LPNs, laboratory technicians, registered dietician/Certified DSMT/MNT educators, PTs, OTs, and other allied health personnel—the same lines that were used for the proposed methodology for which the commenters agreed was appropriate. Using this finalized methodology, we derive a 2017-based FQHC market basket Clinical Staff Compensation cost weight of 16.8 percent compared to the proposed rule with 16.2 percent.

To further divide the Clinical Staff Compensation costs into Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, and Clinical Staff Contract Labor costs, we are using the shares derived for each of these costs using the proposed methodologies for each FQHC provider as described in sections III.D.3.a.4, D.3.a.5 and D.3.a.6. of this final rule. Specifically, for each line included in the Clinical Staff Compensation category, the Clinical Staff Wages and Salaries costs is equal to the Clinical Staff Compensation costs as described above multiplied by the Clinical Staff Wages and Salaries costs (described in section III.D.3.a.4. of this final rule) as a percent of Clinical Staff Compensation costs. This same methodology is being used for the FQHC Practitioner Wages and Salaries, Employee Benefits, and Contract Labor, which again reflects the net expenses (Worksheet A, column 7) to address the commenters concerns. Therefore, for this final rule, the Clinical Staff Wages and Salaries cost weight is 12.9 percent, which accounts for 77 percent of the Clinical Staff Compensation cost weight. The Clinical Staff Employee Benefit cost weight is 3.1 percent, which accounts for 18 percent of the Clinical Staff Compensation cost weight. The Clinical Staff Contract Labor cost weight is 0.8 percent, which accounts for 5 percent of the Clinical Staff Compensation cost weight.

(7) Non-Health Staff Compensation Costs

As stated above, the Non-Health Staff Compensation costs are for personnel in general service cost centers including: Employee Benefits department; Administrative & General; Plant Operation & Maintenance; Janitorial; Medical Records; Pharmacy; Medical Supplies; Transportation; and Other General Services.

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining Non-Health Staff Compensation costs using net expenses (that is, costs after reclassifications and adjustments) as the estimated share of compensation costs from Worksheet A, column 7 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Since the net expenses for the General Service Cost centers include both compensation and other costs we estimate the share of net expenses for each general service cost center that reflects compensation costs.

First, we estimate a share of Non-Health Staff Wages and Salaries costs for each general service cost center as reported on Worksheet A, column 1 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12 divided by Worksheet A, column 1 and 2 for lines 3, 4, 5, 6, 7, 9, 10, 11, and 12. Then, we multiply the Non-Health Staff Net expenses (that is, costs after reclassifications and adjustments) by the Non-Health Staff Wages and Salaries share to derive estimated Non-Health Staff Wages and Salaries for each general service cost center (lines 3–7 and lines 9–12).

Second, we estimate Non-Health Staff Employee Benefit costs by multiplying the Non-Health Staff Wages and Salaries costs (step one) by the facility benefit to salary ratio. Finally, we add the derived Non-Health Staff Wages and Salaries costs and the derived Non-Health Staff Employee Benefits costs for each general service cost center (line 3–7 and lines 9–12). The results is the 2017-based FQHC market basket Non-health Staff Compensation cost weight of 27.2 percent compared to the proposed rule with 25.4 percent.

(8) Pharmaceuticals Costs

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are calculating Pharmaceuticals costs as the non-compensation costs for the pharmacy cost center. We define this as Worksheet A, column 7, line 9 less derived Pharmacy compensation costs. Similar to the methodology used for the Non-Health Staff compensation, we derive estimated Pharmacy compensation costs.

First we derive the share of pharmacy wages and salaries as Worksheet A, column 1, line 9 divided by the sum of Worksheet A, Column 1 & 2, for line 9. Then, we multiply the pharmacy wages and salaries share by pharmacy net expenses (Worksheet A, column 7, line 9).

Second, we estimate Pharmacy employee benefits by multiplying the derived Pharmacy wages and salaries by the facility benefit to salary ratio. The derived Pharmacy compensation costs are equal to the sum of the estimated pharmacy wages and salaries and pharmacy benefits costs. Using this finalized methodology, we derive a 2017-based FQHC market basket Pharmacy cost weight of 2.4 percent compared to the proposed rule with 3.9 percent.

(9) Medical Supplies

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are calculating medical supplies costs as the non-compensation costs for

the Medical Supplies costs center. We define this as Worksheet A, column 7, line 10 less derived Medical Supplies compensation costs. Similar to the methodology used for the Non-Health Staff compensation, we estimate Medical Supplies compensation costs.

First, we derive the share of medical supplies wages and salaries as Worksheet A, column 1, line 10 divided by the sum of Worksheet A, Column 1 & 2, line 10. Then, we multiply the medical supplies wages and salaries share by the medical supplies net expense (Worksheet A, column 7, line 10).

Second we estimate Medical Supplies employee benefits by multiplying the derived Medical Supplies wages and salaries by the facility benefit to salary ratio. The derived Medical Supplies compensation costs are equal to the sum of the estimated medical supplies wages and salaries and medical supplies benefits costs. Using this finalized methodology, we derive a 2017-based FQHC market basket Medical Supplies cost weight of 2.2 percent compared to the proposed rule with 2.4 percent.

(10) Fixed Capital

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining fixed capital costs to be equal to costs reported on Worksheet A, line 1, column 7 of the Medicare Cost Report. Using this finalized methodology, we derive a 2017-based FQHC market basket fixed capital cost weight of 4.4 percent compared to the proposed rule with 4.6 percent.

(11) Moveable Capital Costs

In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining moveable capital costs to be equal to the capital costs as reported on Worksheet A, line 2, column 7. Using this finalized methodology, we derive a 2017-based FQHC market basket Moveable Capital cost weight of 2.0 percent compared to the proposed rule with 1.9 percent.

b. Major Cost Category Computation

After we derive costs for the major cost categories for each provider using the Medicare cost report data as previously described, we proposed to trim the data for outliers. For each of the eleven major cost categories, we proposed to divide the calculated costs for the category by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of FQHC providers. For the 2017-based FQHC market basket (similar to the 2013-based FQHC market basket), we proposed that total Medicare allowable costs would be equal to the total costs as reported on Worksheet A, columns 1 and 2, lines 1 through 7 and lines 9 through 12; Worksheet A, column 1, lines 23 through 36; and Worksheet S3 Part II, columns 1 and 2, lines 2 through 14. In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, we are defining Medicare allowable costs for freestanding FQHC facilities as the total net expenses (after reclassifications and adjustments) reported on: Worksheet A, column 7, for lines 1 through 7, lines 9 through 12; and lines 23 through 36. These are the same cost centers that were used in the proposed market basket for which the commenters agreed was appropriate.

For the FQHC Practitioner Wages and Salaries, FQHC Practitioner Employee Benefits, FQHC Practitioner Contract Labor, Clinical Staff Wages and Salaries, Clinical Staff Employee Benefits, Clinical Staff Contract Labor, Non-Health Staff Compensation, Pharmaceuticals, Medical Supplies, Fixed Capital, and Moveable Capital cost weights, after excluding cost weights that are less than or equal to zero, we proposed to then remove those providers whose derived cost weights fall in the top and bottom 5 percent of provider-specific derived cost weights to ensure the exclusion of outliers. A 5 percent trim is the standard trim applied to the mean cost weights in all CMS market baskets and is consistent with the trimming used in the 2013-based FQHC market basket. After the outliers have been excluded, we add the costs for each category across all remaining providers. We proposed to then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the 2017-based FQHC market basket for the given category. This trimming process is done for each cost weight separately. We did not receive any comments on this proposal, and therefore, we are going to use the same trimming methodology to remove outliers as proposed but with the revised cost weights reflecting the new methodology in response to public comment.

Finally, we proposed to calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the eleven major cost categories listed. We referred readers to Table 35 for the resulting cost weights for these major cost categories.

Table 35 also shows the proposed and final 2017-based FQHC market basket cost weights compared to the 2013-based FQHC market basket cost weights.

TABLE 35: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	Final 2017-Based FQHC Cost Report Weights (Percent)	Proposed 2017-Based FQHC Cost Report Weights (Percent)	2013-Based FQHC Market Basket (Percent)
FQHC Practitioner Compensation*	*28.4*	*30.0*	31.7
FQHC Practitioner Wages & Salaries	19.4	20.5	-
FQHC Practitioner Employee Benefits	4.5	4.5	-
FQHC Practitioner Contract Labor	4.6	4.9	-
Clinical Staff Compensation*	*16.8*	*16.2*	9.5
Clinical Staff Wages & Salaries	12.9	12.4	-
Clinical Staff Employee Benefits	3.1	3.0	-
Clinical Staff Contract Labor	0.8	0.8	-
Non-Health Staff Compensation*	27.2	25.4	27.4
Pharmaceuticals	2.4	3.9	5.1
Medical Supplies	2.2	2.4	-
Fixed Capital	4.4	4.7	4.5
Moveable Capital	2.0	1.9	1.7
All Other (Residual)	16.5	15.5	20.1

*Employee Benefits weight from the 2013-based FQHC Market Basket (10.7 percent), which was derived from the Medicare Cost Reports (81 FR 80395) and distributed across the three compensation categories: FQHC Practitioner, Clinical Staff, and Non-Health Staff based on the relative shares of each category.
Note: Totals may not sum to 100.0 due to rounding

The total compensation cost weight of 72.5 percent (sum of FQHC Practitioner Compensation, Clinical Compensation, Non-health Staff Compensation) calculated from the Medicare cost reports for the final 2017-based FQHC market basket is approximately 4.0 percentage point higher than the total compensation cost weight for the 2013-based FQHC market basket (68.6 percent). The 2017-based cost weight for FQHC Practitioner Compensation are about 3 percentage points lower compared to the 2013-based FQHC market basket, while the clinical staff compensation cost weight is about 7 percentage points higher. Part of the reason for the shift in the weights between compensation categories may be due to the change to the FQHC Medicare cost report form. On the 1992 Medicare cost report form (used for the 2013-based FQHC market basket), there were four open ended ''fill-in'' categories for healthcare staff costs and costs under agreement. Since we were unable to determine what specific category the ''other health care staff'' costs should be allocated to (that is, either FQHC practitioner, or clinical staff) we used a methodology where we applied the expenses for the ''other health care staff costs'' between the categories for FQHC practitioner and clinical staff, based on the relative shares of expenses for both categories, excluding the open-ended fill in lines of Worksheet A, lines 9–11 and line 15. This may have resulted in an over allocation of some of the 2013 expenses to the FQHC Practitioner category relative to the clinical staff. On the 2014 Medicare cost report form, there is no longer an ambiguous category for other direct patient care staff costs.

The final 2017-based Pharmaceuticals cost weight is roughly 2.7 percentage points lower than the cost weight in the 2013-based FQHC market basket. The pharmaceutical costs included in the weight for 2017-based FQHC market basket includes only non-compensation costs reported in Pharmacy (under general services). We believe the cost share is lower with the new data because there is more specificity on where to report reimbursable and non-reimbursable drugs. Additionally, using the net expense data (that is after reclassifications and adjustments) results in a lower share for pharmacy expenses relative to if total costs are used. This implies that there are notable reclassifications and adjustments to the Medicare Allowable pharmacy expenses as mentioned by commenters as a reason for the concern for not using Net expense data.

As we did for the 2013-based FQHC market basket, we proposed to allocate the contract labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs comprise both Wages and Salaries and Employee Benefits for both FQHC Practitioners and Clinical Staff. The contract labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. This rounded percentage based on the proposed cost weights was 82 percent for FQHC Practitioners and 80 percent for clinical staff. Therefore, we proposed to allocate 82 percent of the FQHC Practitioner Contract Labor cost weight to the FQHC Practitioner Wages and Salaries cost weight and 18 percent to the FQHC Practitioner Employee Benefits cost weight. Similarly, we proposed to allocate 80 percent of the clinical staff contract labor cost weight to the Clinical Staff Wages and Salaries cost weight and 20 percent to the clinical staff employee benefits cost weight. In response to comment, in the final 2017-based FQHC market basket, we are allocating 81 percent of the FQHC Practitioner Contract Labor to FQHC Practitioner Wages and Salaries and 19 percent to the FQHC Practitioner Employee Benefits. We are also allocating 81 percent of the Clinical Staff Contract Labor to Clinical Staff Wages and Salaries and 19 percent to

the Clinical Staff Employee Benefits. We refer readers to Table 36 that shows the final Wages and Salaries and Employee Benefits cost weights after Contract Labor cost weight allocation for the final 2017-based FQHC market basket.

TABLE 36: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	Final 2017-Based FQHC Practitioner	Final 2017-Based Clinical Staff	Proposed 2017-Based FQHC Practitioner	Proposed 2017-Based Clinical Staff
Wages and Salaries	23.1	13.6	24.6	13.0
Employee Benefits	5.4	3.3	5.4	3.2
Compensation	28.4	16.8	30.0	16.2

*Totals may not sum due to rounding

c. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2017 Medicare cost report data into more detailed cost categories, we proposed to use the 2012 Benchmark Input-Output (I–O) ''Use Tables/Before Redefinitions/Purchaser Value'' for NAICS 621100, Offices of Physicians, published by the Bureau of Economic Analysis (BEA). We note that the BEA benchmark I–O data is used to further disaggregate residual expenses in other CMS market baskets. Therefore, we noted that we believe the data from this industry are the most technically appropriate for disaggregation of the residual expenses since both physician offices and FQHCs provide similar types of care. These data are publicly available at *https://www.bea.gov/industry/input-output-accounts-data*. For the 2013-based FQHC market basket, we used the relative shares of certain categories from the 2006-based MEI (81 FR 80396).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[53] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2012 Benchmark I–O data forward to 2017 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. We repeated this practice for each year. We then calculated the cost shares that each cost category represents of the 2012 data inflated to 2017. These resulting 2017 cost shares were applied to the ''All Other'' residual cost weight to obtain the detailed cost weights for the proposed 2017-based FQHC market basket. For example, the cost for Medical Equipment represents 7.2 percent of the sum of the ''All Other'' 2012 Benchmark I–O Offices of Physicians Expenditures inflated to 2017. Therefore, the proposed Medical Equipment cost weight represents 7.2 percent of the proposed 2017-based FQHC market basket's ''All Other'' cost category (16.5 percent), yielding a Medical Equipment cost weight of 1.2 percent in the 2017-based FQHC market basket (0.072×16.5 percent = 1.2 percent).

Using this methodology, we proposed to derive six detailed FQHC market basket cost category weights from the proposed 2017-based FQHC market basket residual cost weight (15.5 percent). These categories are: (1) Utilities; (2) Medical Equipment; (3) Miscellaneous Products; (4) Professional, Scientific, and Technical Services; (5) Administrative Support and Waste Management Services; (6) All Other Services. We note that for the 2013-based FQHC market basket, we had Telephone and Postage cost weights. For the 2017-based FQHC market basket, we proposed to include Telephone and Postage costs in the Miscellaneous Products cost weight due to the small amount of costs in this category (each were less than .05 percent).

We did not receive any comments on our proposed derivation of the detailed operating cost weights. Therefore, we are finalizing our methodology as proposed. In response to public comment to use net costs rather than total costs to derive the FQHC market basket cost weights, the ''All Other'' residual cost weight was revised from the proposed rule to reflect the revised methodology as explained in section III.D.3.a of this final rule. The ''All Other'' residual cost weight is 16.5 percent compared to the proposed 15.5 percent weight.

d. 2017-Based FQHC Market Basket Cost Categories and Weights

Table 37 shows the cost categories and weights for the Final 2017-based FQHC market basket compared to the proposed 2017-based FQHC market basket and the 2013-based FQHC market basket.

[53] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

TABLE 37: Final 2017-Based FQHC Market Basket Cost Weights Compared to Proposed 2017-Based FQHC Market Basket, and the 2013-Based FQHC Market Basket Cost Weights

Cost Category	Final 2017-based FQHC Market Basket Cost Weight	Proposed 2017-based FQHC Market Basket Cost Weight	2013-based FQHC Market Basket Cost Weight
Total	**100.0**	**100.0**	**100.0**
Compensation	**72.5**	**71.6**	**68.7**
FQHC Practitioner Compensation	**28.4**	**30.0**	**31.7**
FQHC Practitioner Wages and Salaries	23.1	24.6	-
FQHC Practitioner Employee Benefits	5.4	5.4	-
Clinical Staff Compensation	**16.8**	**16.2**	**9.5**
Clinical Staff Wages and Salaries	13.6	13.0	-
Clinical Staff Employee Benefits	3.3	3.2	-
Non-Health Staff Compensation	**27.2**	**25.4**	**27.4**
All Other Products	**8.5**	**10.0**	**16.1**
Pharmaceuticals	2.4	3.9	5.1
Utilities	0.6	0.5	1.4
Telephone	-	-	1.7
Postage	-	-	1.0
Medical Equipment	1.2	1.1	2.2
Medical Supplies	2.2	2.4	2.0
Miscellaneous Products	2.2	2.1	2.8
All Other Services	**12.6**	**11.8**	**9.0**
Professional, Scientific, and Technical Services	6.4	6.0	2.9
Administrative and Facilities Support Services	1.7	1.6	3.4
All Other Services	4.5	4.2	2.7
Capital-Related Costs	**6.4**	**6.6**	**6.1**
Fixed Assets	4.4	4.7	4.5
Movable Equipment	2.0	1.9	1.7

Note: Totals may not sum due to rounding.

4. Selection of Price Proxies

After developing the cost weights for the 2017-based FQHC market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the price proxies on U.S. Bureau of Labor Statistics (BLS) data, as they produce indexes that best meet the criteria of reliability, timeliness, availability, and relevance, and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the North American Industry Classification System (NAICS) and the occupational ECIs are based on the Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluate the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the

underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

The CPIs, PPIs, and ECIs that we have selected meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 38 lists all price proxies we proposed to use in the 2017-based FQHC market basket. Below is a detailed explanation of the price proxies we proposed for each cost category, many of which are the same as those used for the 2013-based FQHC market basket.

a. Price Proxies for the 2017-Based FQHC Market Basket

(1) FQHC Practitioner Wages and Salaries

We proposed to use the ECI for Wages and Salaries for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure price growth of this category. There is no specific ECI for physicians or FQHC Practitioners, and therefore, we proposed to use an index that is based on professionals that receive advanced training similar to those performing at the FQHC Practitioner level of care. This index is consistent with the price proxy used to measure wages and salaries inflation pressure for physicians own time in the Medicare Economic Index (MEI) and is based on the MEI technical panel recommendation from 2012 (78 FR 74266 through 74271). Additionally, this price proxy is consistent with the proxy used for FQHC practitioner compensation in the 2013-based FQHC market basket (81 FR 80397). We noted that the 2013-based FQHC market basket has a single cost category for Total Compensation reflecting both wages and salaries and employee benefits costs for FQHC Practitioners and this single compensation category uses the similar price proxy, the ECI Total Compensation for Private Industry Workers in Professional and Related, reflecting both types of compensation costs together rather than separately (81 FR 80397).

(2) FQHC Practitioner Employee Benefits

We proposed to use the ECI for Total Benefits for Private Industry Workers in Professional and Related to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. The 2013-based FQHC market basket did not include a separate category for FQHC Practitioner employee benefit costs.

(3) Clinical Staff Wages and Salaries

We proposed to use the ECI for Wages and Salaries for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU10262000000000I) to measure the price growth of this cost category. This cost category consists of wage and salary costs for Nurses, Laboratory Technicians, and all other healthcare staff not included in the FQHC Practitioner compensation categories. Based on the clinical staff composition of these workers, we noted that we believe that the ECI for health-related workers is an appropriate proxy to measure wage and salary price pressures for these workers. We noted that the 2013-based FQHC market basket has a single cost category for Total Compensation reflecting both wages and salaries and employee benefits costs for Clinical Staff and this single compensation category uses the similar price proxy, the ECI Total Compensation for all Civilian Workers in Health Care and Social Assistance, reflecting both types of compensation costs together rather than separately (81 FR 80398).

(4) Clinical Staff Employee Benefits

We proposed to use the ECI for Total Benefits for all Civilian Workers in Health Care and Social Assistance to measure price growth of this category. This ECI is calculated using the ECI for Total Compensation for all Civilian Workers in Health Care and Social Assistance (BLS series code CIU10162200000000I) and the relative importance of wages and salaries within total compensation. The 2013-based FQHC market basket did not include a separate category for Clinical Staff employee benefit costs.

(5) Non-Health Staff Compensation

We proposed to continue to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. The Non-health Staff Compensation cost weight is predominately attributable to administrative and facility type occupations, as reported in the data from the Medicare cost reports. This is the same price proxy used in the 2013-based FQHC market basket (81 FR 80398).

(6) Pharmaceuticals

We proposed to continue to use the PPI Commodities for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This price proxy is used to measure prices of Pharmaceuticals in other CMS market baskets, such as 2014-based Inpatient Prospective Payment System and 2014-based Skilled Nursing Facility market baskets. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(7) Utilities

We proposed to continue to use the CPI for Fuel and Utilities (BLS series code CUUR0000SAH2) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(8) Medical Equipment

We proposed to continue to use the PPI Commodities for Surgical and Medical Instruments (BLS series code WPU1562) as the price proxy for this category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(9) Medical Supplies

We proposed to continue to use a 50/50 blended index that comprises the PPI Commodities for Medical and Surgical Appliances and Supplies (BLS series code WPU156301) and the CPI–U for Medical Equipment and Supplies (BLS series code CUUR0000SEMG). The 50/50 blend is used in all market baskets where we do not have an accurate split available. We noted that we believe FQHCs purchase the types of supplies contained within these proxies, including such items as bandages,

dressings, catheters, intravenous equipment, syringes, and other general disposable medical supplies, via wholesale purchase, as well as at the retail level. Consequently, we proposed to combine the two aforementioned indexes to reflect those modes of purchase. This is the same blended price proxy used in the 2013-based FQHC market basket (81 FR 80398).

(10) Miscellaneous Products

We proposed to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. We noted that we believe that using the CPI for All Items Less Food and Energy is appropriate as it reflects a general level of inflation. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(11) Professional, Scientific, and Technical Services

We proposed to continue to use the ECI for Total Compensation for Private Industry Workers in Professional, Scientific, and Technical Services (BLS series code CIU2015400000000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(12) Administrative and Facilities Support Services

We proposed to continue to use the ECI Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(13) All Other Services

We proposed to continue to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

(14) Fixed Capital

We proposed to continue to use the PPI Industry for Lessors of Nonresidential Buildings (BLS series code PCU531120531120) to measure the price growth of this cost category (81 FR 80398). This is the same price proxy used in the 2013-based FQHC market basket. We noted that we believe this continues to be the most appropriate price proxy since fixed capital expenses in FQHCs should reflect inflation for the rental and purchase of business office space.

(15) Moveable Capital

We proposed to continue to use the PPI Commodities for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category as this cost category represents nonmedical moveable equipment. This is the same proxy used in the 2013-based FQHC market basket (81 FR 80398).

We did not receive any comments on the proposed price proxies in the 2017-based FQHC market basket, and therefore, we are finalizing this proposal without modification.

c. Summary of Price Proxies of the Final 2017-Based FQHC Market Basket

Table 38 shows the cost categories and associated price proxies for the 2017-based FQHC market basket.

TABLE 38: Cost Categories and Price Proxies for the Final 2017-Based FQHC Market Basket

Cost Description	Price Proxies
FQHC Practitioner Wages and Salaries	ECI for Wages and Salaries for Private Industry Workers in Professional and Related
FQHC Practitioner Employee Benefits	ECI for Total Benefits for Private Industry Workers in Professional and Related
Clinical Staff Wages and Salaries	ECI for Wages and Salaries for All Civilian Workers in Health care and Social Assistance
Clinical Staff Employee Benefits	ECI for Total Benefits for All Civilian Workers in Health Care and Social Assistance
Non-Health Staff Compensation	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
Pharmaceuticals	PPI Special Index for Pharmaceuticals for Human Use, Prescription
Utilities	CPI-U for Fuels and Utilities
Medical Equipment	PPI Commodity Index for Surgical and Medical Instruments
Medical Supplies	Composite: PPI Commodity Index for Medical and Surgical Appliances and Supplies (50%) and CPI for Medical Equipment and Supplies (50%)
Miscellaneous Products	CPI-U for All items less food and energy
Professional, Scientific, and Technical Services	ECI for Total compensation for Private industry workers in Professional, Scientific, and Technical Services
Administrative and Facilities Support Services	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support
All Other Services	ECI for Total Compensation for Private Industry Workers in Service Occupations
Fixed Capital	PPI Industry Index for Lessors of Nonresidential Buildings
Movable Capital	PPI Commodity Index for Machinery and Equipment

Comment: Several commenters applauded CMS, both for implementing an FQHC-specific market basket adjuster, per section 1834(o)(2)(B) of the Act, and for taking the initiative to rebase the market basket percentage, effective in 2021, using more recent cost data. One commenter stated they had been a long-term supporter of the FQHC specific market basket serving as the annual update method for health centers, in both Medicare and Medicaid. The commenter stated that they believe that the alternative, the MEI, is outdated and does not appropriately capture the services that health centers provide and therefore is not an appropriate update factor. The commenters appreciated that CMS updates the calculation periodically so that the cost weights reflect a current mix of goods and services purchased in providing FQHC services. The commenters stated that they did not have concerns with the overall structure of the calculation, and they noted that they believe the use of a fixed-weight, Laspeyres-type price index that uses cost weights and price proxies (based on publicly available cost indexes) is a reasonable way to measure the increase in the price over time of goods and services needed to furnish FQHC services.

Response: We appreciate the commenters' support of the FQHC market basket and the periodic rebasing and revision of the market basket to account for changes in the mix of goods and services purchased in providing FQHC services as well as the general methodological approach of using Medicare Cost Report data, a Laspeyres-type index formula, and the use of publically available price proxies when available and appropriate.

In response to public comment, we are finalizing the 2017-basd FQHC market basket with modification effective with CY 2021 FQHC PPS update.

5. CY 2021 Productivity Adjusted Market Basket Update for FQHCs

For CY 2021 (that is, January 1, 2021 through December 31, 2021), we proposed to use the 2017-based FQHC market basket increase factor to update the PPS payments to FQHCs. Consistent with CMS practice, we estimated the market basket update for the FQHC PPS based on the most recent forecast from IGI. IGI is a nationally recognized economic and financial forecasting firm with which we contract to forecast the components of the market baskets and multifactor productivity (MFP). We proposed to use the update based on the most recent historical data available at the time of publication of the final rule. For example, the final CY 2021 FQHC update would be based on the four-quarter moving-average percent change of the 2017-based FQHC market basket through the second quarter of 2020 (based on the final rule's statutory publication schedule). At the time of the proposed rule, we did not have the second quarter of 2020 historical data, and therefore, we proposed to use the most recent projection available at the time.

Based on IGI's third quarter 2020 forecast with historical data through the second quarter of 2020, the final 2017-based FQHC market basket increase factor for CY 2021 is 2.4 percent. For comparison, the 2013-based FQHC market basket update is projected to be 2.3 percent in CY 2021; this estimate is based on IGI's third quarter 2020 forecast (with historical data through the second quarter of 2020). We note that the forecast used for the proposed market basket update was developed prior to the economic impacts of the COVID–19 pandemic. The lower final update (2.4 percent) for CY 2021 relative to the proposed rule (2.5 percent) is primarily driven by slower anticipated compensation growth for both health-related and other occupations as labor markets have been significantly impacted during the recession that started in February 2020.

Section 1834(o)(2)(B)(ii) of the Act describes the methods for determining updates to FQHC PPS payment. We have included a productivity adjustment to the FQHC PPS annual payment update since implementation of the FQHC PPS (81 FR 80393) and we proposed to continue to include a productivity adjustment to the 2017-based FQHC market basket. We proposed to use the most recent estimate of the 10-year moving average of changes in annual private nonfarm business (economy-wide) multifactor productivity (MFP), which is the same measure of MFP applied to other CMS Market Basket updates including the MEI. The BLS publishes the official measure of private nonfarm business MFP (see *http://www.bls.gov/mfp* for the published BLS historical MFP data). For the final FQHC market basket update, we proposed to use the most recent historical estimate of annual MFP as published by the BLS. Generally, the most recent historical MFP estimate is lagged 2 years from the payment year.

Therefore, we proposed to use the 10-year moving average percent change in annual private nonfarm business MFP through 2019 as published by BLS in the CY 2021 FQHC market basket update. We noted that MFP is derived by subtracting the contribution of labor and capital input growth from output growth. Since at the time of development of the proposed rule the 2019 MFP was not yet published by BLS, we proposed to use IGI's first quarter 2020 forecast of MFP. A complete description of the MFP projection methodology is available at *http://www.cms.gov/Research-Statistics-Dataand-Systems/Statistics-Trends-andReports/MedicareProgram RatesStats/MarketBasketResearch.html*.

Using IGI's first quarter 2020 forecast, the productivity adjustment for CY 2021 (the 10-year moving average of MFP for the period ending CY 2019) was projected to be 0.6 percent. Therefore, the proposed CY 2021 productivity-adjusted FQHC Market basket update was 1.9 percent, based on IGI's first quarter 2020 forecast with historical data through the fourth quarter of 2019. This reflected a 2.5-percent increase in the proposed 2017-based FQHC market basket and a 0.6-percent adjustment for productivity. Finally, we proposed that if more recent data subsequently become available, we would use such data, if appropriate, to determine the CY 2021 market basket update and the MFP adjustment for the final rule.

For this final rule, as proposed, we are using the latest historical data for MFP as published by the BLS to determine the MFP adjustment. The 10-year moving average percent change in MFP for the period ending CY 2019 as published by BLS is 0.7 percent. Therefore, the final CY 2021 productivity-adjusted FQHC Market basket update is 1.7 percent, based on IGI's third quarter 2020 forecast with historical data through the second quarter of 2020. This reflects a 2.4 percent increase in the final 2017-based FQHC market basket less a 0.7 percentage point adjustment for productivity.

E. Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention That Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

Opioid overdose deaths continue to impact communities across the United States. In 2018, about 47,000 Americans died as a result of an opioid overdose, where 32 percent of these deaths involved a prescription opioid.[54] In addition to the risk of death from overdose, opioids carry a number of other health risks, including respiratory

[54] Wilson N, Kariisa M, Seth P, et al. Drug and Opioid-Involved Overdose Deaths—United States, 2017–2018. MMWR Morb Mortal Wkly Rep 2020;69:290–297.

depression, drowsiness, confusion, nausea, increased drug tolerance, and physical dependence. An estimated 1.4 million people in the United States have substance use disorders (SUDs) involving prescription opioid pain relievers.[55]

CMS has a vital role in addressing opioid use disorder prevention, treatment and recovery. The intent of the SUPPORT Act (Pub. L. 115–271, enacted on October 24, 2018) is to provide for opioid use disorder prevention, treatment and recovery. In section 2002 of the SUPPORT Act, Comprehensive Screening for Seniors, the Congress required the Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) to include screening for potential SUDs and a review of any current opioid prescriptions. We believe that these provisions are complementary to the existing components of the IPPE and AWV. We proposed to add these new elements to the IPPE and AWV regulations, to draw attention to their importance and fulfil the section 2002 SUPPORT Act requirements. In the CY 2021 PFS proposed rule (85 FR at 50224), we provided background on the IPPE and AWV, discussed how the requirements of the SUPPORT Act are related to the IPPE and AWV, and made proposals to implement these provisions.

1. Background: IPPE and AWV

a. IPPE Required Elements

The IPPE is defined in section 1861(ww) of the Act and codified in regulations at § 410.16. The IPPE must be performed within 1 year after the effective date of a beneficiary's first Medicare Part B coverage period as stated in section 1861(hhh)(4)(G) of the Act. The IPPE includes all of the following services furnished to an eligible beneficiary by a physician or other qualified NPP with the goal of health promotion and disease detection:

- Review of the beneficiary's medical and social history with attention to modifiable risk factors for disease, as those terms are defined in § 410.16.
- Review of the beneficiary's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the physician or other qualified NPP may select from various available standardized screening tests designed for this purpose and recognized by national professional medical organizations.
- Review of the beneficiary's functional ability, and level of safety as those terms are defined in § 410.16 based on the use of appropriate screening questions or a screening questionnaire, which the physician or other qualified NPP may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.
- An examination to include measurement of the beneficiary's height, weight, body mass index, blood pressure, a visual acuity screen, and other factors as deemed appropriate, based on the beneficiary's medical and social history, and current clinical standards.
- End-of-life planning upon agreement with the individual.
- Education, counseling, and referral, as deemed appropriate by the physician or qualified NPP, based on the results of the review and evaluation services described in § 410.16.
- Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits.

b. AWV Required Elements

Section 1861(hhh) of the Act expanded Medicare coverage under Part B to include an AWV effective for services furnished on or after January 1, 2011. We codified the AWV at § 410.15.

The AWV is a wellness visit that focuses on identification of certain risk factors, personalized health advice, and referral for additional preventive services and lifestyle interventions (which may or may not be covered by Medicare). The elements included in the AWV differ from comprehensive physical examination protocols with which some providers may be familiar since it is a visit that is specifically designed to provide personalized prevention plan services as defined in the Act. The AWV includes a health risk assessment (HRA) and the AWV takes into account the results of the HRA.

The AWV may be performed when the beneficiary is no longer within 12 months after the effective date of his or her first Medicare Part B coverage period and when the beneficiary has not received either an IPPE or AWV within the past 12 months. The AWV may be performed by a physician, NPP (physician assistant, nurse practitioner, or clinical nurse specialist), medical professional (including a health educator, a registered dietitian, or nutrition professional, or other licensed practitioner) or a team of such medical professionals, working under the direct supervision of a physician. In summary, the first AWV includes the following:

- Review (and administration if needed) of a health risk assessment (as defined in § 410.15).
- Establishment of an individual's medical and family history.
- Establishment of a list of current providers and suppliers that are regularly involved in providing medical care to the individual.
- Measurement of an individual's height, weight, body-mass index (or waist circumference, if appropriate), blood pressure, and other routine measurements as deemed appropriate, based on the beneficiary's medical and family history.
- Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.
- Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations.
- Review of the individual's functional ability and level of safety, based on direct observation or the use of appropriate screening questions or a screening questionnaire, which the health professional as defined in § 410.15 may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations.
- Establishment of the following:

++ A written screening schedule for the individual such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices, and the individual's health risk assessment (as that term is defined in § 410.15), health

[55] Substance Abuse and Mental Health Services Administration. (2020). Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20–07–01–001, NSDUH Series H–55). Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from *https://www.samhsa.gov/data/*.

status, screening history, and age-appropriate preventive services covered by Medicare.

++ A list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an IPPE (as described under § 410.16), and a list of treatment options and their associated risks and benefits.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions to reduce health risks and promote self-management and wellness, including weight loss, physical activity, smoking cessation, fall prevention, and nutrition.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Any other element determined appropriate through the national coverage determination process.

In summary, subsequent AWVs include the following:

- Review (and administration, if needed) of an updated health risk assessment (as defined in § 410.15).
- An update of the individual's medical and family history.
- An update of the list of current providers and suppliers that are regularly involved in providing medical care to the individual as that list was developed for the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.
- Measurement of an individual's weight (or waist circumference), blood pressure and other routine measurements as deemed appropriate, based on the individual's medical and family history.
- Detection of any cognitive impairment that the individual may have, as that term is defined in § 410.15.
- An update to the following:

++ The written screening schedule for the individual as that schedule is defined in paragraph (a) of § 410.15 for the first AWV providing personalized prevention plan services.

++ The list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual as that list was developed at the first AWV providing personalized prevention plan services or the previous subsequent AWV providing personalized prevention plan services.

++ Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs as that advice and related services are defined in paragraph (a) of § 410.15.

++ At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

++ Any other element determined appropriate through the national coverage determination process.

2. Section 2002 of the SUPPORT Act Requirement

In section 2002 of the SUPPORT Act, sections 1861(ww) and 1861(hhh)(2) of the Act were amended to include a review of any current opioid prescriptions and screening for potential SUDs as elements of the IPPE and AWV, effective January 1, 2020.

3. Revisions to Section 2002 of the SUPPORT Act Requirements

We proposed to add the requirements of section 2002 of the SUPPORT Act to our regulations at §§ 410.15 and 410.16 for the AWV and IPPE, respectively.

Section 2002 of the SUPPORT Act, requires a review of any current opioid prescriptions as part of the IPPE and AWV. Such review includes a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individual's severity of pain and current treatment plan, educational information on non-opioid treatment options, and a referral to a specialist, as appropriate. Section 2002 of the SUPPORT Act also requires adding an element to the IPPE and AWV to include screening for potential SUDs. Along with the screening for SUD, a referral for treatment, as appropriate, was added to the AWV.

The definitions and conditions for and limitations on coverage of the IPPE outlined in § 410.16 includes a review of the beneficiary's medical and social history. The medical history is defined to include a review of current medications, which would include a review of current opioid prescriptions. Furthermore, social history is defined to include, at a minimum, a history of alcohol, tobacco, and illicit drug use. Illicit drug use may include the non-medical use of prescription drugs. The physician or other qualified health professional may then provide education, counseling, and referral, as deemed appropriate, based on the results of the review and evaluation services provided during the IPPE.

The definitions and conditions for and limitations on coverage of the AWV in § 410.15 includes a health risk assessment, which entails an evaluation of psychosocial risks, including but not limited to, depression/life satisfaction, stress, anger, loneliness/social isolation, pain, and fatigue. The patient's substance use, if applicable, could be reviewed as part of the health risk assessment. The AWV also covers establishment of, or an update to the individual's medical and family history. The medical history includes medication use, and may have included a review of any opioid prescriptions. The health professional may also establish or update a list of risk factors and conditions for which primary, secondary or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through the initial or subsequent AWV or IPPE, and a list of treatment options and their associated risks and benefits. If the clinician detected, through the above methods for screening, that a patient was at high-risk for SUD in the course of the visit, it would have been appropriate to note in the patient's IPPE written plan or the AWV personalized prevention plan and to have referred the patient for further assessment and treatment.

Awareness of a patient's use of substances, including nonmedical use of prescription drugs and illicit drug use, is an important aspect of the IPPE and AWV. In general, screening for potential SUDs may include screening questions, the use of a specific tool, screening for licit and/or illicit drugs (for example, alcohol, non-medical use of prescription opioids, methamphetamine, heroin, cocaine, and other substances), review of the beneficiary's medical and social history and medical records, or prescription drug monitoring program query when clinically indicated. Given the existing elements of the IPPE and AWV, we do not expect the proposed new regulatory elements to add significant burdens on physicians and practitioners who furnish these services because review of medical and social

history, risk factor identification, education, counseling, and referrals are already fundamental parts of the IPPE and AWV. The new regulatory elements elevate the importance of physicians' and other qualified health professionals' vigilance in identifying and addressing opioid risks and SUDs in Medicare beneficiaries.

4. Summary of Proposed Regulatory Text Changes

We proposed to add elements to our regulations to reflect the provisions of section 2002 of the SUPPORT Act. Consistent with sections 1861(ww) and 1861(hhh)(2) of the Act, we proposed to amend §§ 410.15 and 410.16 by: (1) Adding the term ''screening for potential substance use disorders''; (2) Adding the term ''a review of any current opioid prescriptions'' and its definition; and (3) revising the ''Initial Preventive Physical Examination,'' ''first annual wellness visit providing personalized prevention plan services,'' and ''subsequent annual wellness visit providing personalized prevention plan services''.

a. ''Screening for Potential Substance Use Disorders''

We proposed to revise §§ 410.15 and 410.16 by adding the element ''Screening for Potential Substance Use Disorders'' and describing the requirement as a review of the individual's potential risk factors for SUD and referral for treatment as appropriate.

b. Definition of ''a review of any current opioid prescriptions''

We proposed to revise §§ 410.15 and 410.16 by adding the element ''a review of any current opioid prescriptions'' and defining such term, consistent with section 1861(ww)(4) of the Act, as a review of any current opioid prescriptions, including a review of the potential risk factors to the individual for opioid use disorder, an evaluation of the individuals' severity of pain and current treatment plan, the provision of information on non-opioid treatment options, and a referral to a specialist, as appropriate.

c. Proposed Changes to the ''Initial Preventive Physical Examination,'' ''First Annual Wellness Visit'' and ''Subsequent Annual Wellness Visit''

In §§ 410.15 and 410.16, we adopted the components of the IPPE and AWV, consistent with the statutory elements described in sections 1861(ww) and 1861(hhh)(2) of the Act. The IPPE, first and subsequent AWVs are meant to represent a beneficiary visit focused on prevention. Among other things, the IPPE and AWV encourage beneficiaries to obtain the preventive services covered by Medicare that are appropriate for them. First and subsequent AWVs also include elements that focus on the furnishing of personalized health advice and referral, as appropriate, to health education, preventive counseling services, or programs aimed at reducing identified risk factors and improving self-management, or community-based lifestyle interventions.

We proposed to revise ''initial preventive physical examination,'' ''first annual wellness visit providing personalized prevention plan services,'' and ''subsequent annual wellness visit providing personalized prevention plan services'' by adding:

- In § 410.15(a):

++ A revised paragraph (xi) to the definition of the term ''First annual wellness visit providing personalized prevention plan services,'' and a revised paragraph (ix) to the definition of the term ''Subsequent annual wellness visit'' that would add furnishing of a review of any current opioid prescriptions as that term is defined in this section.

++ A new paragraph (xii) to the definition of ''First annual wellness visit providing personalized prevention plan services,'' and a new paragraph (x) to the definition of ''Subsequent annual wellness visit'' that would add screening for potential SUDs including a review of the individual's potential risk factors for SUD and referral for treatment as appropriate.

++ A new paragraph (xiii) to the definition of ''First annual wellness visit providing personalized prevention plan services,'' and a new paragraph (xi) to the definition of ''Subsequent annual wellness visit'' that would add any other element determined appropriate through the national coverage determination process.

- In § 410.16:

++ A revised paragraph (a)(6) to the definition of ''Initial preventive physical examination'' that would include a review of any current opioid prescriptions as that term is defined in this section.

++ A revised paragraph (a)(7) to the definition of ''Initial preventive physical examination'' that would add screening for potential SUDs to include a review of the individual's potential risk factors for SUD and referral for treatment as appropriate.

++ A new paragraph (a)(8) to the definition of ''Initial preventive physical examination'' that would add, education, counseling, and referral, as deemed appropriate by the physician or qualified NPP, based on the results of the review and evaluation services described in this section.

++ A new paragraph (a)(9) to the definition of ''Initial preventive physical examination'' that would include, education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo), (pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

5. Summary of Public Comments and Responses

We received public comments on the proposed revisions to the requirements under section 2002 of the SUPPORT Act. The following is a summary of the comments we received and our responses.

Comment: The vast majority of commenters supported the proposal to add the requirements of section 2002 of the SUPPORT Act to the regulations at §§ 410.15 and 410.16. Commenters stated that they believe these provisions are complementary to the existing components of the IPPE and AWV and help underscore the importance of prevention and appropriate pain management to stymie the opioid epidemic and detect substance use disorders on a regular schedule. Furthermore, commenters specifically noted that while Medicare has previously emphasized a review of opioid prescriptions is appropriate when collecting a patient's medical and social history within the IPPE and AWV, adding explicit requirements to the regulations regarding opioid prescription review and substance use disorder screening is an important distinction and welcomed by the majority of commenters.

Response: We appreciate the commenters for their support of CMS' efforts to include section 2002 of the SUPPORT ACT in the regulations, which are intended to strengthen provider engagement with patients on appropriate pain management and detection of substance use disorders through the IPPE and AWV.

Comment: According to one commenter a thorough patient assessment for pain and opioid use could take 30–90 minutes and such services should not be part of the AWV or IPPE but should be a separate encounter.

Response: We thank the commenter for highlighting the time it can take for practitioners to appropriately care for patients with pain. Section 2002 of the SUPPORT Act modified the statute to require the addition of certain additional services to the AWV and IPPE. We are not adopting the commenter's suggestion to only pay for these additional services as a separate encounter. We note, however, that there are other opportunities throughout the year outside of the AWV and IPPE, such as E/M services for practitioners to evaluate their patient's pain, consider treatment options and review medications when those services would be reasonable and necessary. In addition, other medically necessary services may be provided on the same date of service as an AWV or IPPE. The Part B deductible and coinsurance or copayment obligations would apply to those additional medically necessary services.

Comment: Some commenters advocated for CMS to increase the payment rate for the AWV and IPPE as a result of these additional required elements. Another commenter stated that the increase in reimbursement for CY 2021 will offset the additional work related to these new requirements. One commenter agreed with CMS that the new elements are aligned and similar to the services already being furnished during the visits and, therefore, would not result in significant added burden. One commenter disagreed with adding the requirements to the AWV and IPPE under section 2002 of the SUPPORT Act because practitioners already address prescriptions and substance abuse issues during these visits and formally including them adds to the paperwork and documentation burden around the visits.

Response: We note that we are required by law through section 2002 of the SUPPORT Act to include the new elements in the AWV and IPPE.

Commenters had various opinions about the appropriate payment rate for the AWV and IPPE with the additional requirements. We note for commenters that in section III.F. of this final rule, we finalized increases in the values of office/outpatient E/M visit codes for CY 2021. The AWV and IPPE services are valued via direct cross walk from the office/outpatient E/M visits. To maintain payment accuracy for the IPPE and the AWV, we finalized adjusting the valuation of these services to reflect the changes in value for E/M services to which they are crosswalked. The payment increase coincides with but is not related to the newly required elements in the AWV and IPPE.

We continue to agree with commenters who believe any additional burden for the new required elements will be minimal and we disagree with commenters that state the additional work will be a significant burden.

Comment: Commenters requested CMS clarify in more detail what is required of practitioners to meet the new required elements of the AWV and IPPE. One commenter specifically requested clarification that if a patient is found at risk for potential substance use disorder after screening that a comprehensive evaluation of that finding is not part of the AWV and IPPE. Another commenter specifically requested clarification around screening.

Response: In an effort to minimize burden and allow flexibility, we have not been more prescriptive with the regulatory language. We believe this allows practitioners to tailor screening to their patients. Medically necessary services beyond the scope of those required as part of the AWV and IPPE, as discussed in an earlier response, may be provided on the same date of service as an AWV or IPPE. The deductible and coinsurance or copayment may apply for these other medically necessary services.

Comment: One commenter asked for clarification on how CMS will enforce these new requirements.

Response: We are planning to enforce the new elements of the AWV and IPPE in the same manner as other services furnished to Medicare beneficiaries.

Comment: One commenter asked CMS to consider the community pharmacy as a provider of screening and referral services.

Response: We appreciate that the commenter is looking to expand access to screening and referral services by including community pharmacies as potential suppliers of these services, but this expansion would exceed the scope of our proposed rule. We did not seek to amend the definition of either ''health professional'' for the AWV or the definition of ''qualified nonphysician practitioner'' for the IPPE. The types of practitioners that are eligible to furnish the AWV are specified in section 1861(hhh)(3) of the Act and defined in our regulations in § 410.15(a). For the IPPE, the practitioners eligible to furnish these services under certain conditions are based on statutory requirements in sections 1861(s)(2)(K) and (ww)(1) of the Act and are defined in our regulations at § 410.16(a).

As a result of the comments, we are finalizing the proposal to add explicit requirements to the regulations regarding opioid prescription review and substance use disorder screening. Specifically, we are adding the requirements of section 2002 of the SUPPORT Act to §§ 410.15 and 410.16 for the AWV and IPPE, respectively.

We did not receive public comments on our proposed regulatory text, and, therefore, we are finalizing the regulatory language as proposed.

F. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

1. Background

Sections 1903(a)(3)(F) and 1903(t) of the Act provide the statutory basis for incentive payments made to Medicaid EPs and eligible hospitals for the adoption, implementation, upgrade, and meaningful use of Certified EHR Technology (CEHRT). We have implemented these statutory provisions in prior rulemakings to establish the Medicaid Promoting Interoperability Program.

Under sections 1848(o)(2)(A)(iii) and 1903(t)(6)(C)(i)(II) of the Act, and the definition of ''meaningful EHR user'' in regulations at § 495.4, one of the requirements of being a meaningful EHR user is to successfully report the clinical quality measures selected by CMS to CMS or a state, as applicable, in the form and manner specified by CMS or the state, as applicable. Section 1848(o)(2)(B)(iii) of the Act requires that in selecting electronic clinical quality measures (eCQMs) for EPs to report under the Promoting Interoperability Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. We have taken steps to align various quality reporting and payment programs that include the submission of eCQMs.

In the CY 2020 PFS final rule (84 FR 62568, 62900), we established for 2020 that Medicaid EPs are required to report on any six eCQMs that are relevant to the EP's scope of practice, regardless of whether they report via attestation or electronically. We also adopted the Merit-based Incentive Payment System (MIPS) requirement that EPs report on at least one outcome measure (or, if an applicable outcome measure is not available or relevant, one other high priority measure). We explained that if no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, the EP may report on any six eCQMs that are relevant.

2. eCQM Reporting Requirements for EPs Under the Medicaid Promoting Interoperability Program for 2021

We annually review and revise the list of eCQMs for each MIPS performance year to reflect updated clinical standards and guidelines. In Appendix 1 of the CY 2021 PFS proposed rule (85 FR 50412), we proposed to amend the list of available eCQMs for the CY 2021 performance period. In Appendix 1 of this final rule, we list the clinical quality measures added (Table Group A), removed (Table Group C), and changed (Table Group D) for the CY 2021 performance period. To keep eCQM specifications current and minimize complexity, we proposed to align the eCQMs available for Medicaid EPs in 2021 with those available for MIPS eligible clinicians for the CY 2021 performance period. Specifically, we proposed that the eCQMs available for Medicaid EPs in 2021 would consist of the list of quality measures available under the eCQM collection type on the final list of quality measures established for the MIPS CY 2021 performance period.

In previous years, CMS proposals to align the list of eCQMs for MIPS and the Medicaid Promoting Interoperability Program for EPs received positive comments that indicated that alignment between these two programs would help reduce health care provider reporting burden (84 FR 62900; see also 83 FR 59452, 59702). These comments thus suggest that aligning the eCQM lists might encourage EP participation in the Medicaid Promoting Interoperability Program by giving Medicaid EPs that are also MIPS eligible clinicians the ability to report the same eCQMs for both programs. Not aligning the eCQM lists could lead to increased burden, because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program if they opt to report on newly added eCQMs for MIPS. In addition, we believe that aligning the eCQMs available in each program would help to ensure the most uniform application of up-to-date clinical standards and guidelines possible.

As discussed in the CY 2021 PFS proposed rule (85 FR 50227), we anticipate that the proposal would reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change would not be significant, particularly in light of our belief that many EPs would report eCQMs to meet the quality performance category of MIPS, and therefore, should be prepared to report on the available eCQMs for 2021. We noted that we expect that the proposal would have only a minimal impact on states, by requiring minor adjustments to state systems for 2021 to maintain current eCQM lists and specifications.

For 2021, we proposed to again require (as we did for 2020) that Medicaid EPs report on any six eCQMs that are relevant to their scope of practice, regardless of whether they report via attestation or electronically. This policy of allowing Medicaid EPs to report on any six measures relevant to their scope of practice would generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established at § 414.1335(a)(1). MIPS eligible clinicians who elect to submit eCQMs must generally submit data on at least six quality measures, including at least one outcome measure (or, if an applicable outcome measure is not available, one other high priority measure). We referred readers to § 414.1335(a) for the data submission criteria that apply to individual MIPS eligible clinicians and groups that elect to submit data with other collection types.

In addition, as we did for 2020, we proposed that for 2021, EPs in the Medicaid Promoting Interoperability Program would be required to report on at least one outcome measure (or, if an outcome measure is not available or relevant, one other high priority measure). We noted that this policy would improve alignment with the MIPS quality performance category requirements for eligible clinicians using the eCQM collection type. We also proposed that if no outcome or high priority measures are relevant to a Medicaid EP's scope of practice, the clinician may report on any six eCQMs that are relevant, as was the policy in 2020.

In the CY 2020 PFS final rule (84 FR 62899 and 62900), we established the following three methods to identify which of the available measures are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program. We proposed to use the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2021:

- The same set of measures that are identified as high priority measures for reporting on the quality performance category for eligible clinicians participating in MIPS.
- All e-specified measures from the previous year's core set of quality measures for Medicaid and the Children's Health Insurance Program (CHIP) (Child Core Set) or the core set of health care quality measures for adults enrolled in Medicaid (Adult Core Set) (hereinafter together referred to as ''Core Sets'') that are also included on the MIPS list of eCQMs.

Sections 1139A and 1139B of the Act require the Secretary to identify and publish core sets of health care quality measures for child Medicaid and CHIP beneficiaries and adult Medicaid beneficiaries. These measure sets are required by statute to be updated annually and are voluntarily reported by states to CMS. These Core Sets are composed of measures that specifically focus on populations served by the Medicaid and CHIP programs and are of particular importance to their care. The MIPS eCQM list includes several, but not all, of the measures in the Core Sets. Because the Core Sets are released at the beginning of each year, it is not possible to update the list of high-priority eCQMs with those added to the current year's Core Sets.

The eCQMs that would be available for Medicaid EPs to report in 2021, that are both part of the Core Sets and on the MIPS list of eCQMs, and that would be considered high priority measures under the proposal are: CMS2, ''Preventive Care and Screening: Screening for Depression and Follow-Up Plan''; CMS122, ''Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)''; CMS125, ''Breast Cancer Screening''; CMS128, ''Anti-depressant Medication Management''; CMS136, ''Follow-Up Care for Children Prescribed ADHD Medication (ADD)''; CMS137, ''Initiation and Engagement of Alcohol and Other Drug Dependence Treatment''; CMS153, ''Chlamydia Screening for Women''; CMS155, ''Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents''; and CMS165, ''Controlling High Blood Pressure.''

- Through an amendment to § 495.332(f), we gave each state the flexibility to identify which of the eCQMs available for reporting in the Medicaid Promoting Interoperability Program are high priority measures for Medicaid EPs in that state, with review and approval by CMS, through the State Medicaid HIT Plan (SMHP). States are thus able to identify high priority measures that align with their state health goals or other programs within the state.

All eCQMs identified via any of these three methods are high priority measures for EPs participating in the Medicaid Promoting Interoperability Program for 2020. We proposed to use

the same three methods for identifying high priority eCQMs for the Medicaid Promoting Interoperability Program for 2021. We solicited comments as to whether any of these methods should be altered or removed, or whether any additional methods should be considered for 2021.

Finally, we note that the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program is a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, or falls before a state-specific alternative date prior to October 31, 2021 that is specified in the SMHP, as described in § 495.332(f)(4). This 2021 eCQM reporting period will help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. (See 83 FR 59452, 59704 through 59706).

We received public comments on our proposals for eCQM reporting requirements for EPs under the Medicaid Promoting Interoperability Program for 2021. The following is a summary of the comments we received and our responses.

Comment: The overwhelming majority of commenters supported our proposals and stated that having the same eCQM specifications for the Medicaid Promoting Interoperability program and the MIPS quality performance category requirements for eligible clinicians using the eCQM collection type would indeed reduce the reporting burden on health care providers.

Response: We appreciate the support for our proposals.

Comment: Two commenters noted that the accuracy of eCQM data may be skewed by the timeline necessitating that EPs submit less than a full year of data. They explain that some measures are seasonal, such as those related to influenza, and an EP may report data that do not represent their true level of care over a full year. We also note that both of these commenters supported our proposals.

Response: We acknowledge and understand that reporting periods of less than a year may result in inaccurate or incomplete data. However, the applicable meaningful use requirement to receive an incentive payment is that an EP must simply report the eCQM data to the state. The actual data reported are not used to determine whether an EP is eligible for an incentive payment as a meaningful user of CEHRT. Furthermore, the length of the eCQM reporting period for Medicaid EPs in 2021 is consistent with the length of the eCQM reporting period for 2020. Therefore, health care providers and states should already be aware of issues regarding the statistical validity of partial-year eCQM data. Additionally, when we established the 90-day eCQM reporting period for 2020, we concluded that, generally, the potential data quality issues associated with a shorter eCQM reporting period were outweighed by the benefits of that shorter period to all stakeholders (including to states preparing for the final year of the Medicaid Promoting Interoperability program in 2021), and that establishing 90-day eCQM reporting periods in both 2020 and 2021 might provide better data for comparison across the 2 years (see 84 FR 62901 and 62902). Finally, when we established the 90-day eCQM reporting period for 2021, we noted that it would help ensure that states can make all incentive payments before the statutory deadline (see 83 FR 59705).

Comment: One health care provider commented that the statutory deadline created a shortened time period to update the eCQM specifications in their EHR, which could have cost and staff workload implications. The commenter suggested that we allow EPs the option to report using 2020 specifications or to extend the reporting and payment deadlines.

Response: The December 31, 2021 deadline for payments is statutory and we do not have the authority to alter that deadline. In the 2019 PFS final rule (83 FR 59452), we explained that for states to make payments by that deadline, there must be sufficient time after EHR and eCQM reporting periods end for Medicaid EPs to attest to states, for states to conduct their prepayment processes, and for states to issue payments. Therefore, we amended § 495.4 to provide that the EHR reporting period in 2021 for all EPs in the Medicaid Promoting Interoperability Program will be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. We also established that the eCQM reporting period in 2021 for EPs in the Medicaid Promoting Interoperability Program will be a minimum of any continuous 90-day period within CY 2021, provided that the end date for this period falls before October 31, 2021, to help ensure that states can issue all Medicaid Promoting Interoperability Program payments on or before December 31, 2021. However, we also allowed states the flexibility to set alternative, earlier final end dates for EHR or eCQM reporting periods for Medicaid EPs in CY 2021, with prior approval from us, through their State Medicaid HIT Plans (SMHP). Any alternative end date for CY 2021 EHR and eCQM reporting periods set by a state may not be any earlier than the day prior to the attestation deadline for Medicaid EPs attesting to that state. For more information, see our discussion of the EHR and eCQM reporting periods for 2021 at 83 FR 59704–6.

We believe that allowing some EPs to report eCQMs in 2021 according to 2020 specifications, and some to report eCQMs in 2021 according to 2021 specifications, could cause undue confusion about the requirements for providers participating in the Medicaid Promoting Interoperability Program and/or MIPS and increase the administrative burden on states to determine which EPs submitted data in accordance with which specifications. As explained above, we believe that the latest eCQM specifications provide the most up-to-date clinical standards and guidelines. Furthermore, none of the EHR vendors who submitted comments indicated that the accelerated 2021 timeline would pose an obstacle to issuing system updates in time for EPs to attest to meaningful use. For the reasons explained in our proposal, we believe that maintaining a single set of the most up-to-date eCQM specifications for EPs to use in 2021 reduces the burden on EPs who may be reporting to multiple quality programs.

After considering public comments, we are finalizing the proposals in this section as proposed.

G. Medicare Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended Title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 to the Act to establish the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.) Eligible groups of providers and suppliers, including physicians, hospitals, and other healthcare

providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). Under the Shared Savings Program, providers of services and suppliers that participate in an ACO continue to receive traditional Medicare FFS payments under Parts A and B, but the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements.

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted on February 9, 2018), further amended section 1899 of the Act to provide for the following: Expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries, greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent major update to the program rules appeared in the June 9, 2015 **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled, ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016 **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program—Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program—Accountable Care Organizations—Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act'', appeared in the November 23, 2018 **Federal Register** (83 FR 59452) (herein referred to as the ''November 2018 final rule'' or the ''CY 2019 PFS final rule''). In the November 2018 final rule, we finalized a voluntary 6-month extension for existing ACOs whose participation agreements would otherwise expire on December 31, 2018; allowed beneficiaries greater flexibility in designating their primary care provider and in the use of that designation for purposes of assigning the beneficiary to an ACO if the clinician they align with is participating in an ACO; revised the definition of primary care services used in beneficiary assignment; provided relief for ACOs and their clinicians impacted by extreme and uncontrollable circumstances in performance year 2018 and subsequent years; established a new Certified Electronic Health Record Technology (CEHRT) use threshold requirement; and reduced the Shared Savings Program quality measure set from 31 to 23 measures (83 FR 59940 through 59990 and 59707 through 59715).

A final rule redesigning the Shared Savings Program appeared in the December 31, 2018 **Federal Register** (Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations-Pathways to Success and Uncontrollable Circumstances Policies for Performance Year 2017; final rule) (83 FR 67816) (hereinafter referred to as the ''December 2018 final rule''). In the December 2018 final rule, we finalized a number of policies for the Shared Savings Program, including a redesign of the participation options available under the program to encourage ACOs to transition to two-sided models; new tools to support coordination of care across settings and strengthen beneficiary engagement; and revisions to ensure rigorous benchmarking.

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'', which was effective on the March 31st date of display and appeared in the April 6, 2020 **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31st COVID–19 IFC''), we removed the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for COVID–19 (85 FR 19267 and 19268). In the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'' which was effective on May 8th and appeared in the May 8, 2020 **Federal Register** (85 FR 27573 through 27587) (hereinafter referred to as the ''May 8th COVID–19 IFC''), we modified Shared Savings Program policies to: (1) Allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by 1-year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for performance year 2021; (2) adjust program calculations to remove payment amounts for episodes of care for treatment of COVID–19; and (3) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19 starting in January 2020.

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. Refer to the CY 2020 PFS proposed rule for a summary of policies finalized in prior rules (84 FR 40705).

Policies applicable to Shared Savings Program ACOs for purposes of reporting for other programs have also continued to evolve based on changes in the law. The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA) established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APMs) and related policies applicable to eligible clinicians who participate in the Shared Savings Program. These policies included requirements for Shared Savings Program ACOs regarding reporting for the MIPS Quality performance category and a policy that gives ACOs full credit for the MIPS Improvement Activities performance category based on their participation in the Shared Savings Program.

In the CY 2021 PFS proposed rule (85 FR 50229), we explained our belief that the changes we were proposing to the quality reporting requirements under the Shared Savings Program for performance year 2021 and subsequent years would reduce ACO burden by establishing a smaller measure set, out of which ACOs would only be required to actively report 3 measures. This would represent a significant reduction in reporting requirements from the 10 measures on which ACOs are currently required to actively report. Under our proposal, reporting for these measures would begin in January 2022, for the 2021 performance year. We also noted that we believed this timeline would allow organizations sufficient time to prepare to report on the new measure set. In addition, the reporting options for the three ACO-reported measures would leverage existing MIPS collection types and more closely align existing CEHRT and registries used by ACOs and their clinicians, including use of APIs to submit data.

In sections III.G.1 through III.G.4 of this final rule, we summarize and respond to public comments we received on proposed modifications to the Shared Savings Program's policies discussed in section III.G. of the CY 2021 PFS proposed rule (85 FR 50228 through 50252). Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the policies addressed in section III.G. of the CY 2021 PFS proposed rule, and will not be addressed in this section of this final rule. As a general summary, in sections III.G.1 through III.G.4 of this final rule we are finalizing the following changes to the Shared Savings Program's regulations to:

- Modify the approach to measuring ACO quality performance under the Shared Savings Program which includes:

++ Applying the Alternative Payment Model (APM) Performance Pathway (APP) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021. Specifically, we are finalizing that:

—For performance year 2021, ACOs will be required to report quality data via the APP, and can choose to report either the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate 2 measures using administrative claims data.

—For performance year 2022 and subsequent performance years, ACOs will be required to actively report quality data on the 3 eCQM/MIPS CQM measures via the APP. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate two measures using administrative claims data.

++ Revising the Shared Savings Program Quality Performance Standard. ACOs will meet the quality performance standard if:

—For performance years 2021 and 2022, ACOs achieve a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores; and

—For performance year 2023 and subsequent performance years, ACOs achieve a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores.

++ Changing the methodology for determining shared savings and shared losses based on ACO quality performance.

++ Revising the approach to monitoring ACO quality performance and addressing ACOs that fail to meet the Quality Performance Standard.

++ Updating the process used to validate ACO Quality Data Reporting, where we are finalizing that CMS retains the right to audit and validate quality data reported by an ACO via the APP according to the MIPS DVA process for performance years beginning on or after January 1, 2021.

++ Updating the extreme and uncontrollable circumstances policy as it relates to quality performance.

- Update the definition of primary care services used in beneficiary assignment, and codify in regulations the adjustment that is made to an ACO's historical benchmark to reflect any changes to the beneficiary assignment methodology specified in part 425, subpart E, during an ACO's agreement period, including revisions to the definition of primary care services at § 425.402(c).

- Revise the repayment mechanism arrangement policy in the following manner:

++ To reduce the repayment mechanism amount for certain ACOs entering an agreement period starting on January 1, 2022, and in subsequent years.

++ To allow a one-time opportunity for certain ACOs that renewed for a new agreement period beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of their existing repayment mechanisms.

++ To permit a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, to use its existing repayment mechanism to support its new agreement period, in a similar manner as applies to renewing ACOs.

In section III.G.5. of this final rule, we summarize and respond to public comments received in response to the May 8th COVID–19 IFC, and discuss our final policies after taking into consideration the public comments.

1. Quality and Other Reporting Requirements

a. Background

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the November 2011 final rule establishing the Shared Savings Program, we adopted a quality measure set spanning four domains: patient experience of care, care coordination/patient safety, preventative health, and at-risk population (76 FR 67872 through 67891). Since then, we have updated the measures that comprise the quality performance measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, and 2019 PFS final rules (79 FR 67907 through 67920, 80 FR 71263 through 71268, 81 FR 80484 through 80489, and 83 FR 59707 through 59715 respectively).

As we stated in the November 2011 final rule (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality

health care at the individual and population levels, with a focus on outcomes. In the CY 2019 PFS final rule, we finalized that for performance years (or a performance period) starting in 2019 and subsequent years, 23 quality measures would be used to determine ACO quality performance (83 FR 59707 through 59715). The information used to determine ACO performance on these quality measures is submitted by the ACO through the CMS Web Interface, calculated by us from administrative claims data, and collected via a patient experience of care survey referred to as the Consumer Assessment of Healthcare Provider and Systems (CAHPS) for ACOs Survey.

Eligible clinicians who are participating in an ACO and who are subject to MIPS (MIPS eligible clinicians) are currently scored under the APM scoring standard under MIPS (81 FR 77260). These MIPS eligible clinicians include any eligible clinicians who are participating in an ACO in a track, or payment model within a track (Track 1 and Levels A through D of the BASIC track) of the Shared Savings Program that is not an Advanced APM, as well as those MIPS eligible clinicians participating in an ACO in a track, or payment model within a track (Track 2, Level E of the BASIC track, and the ENHANCED track, or the Medicare ACO Track 1+ Model (Track 1+ Model)) that is an Advanced APM, but who do not become Qualifying APM Participants (QPs) as specified in § 414.1425, and are not otherwise excluded from MIPS.

b. Applying the Alternative Payment Model (APM) Performance Pathway (APP) to Shared Savings Program ACOs

As provided in section 1899(d)(2) of the Act and § 425.502(a) of the Shared Savings Program regulations, ACOs must meet a quality performance standard to qualify to share in savings. In the CY 2017 PFS final rule, we finalized revisions to § 425.502 related to the quality performance standard and minimum attainment, including clarifying that the quality performance standard is the overall standard the ACO must meet to qualify to share in savings; defining the minimum attainment level for pay for performance measures at the 30th percent or the 30th percentile of the quality performance benchmark and for pay for reporting measures at the level of complete and accurate reporting; specifying that only pay for performance measures are assessed on a sliding scale while pay for reporting measures earn the maximum number of points for a measure when the minimum attainment level is met (81 FR 80492 through 80494).

We explained in the CY 2021 PFS proposed rule (85 FR 50230) that currently, the quality performance standard is based on an ACO's experience in the program rather than its financial track. The quality performance standard is currently defined at the level of full and complete reporting (pay-for-reporting (P4R)) for the first performance year of an ACO's first agreement period under the Shared Savings Program. In the second or subsequent years of the ACO's first agreement period and all years of subsequent agreement periods, quality measures are scored as pay-for-performance (P4P) according to the phase-in schedule for the specific measure and the ACO's performance year in the Shared Savings Program:

- For all performance years, ACOs must completely and accurately report all quality data used to calculate and assess their quality performance.
- CMS designates a performance benchmark and minimum attainment level for each P4P measure and establishes a point scale for the measure. An ACO's quality performance for a measure is evaluated using the appropriate point scale, and these measure-specific scores are used to calculate the final quality score for the ACO.
- ACOs must meet minimum attainment (defined as 30 percent or the 30th percentile of the performance benchmark for P4P measures) on at least one measure in each domain to be eligible to share in any savings generated (§ 425.502(d)(2)(iii)(A)).

In the CY 2020 PFS proposed rule (84 FR 40709 through 40713), we sought comment on how we might align the Shared Savings Program quality reporting requirements and scoring methodology more closely with the MIPS quality reporting and scoring methodology. We discussed utilizing the MIPS Quality performance category score to adjust shared savings and shared losses under the Shared Savings Program, as applicable. We also sought comment on a possible new approach to determining the threshold for minimum attainment. Under this potential policy, minimum attainment would continue to be defined as complete and accurate reporting for ACOs in their first performance year of their first agreement period, while a MIPS Quality performance category score at or above the 4th decile across all MIPS Quality performance category scores would be required for ACOs in all other performance years under the Shared Savings Program. ACOs with MIPS Quality performance category scores below the 4th decile of all MIPS Quality performance category scores would not meet the quality performance standard for the Shared Savings Program, and thus, would not be eligible to share in savings or would owe the maximum shared losses, if applicable. In addition, we sought comment on a potential policy under which ACOs with quality scores below the 4th decile of all MIPS Quality performance category scores would be subject to compliance actions and possible termination.

We noted in the CY 2021 PFS proposed rule (85 FR 50230) that the majority of feedback received in response to our comment solicitation did not support this approach as it would hold ACOs to a higher standard to be eligible to share in savings, if earned. In addition, commenters that opposed aligning the Shared Savings Program quality score with the MIPS Quality performance category score, stated that significant restructuring of the Shared Savings Program quality performance requirements would introduce more confusion for ACOs that are also transitioning into new tracks under the December 2018 final rule. Commenters also expressed concern regarding the uncertainty associated with such an approach, as we had also proposed extensive revisions to MIPS as the program transitions to MIPS Value Pathways. Furthermore, commenters noted that ACOs are unique in that they are responsible for the total cost of care of their beneficiaries and should not be compared to clinicians in MIPS who are not participating in total cost of care programs.

In the CY 2021 PFS proposed rule (85 FR 50230 and 50231), we acknowledged the commenters' concerns, but noted that section 1899(b)(3)(C) of the Act not only gives us discretion to establish quality performance standards for the Shared Savings Program, but also indicates that we should seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for purposes of assessing quality of care. The Shared Savings Program is now in its eighth performance year, and 85 percent of ACOs participating in the program are considered PY3 ACOs for purposes of quality reporting, with 65 percent of those ACOs participating in a second or subsequent agreement period. In light of the maturity of the program and consistent with section 1899(b)(3)(C) of the Act, we stated that we believe that it is appropriate to require a higher standard of care in order for ACOs to continue to share in any savings they achieve. In addition, holding ACOs to a higher standard is in line with CMS' goals of incentivizing

value-based care and driving the Medicare system to greater value and quality. However, we explained that after taking into consideration the stakeholder feedback, we had also considered ways to reduce reporting burden, offer more flexibility in the way quality data can be reported and submitted, and create a more meaningful measure set that would focus on population health measures and be more outcome-oriented, while also including patient experience of care metrics.

We stated in the CY 2021 PFS proposed rule (85 FR 50231) that although the Alternative Payment Model Performance Pathway (APP) was designed for all MIPS APMs, it is also responsive to the concerns raised by commenters in their responses to our solicitation in the CY 2020 PFS proposed rule, while still taking into consideration the maturity of the Shared Savings Program, ACOs' quality performance over time, and the intent of section 1899(b)(3)(C) of the Act. The APP contains a narrower measure set than has previously been used for Shared Savings Program quality measurement, 6 measures versus the current 23 scored measures, and is specifically intended for use in APMs and population health. The design of the APP aligns with stakeholder interests expressed through comments on our solicitation about aligning the Shared Savings Program with MIPS in the CY 2020 PFS proposed rule. These comments suggested adopting a smaller, more focused measure set in recognition of the fact that APM Entities are incentivized through the terms of the respective APMs to improve value. The measure set proposed for the APP aligns with the Meaningful Measures framework by identifying measures that address the highest priorities for quality measurement and improvement, while also reducing reporting burden, promoting alignment of measures and consolidation of reporting requirements across CMS programs moving payment toward value, and identifying consumers' key quality performance metrics. We noted that the measures proposed for inclusion in the APP measure set encompass the meaningful measure domains of patient voice, wellness and prevention, seamless communication, chronic disease management, and behavioral health. For these reasons, we stated in the CY 2021 PFS proposed rule that we believe that the proposed APP, along with the narrower measure set, which comprises it, would be appropriate to assess the quality performance of Shared Savings Program ACOs.

The construction of the proposed APP for Shared Savings Program ACOs and the proposed measures within it were described in detail in section III.G.1.b.(1) of the CY 2021 PFS proposed rule (85 FR 50231 through 50235). A detailed discussion of the proposal for use of the APP for MIPS APMs more generally can be found in section IV.A.3.b. of the CY 2021 PFS proposed rule (85 FR 50285 through 50288).

(1) APM Performance Pathway for Shared Savings Program ACOs

In section III.G.1.b.(1) of the CY 2021 PFS proposed rule (85 FR 50231 through 50235), we described the proposals related to the APM Performance Pathway for Shared Savings Program ACOs. In response to the stakeholder feedback and in order to improve alignment and integration with the Quality Payment Program policies and operations, align with CMS' Meaningful Measure Framework, increase participation in APMs and Advanced APMs by reducing reporting burden, and raise the quality performance standard under the Shared Savings Program, we proposed to revise the Shared Savings Program quality performance standard effective for performance year 2021 and subsequent performance years. We explained that the proposed revision would align the Shared Savings Program quality performance standard with the proposed APP under the Quality Payment Program as participants in the Shared Savings Program would be required to report quality for purposes of the Shared Savings Program via the APP, which was described in more detail in section IV.A.3.b. of the CY 2021 PFS proposed rule (85 FR 50285 through 50288).

At a high level, we proposed that the APP would replace the current Shared Savings Program quality measure set to streamline reporting requirements for Shared Savings Program ACOs and would be a complementary path to the MIPS Value Pathways. The APP is designed to reduce reporting burden, create new scoring opportunities for participants in MIPS APMs, and encourage participation in APMs.

Under this proposed new approach, ACOs would only need to report one set of quality metrics that would satisfy the reporting requirements under both MIPS and the Shared Savings Program. There would not be separate quality reporting requirements under the Shared Savings Program, as under the proposed new approach the quality measures reported for purposes of the APP would also be used to determine the quality performance of the ACO for purposes of the Shared Savings Program, which is used for purposes of calculating shared savings and also shared losses, where applicable. We stated that we believe this approach of streamlining the quality reporting requirements under the Shared Savings Program while maintaining alignment with the Quality Payment Program will help ACOs and their participating providers and suppliers dedicate their finite resources to engaging in efforts to improve quality and reduce costs for their assigned beneficiary population. In addition, we explained that using a single methodology to measure quality performance under both the Shared Savings Program and MIPS would allow ACOs to better focus on increasing the value of healthcare, improving care, and engaging patients. It would also reduce burden as ACOs would be able to track to a smaller set of measures under a unified scoring methodology.

We received many public comments on the proposals to apply the APP to determine the quality performance of Shared Savings Program ACOs. The following is a summary of the comments we received and our responses.

Comment: We received many comments on the proposal to apply the APP to determine quality performance of Shared Savings Program ACOs. Supportive commenters noted that this proposal would align reporting requirements for MIPS and the Shared Savings Program, shift the focus from process measures to clinical outcomes, move toward eliminating unnecessary and inappropriate measures, focus on appropriate measures for ACO accountability, and provide entities more flexibility for reporting and allow MIPS eligible clinicians the option of reporting quality data separately from the ACO for purposes of MIPS scoring. Further, one commenter noted that alignment between MIPS and quality reporting requirements for Advanced APMs would create a better glidepath for healthcare providers looking to transition away from fee-for-service. Additionally, commenters noted that streamlined reporting requirements, a smaller set of measures, and a unified scoring methodology for the Shared Savings Program and MIPS would result in reduced burden for ACOs and allow ACOs to dedicate limited resources toward improving care for beneficiaries. One commenter noted that alignment of Shared Savings Program quality reporting requirements under the APP with reporting requirements under the MIPS program would minimize the

barrier for practices transitioning to an APM.

However, a majority of commenters expressed concerns about the proposal. The most common concerns were the time, effort, and cost involved in transitioning to a new measure set, new reporting mechanisms, and all-payer reporting, with potentially unintended negative impacts on quality, particularly during a time when healthcare organizations are impacted by the PHE for COVID–19. Specific concerns included the time needed to identify and implement new data collection mechanisms, modify operational workflows and clinical strategies to align with the six APP quality measures, secure new technology capabilities, assess and respond to the impacts of the PHE for COVID–19, understand the differences in measure specifications, train clinicians and office staff on a new reporting platform, and evaluate performance against the consolidated measure set to understand the impact this change will have on scoring standards. Comments included requests that implementation of the APP be delayed until 2022 or later; a voluntary transition period be offered to allow time for ACOs to adapt to the new requirements; a modified plan be implemented to allow ACOs to only report on a sample of patients while they prepare to implement automated population measurement; the first year following implementation of the APP be a pay-for-reporting year; exemptions to reporting requirements be offered; a bonus be offered to ACOs that are able to make the transition in 2021 without penalizing ACOs that need more time to prepare; and the timelines for implementing the APP and implementing the MIPS Value Pathways be aligned. One commenter requested that if the proposal is delayed until 2022 that CMS confirm the measure set that will be used starting in performance year 2022 in the CY 2021 PFS final rule so that ACOs have time to prepare. Commenters suggested that more stakeholder feedback should be collected before the proposed changes are finalized and that CMS should provide time for provider education, outreach, and support between finalizing a rule and implementing significant revisions to the quality reporting requirements.

Some commenters supported sunsetting the CMS Web Interface as a way to meet the CMS objective of increasing the utilization of CEHRT and digital quality measures or interoperability initiatives; but, many commenters had concerns about sunsetting the CMS Web Interface. Several commenters requested that sunsetting the CMS Web Interface should either be a gradual transition or be delayed to allow organizations to prepare for the transition to reporting under the APP and ease financial constraints practices are currently facing due to the PHE for COVID–19.

One commenter noted that even small changes to the program design could cause significant variance in performance for ACOs. The commenter recommended that CMS keep the current measure set, reporting mechanism, and scoring methods in place for performance 2021. Additionally, the commenter stated that healthcare providers should not be held accountable for performance against a benchmark that would not be set until the performance period closed and expressed concern that the PHE would continue to impact quality improvement efforts in 2021. The commenter recommended that CMS continue to monitor data submitted through the CMS Web Interface, evaluate the impact of the PHE for COVID–19 on quality performance, and revert all measures to pay-for-reporting or provide ACOs with the option to choose historical performance scores.

Other concerns raised by commenters included that the proposed APP does not align with the approach CMS uses to assess the quality of care furnished by other non-fee-for-service providers, such as Medicare Advantage organizations, even though the proposal would align quality scoring under the Shared Savings Program with MIPS. Two commenters noted that aligning requirements for Advanced APMs with MIPS program methodologies was a step backwards. One of these commenters stated that the guiding principle should be to ensure that there are strong incentives to participate in Advanced APMs relative to traditional Medicare fee-for-service, including being excluded from MIPS quality reporting processes, to increase the uptake of participation in Advanced APMs and decrease the need for MIPS over time. The other commenter stated that APMs should not have to align with MIPS, but rather MIPS reporting requirements should be structured to encourage clinicians to participate in APMs. Several commenters had concerns about changes to how ACO quality is reported, scored, and assessed and recommended that CMS obtain more stakeholder feedback before moving forward. One commenter expressed concern that the proposed APP does not support the Shared Savings Program's commitment to improved value, stating that the quality performance of ACOs should not be evaluated for purposes of the Shared Savings Program in the same manner as under other APMs or for individual MIPS clinicians because each APM has specific goals and objectives. Further, commenters noted that ACOs are distinct from single physician groups or hospital systems because ACOs are focused on managing population health and total cost of care for their aligned Medicare patient population, and therefore, should not be evaluated and assessed in the same manner as other types of healthcare providers. One commenter noted that the proposed APP will require significant investments while healthcare providers are still recovering from the PHE and this may disproportionately disadvantage smaller and rural ACOs and multi-practice independent physician ACOs operating many EHR systems.

Response: We thank commenters for their detailed feedback on the proposal to apply the APP to Shared Savings Program ACOs beginning in performance year 2021. We appreciate the support for our proposal, but also understand the concerns raised by a number of commenters about the proposed implementation of the APP for Shared Savings Program ACOs starting in performance year 2021. The primary concern expressed by commenters centered around the timeline for ACOs to implement appropriate infrastructure changes in order to be able to report under the APP beginning in performance year 2021, particularly given the PHE for COVID–19. Commenters also raised concerns about the proposed removal of the CMS Web Interface as a collection type. In addition, commenters were concerned about the proposed APP measure set, including use of measures based on all payer data. In light of the significant concerns raised by the commenters about implementing the APP for Shared Savings Program ACOs beginning in performance year 2021, we are modifying our proposal to apply the APP to determine the quality performance of Shared Savings Program ACOs as described below.

As discussed in section IV.A.3.c.1.c. of this final rule, we are extending the use of the CMS Web Interface as a collection type for the Quality Payment Program for CY 2021, and will sunset the CMS Web Interface starting with CY 2022. Accordingly, we are also modifying the quality measure set for the APP for Shared Savings Program ACOs to add the CMS Web Interface as an additional reporting option for performance year 2021, as discussed in this section and section IV.A.3.b. of this final rule. In addition, as discussed in

section III.G.1.c. of this final rule, we are modifying the proposed quality performance standard to include a gradual phase-in of the increase in the level of quality performance that would be required for ACOs to meet the quality performance standard under the APP for Shared Savings Program ACOs. We believe that these changes alleviate many of the concerns raised by commenters about the implementation of the APP for Shared Savings Program ACOs beginning in performance year 2021.

Therefore, we are finalizing, with modifications, our proposed revisions to the quality reporting requirements under the Shared Savings Program effective for performance year 2021 and subsequent performance years. These revisions will align the Shared Savings Program quality reporting requirements with the requirements that will apply under the APP under the Quality Payment Program as Shared Savings Program ACOs will be required to report quality data for purposes of the Shared Savings Program via the APP. Under this new approach, ACOs will only need to report one set of quality metrics via the APP that will satisfy the quality reporting requirements under both the Shared Savings Program and the MIPS. As discussed in the CY 2021 PFS proposed rule (85 FR 50231), there will not be separate quality reporting requirements under the Shared Savings Program as the quality measures reported for purposes of the APP will be used to determine the quality performance of the ACO for purposes of calculating shared savings and also shared losses, where applicable. The final APP quality measure set is listed in Tables 40 and 46 in this final rule. The policies finalized for the APP are discussed in section IV.A.3.b. of this final rule. In order to meet the quality reporting requirements under the Shared Savings Program, ACOs must meet the requirements described below and summarized in Table 39.

- For performance year 2021, ACOs will be required to report quality data via the APP, and can choose to actively report either the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate 2 measures using administrative claims data.

As noted in Tables 40 and 46 in this final rule three of the CMS Web Interface measures (Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134)) do not have benchmarks, and therefore, will not be scored. However, these measures are required to be reported in order to complete the CMS Web Interface dataset. Based on the ACO's chosen reporting option, either 6 or 10 measures will be included in the calculation of the ACO's quality performance score.

- For performance year 2022 and subsequent performance years, ACOs will be required to actively report quality data on the 3 eCQM/MIPS CQM measures via the APP. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate two measures using administrative claims data. All 6 measures will be included in the calculation of the ACO's quality performance score.

TABLE 39: Summary of final policies on applying the APP to Shared Savings Program ACOs beginning performance year 2021

	Performance Year (PY) 2021 (Reporting in CY 2022)	PY 2022 (Reporting in CY 2023)	PY 2023 (Reporting in CY 2024) and Subsequent PYs
Quality Reporting requirements	ACOs will be required to report the 10 measures under the CMS Web Interface **or** the 3 eCQM/MIPS CQM measures. ACOs will be required to field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. Based on the ACO's chosen reporting option, either 6 or 10* measures will be included in calculating the ACO's quality performance score.	ACOs will be required to actively report on the 3 eCQM/CQM MIPS measures and field the CAHPS for MIPS survey. CMS will calculate the HWR and MCC measures using administrative claims data. All 6 measures will be included in calculating the ACO's quality performance score.	Same as PY2022
Quality Performance Standard	A quality performance score that is equivalent to or higher than the **30th** percentile across all MIPS Quality performance category scores. Quality performance standard met: ACOs are eligible to share in savings at the maximum sharing rate; ACOs in two-sided models share in losses based on their quality score or at a fixed percentage based on Track. Quality performance standard not met: ACOs are ineligible to share savings and owe the maximum amount of shared losses, if applicable.	Same as PY 2021 Shared savings and shared losses determinations same as PY2021	A quality performance score that is equivalent to or higher than the **40th** percentile across all MIPS Quality performance category scores. Shared savings and shared losses determinations same as PY2021

* For performance year 2021, if ACOs choose to report via the CMS Web Interface, they will be required to report all 10 measures, but will be scored on only 7 of those measures.

The quality reporting requirements described above will provide ACOs with a one-year transition period during performance year 2021 where they will have the option either to continue to report via the CMS Web Interface or to report on the 3 eCQM/CQM MIPS measures before being required to report on the 3 eCQM/MIPS CQM measures beginning in performance year 2022. As discussed in section III.G.1.c. of this final rule, we are also finalizing policies to phase-in the increase in the quality performance standard over 3 years. We believe that the phase-in policies, as summarized in Table 39, for applying the APP to Shared Savings Program ACOs address concerns raised by the commenters regarding the proposed timeline for implementing the APP and also help to mitigate the impact of the PHE for COVID–19 on ACOs. The phase-in policies provide ACOs with additional time to set up their systems and educate providers and office staff in order to report on the 3 eCQM/MIPS CQM measures beginning in performance year 2022 and will also allow ACOs to become familiar with the new quality reporting requirements under the APP and gain experience reporting on the new measures before they are assessed under the higher quality performance standard beginning in performance year 2023. Commenters' concerns related to the APP quality measure set are addressed later in this section.

In the CY 2021 PFS proposed rule, we explained that the APP is designed to reduce reporting burden by enabling ACOs to track to a smaller set of measures under a unified scoring methodology. The policies we are adopting in this final rule are consistent with our goal of reducing reporting burden for ACOs. Under our final policies, the total number of measures will be reduced from 23 to either 6 or 13 measures (depending on the ACO's chosen reporting option) for performance year 2021 and to 6 measures beginning in performance year 2022.

For the commenter that expressed concern that providers should not be held accountable for performance against a benchmark that would not be set until the end of the performance period, we note that as discussed in section IV.A.3.d.1.b.ii. of this final rule, we are not finalizing the proposal to use performance period benchmarks and instead will continue to use historical benchmarks for quality measures for the CY 2021 MIPS performance period.

We stated in the CY 2021 PFS proposed rule (85 FR 50231) that, under the APP proposed in section III.C.3.b., eligible clinicians in Shared Savings Program ACOs would continue to receive full credit for the improvement activities performance category in 2021 based on their performance of activities required under § 425.112 of the Shared Savings Program regulations, as they do under current MIPS scoring policy. We also proposed that under the APP, the Promoting Interoperability performance category would be reported and scored by MIPS eligible clinicians and groups and calculated in the same manner described at § 414.1375. Shared Savings Program ACOs are not currently assessed on the MIPS Cost performance category as they are already subject to cost and utilization performance

assessments as part of the Shared Savings Program, and we proposed that the cost performance category would continue to be weighted at zero percent under the APP. Under the proposed APP, the four performance categories would be weighted as follows: Quality: 50 percent; Promoting Interoperability: 30 percent; Improvement Activities: 20 percent; and Cost: 0 percent. These policies are being finalized as proposed in section IV.A.3.b.4. of this final rule.

Under the APP, the quality performance score will be calculated for ACOs based on the same MIPS benchmarks that are used for other non-ACO group and individual reporters and reflect the method of data submission (for example, eCQM measures have benchmarks calculated using EHR data and CQM measures have benchmarks calculated using data for each specific non-EHR collection type). As discussed in section IV.A.3.d.1.b.ii of this final rule, we are not finalizing the proposal to use performance period benchmarks and instead will continue to use historical benchmarks for quality measures for the CY 2021 MIPS performance period. However, we note that, for the measures reported under the CMS Web Interface for performance year 2021, we will continue to use the Shared Savings Program benchmarks developed for the CMS Web Interface for performance year 2020. These Shared Savings Program benchmarks are based on data reported by ACOs, physicians, and groups through the CMS Web Interface, claims, and/or a registry from 2016, 2017, and 2018. The use of the Shared Savings Program benchmarks for the CMS Web Interface measures for performance year 2021 will allow us to be consistent with the approach currently used for scoring CMS Web Interface measures in the Shared Savings Program. We note that the Shared Savings Program benchmarks will also be used for the CMS Web Interface measures reported by groups and virtual groups under MIPS.

In the proposed CY 2021 PFS proposed rule (85 FR 50231 and 50232) we proposed that ACOs would be scored on the measures they report and will receive zero points for those measures they do not report. For example, if an ACO reported all three measures it is actively required to report but did not field a CAHPS for MIPS survey measure, the ACO would receive zero points for the CAHPS for MIPS survey measure, and that zero would be included in its MIPS Quality performance category score, along with its performance rates on the three measures it did actively report as well as the two claims-based measures included in the APP measure set. This proposed approach aligns with scoring under MIPS, rather than the current Shared Savings Program quality performance scoring methodology, which uses quality benchmarks established specifically for the Shared Savings Program and awards zero points for quality for ACOs that report some but not all of the required measures. We also noted that we believe this approach would be less punitive for ACOs than the current quality performance standard, under which ACOs that fail to completely report all quality measures receive a zero score for quality. We also noted that we believe that alignment with the MIPS scoring methodology would reduce the burden on ACOs of tracking to two different scoring methodologies. However, we proposed that if an ACO does not report any of the three APP measures it is required to actively report and does not field a CAHPS for MIPS survey the ACO would not meet the quality performance standard for purposes of the Shared Savings Program and would not be able to share in savings and would owe maximum shared losses, if applicable. We explained that if an ACO does not report any of the three measures it is required to actively report and does not field a CAHPS for MIPS survey, we did not believe that the remaining two claims-based measures in the APP core measure set would be sufficient to assess the quality of care provided by an ACO to its assigned beneficiaries and would likely not allow the ACO to achieve a MIPS Quality performance category score at or above the 40th percentile. Under our proposal, there would be no quality ''phase in'' for new ACOs or for newly introduced measures or for quality measures that undergo significant changes. All ACOs, regardless of performance year and agreement period, would be scored on all the measures in the APP for purposes of the Shared Savings Program quality performance standard.

We did not receive any comments on the proposal that if an ACO does not report any of the three APP measures it is required to actively report and does not field a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

Consistent with the quality reporting requirements finalized for Shared Savings Program ACOs under the APP, as discussed above, we are finalizing that:

- *For performance year 2021:* If an ACO does not report any of the ten CMS Web Interface measures or any of the three eCQM/MIPS CQM measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO would not meet the quality performance standard for purposes of the Shared Savings Program.
- *For performance year 2022 and subsequent performance years:* If an ACO does not report any of the three eCQM/MIPS CQM measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO would not meet the quality performance standard for purposes of the Shared Savings Program.

Comment: We received several comments related to the proposal to remove the pay-for-reporting year for ACOs in the first year of their first agreement period. Commenters expressed concern that new ACOs may require an initial performance year in the Shared Savings Program to build operations before they will be prepared to meet pay-for-performance standards. One commenter noted that new ACOs should have 1–2 years to learn the quality measures and plan improvement processes. Additionally, commenters expressed that removing the pay-for-reporting option for new ACOs would deter participation in the Shared Savings Program and negatively impact ACOs that are comprised of smaller physician practices and do not have hospital system support.

Response: We appreciate the commenters' concerns regarding the removal of the pay-for-reporting year for ACOs beginning an initial agreement period under the Shared Savings Program. The goal of the proposal was to align the Shared Savings Program quality performance standard with the APP under the Quality Payment Program, and there is no pay-for-reporting policy under the Quality Payment Program. However, in recognition of the concerns expressed by the commenters, we are modifying our original proposal and finalizing the following policy: Beginning January 1, 2022, for ACOs in the first performance year of their first agreement period under the Shared Savings Program, an ACO would meet the quality performance standard if it meets the MIPS data completeness and case minimum requirements on all three of the eCQM/MIPS CQM measures and fields the CAHPS for MIPS survey via the APP. The scoring policy under MIPS would be the same as for other ACOs.

We note that, as a result of CMS' decision to forgo an application cycle for a January 1, 2021 agreement start date in the Shared Savings Program, there will be no ACOs whose first

performance year of its first agreement period under the Shared Savings Program will begin on January 1, 2021. Therefore, this policy will be applicable for ACOs that are in the first performance year of their first agreement period in performance year 2022 or a subsequent performance year. We believe continuing this policy under the APP will provide new ACOs with additional time to set up their systems and educate providers and office staff, become familiar with the quality reporting requirements under the APP, and gain experience reporting on the measures under the APP before their performance is assessed in order to share in savings.

Comment: We received several comments related to the proposal to remove the pay-for-reporting year for newly introduced quality measures and quality measures that have undergone significant changes. Commenters suggested that a pay-for-reporting transition year ensures that quality measures that are new or have undergone significant changes do not have unintended consequences and allows potential issues with measure specifications to be identified before ACOs are held accountable for measure performance. Additionally, commenters suggested that a pay-for-reporting transition year would allow ACOs to adjust workflows and operations to ensure that quality data for the new or significantly changed measure is appropriately captured.

Response: We appreciate the commenters' concerns regarding the removal of the pay-for-reporting year under the Shared Savings Program for newly introduced quality measures and quality measures that undergo significant changes. We note that for each quality measure that an ACO submits that has significant changes, the total available measure achievement points are reduced by 10 points under the APP under current MIPS scoring policy (§ 414.1380(b)(1)(vii)(A)). We believe that adopting these policies for the Shared Savings Program is consistent with our goal to align the quality scoring methodology under the Shared Savings Program with MIPS. Therefore, we are finalizing our proposal to remove the pay-for-reporting year under the Shared Savings Program for newly introduced quality measures and quality measures that undergo significant changes.

In the CY 2021 PFS proposed rule (85 FR 50232), we stated that for MIPS scoring purposes, an ACO that fails to report via the APP would receive a zero in the Quality performance category under MIPS. If an ACO fails to report via the APP on behalf of its ACO participants then the ACO participants could report outside the ACO, on behalf of the MIPS eligible clinicians who bill through the TIN of the ACO participant and receive a MIPS Quality performance category score calculated at the ACO participant level. If ACO participants report outside the ACO via the APP, they would be eligible to earn full credit for improvement activities based on ACO participation. If ACO participants choose to report outside the ACO via a different MIPS reporting option, then regular MIPS scoring rules would apply (that is, eligibility to earn full credit for improvement activities and zero cost category weight would not be applied). We proposed in the CY 2021 PFS proposed rule (85 FR 50285) that MIPS eligible clinicians participating in ACOs also would have the option of reporting outside the APP, or within it at an individual or group level, for purposes of being scored under MIPS.

Comment: One commenter supported the proposal to allow reporting at the clinician, group practice, or ACO level for purposes of MIPS scoring as it would allow clinicians more flexibility and allow clinicians to be recognized for the work they are doing both inside and outside the context of the ACO. Other commenters expressed concerns regarding a policy under which individual clinicians and group TINs would have the option to report outside of the ACO for the purposes of MIPS scoring. The commenters expressed concerns that this approach would cause unnecessary confusion and instability and could fracture the foundation of the ACO by negating the commitment to the ACO. Similarly, one provider expressed concern that individual reporting adds a layer of complexity that is not conducive to ACO shared learnings and best practice identification. Additionally, commenters were concerned that this approach would not allow for a fair assessment of quality improvement efforts by clinicians or group practices participating in ACOs because certain organizations could select measures for which they have the highest historical performance. One commenter was concerned that reporting separately could disproportionately impact rural and smaller providers. The commenter recommended that CMS instead maintain the APM Scoring Standard approach for all ACO clinicians.

Another commenter had concerns that allowing TINs and/or NPIs to report data on their own, outside of the ACO, would cause even more confusion, citing previous concerns with the QPP help desk not understanding Medicare Shared Savings Program reporting requirements. Specifically, the commenter was concerned that ACO participant practices would think they do not need to report on the same measures that the ACO is required to report on under the Medicare Shared Savings Program.

Response: Policies related to eligible clinicians and groups reporting outside of the APP are discussed in detail in section IV.A.3.c.5 of this final rule. We note that the policy discussion above relates to ACO participants reporting outside of the ACO via the APP when the ACO fails to report data via the APP on behalf of its participant TINs. Eligible clinicians participating in an ACO may report to MIPS independently at the individual or TIN level. If ACO participants report outside the ACO via the APP, they will be eligible to earn full credit for improvement activities based on ACO participation and to have the cost performance category reweighted. However, if ACO participants report to MIPS according to traditional MIPS rules, as a group or individual MIPS eligible clinician, MIPS scoring rules apply. These policies are discussed in further detail in section IV.A.3.b. of this final rule. Additionally, we refer readers to section IV.A.3.e. of this final rule for information concerning our final policy on the hierarchy that will apply when more than one final score is associated with a TIN/NPI. We also refer readers to the discussion earlier in this section where we are finalizing our proposal that if an ACO does not report any of the three APP measures it is required to actively report and does not field a CAHPS for MIPS survey, the ACO would not meet the quality performance standard.

In the CY 2021 PFS proposed rule (85 FR 50232 and 50233), we proposed that for performance year 2021 and subsequent performance years, ACOs would be assessed on a smaller measure set under the APP for Shared Savings Program ACOs. The measures ACOs would be scored on would decrease from 23 measures to 6 measures and the number of measures on which ACOs would be required to actively report would be reduced from 10 to 3.

ACOs would report under the APP on the following 3 measures:

- Quality ID#: 001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%);
- Quality ID#: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and
- Quality ID#: 236 Controlling High Blood Pressure.

ACOs would report these measures via a submission method of their choice

that aligns with the MIPS data submission types for groups at § 414.1325(c) (direct, login and upload, or a third-party intermediary, described at § 414.1400, submitting on behalf of the ACO). ACOs would receive a score of between 3 to 10 points for each measure that meets the data completeness and case minimum requirements, which would be determined by comparing measure performance to established benchmarks. In addition, ACOs would need to field a CAHPS for MIPS survey and would be measured on two claims-based measures: The Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups; and the All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions (MCC). Please see Table 36 in the CY 2021 PFS proposed rule (85 FR 50233) for full details on the measures proposed under the APP.

The measures proposed for inclusion in the measure set for the APP would align with the Meaningful Measures framework by identifying the highest priorities for quality measurement and improvement with the goals of reducing burden, promoting alignment, moving payment toward value, and identifying key quality performance metrics for consumers. The proposed measures would also encompass the meaningful measure domains of patient voice, wellness and prevention, seamless communication, chronic disease management, and behavioral health. We explained that we believe that the measures included in the APP are appropriate to assess the quality performance of Shared Savings Program ACOs as they focus on the management of chronic health conditions that are high priority and have high prevalence among the population of Medicare beneficiaries assigned to ACOs. We also noted that we believe that the measure set chosen for inclusion within the APP would move the quality measure set used in the Shared Savings Program toward a more outcome based, primary care focused measure set. In addition to creating a pathway that would reduce reporting burden for ACOs and allow their participating MIPS eligible clinicians to meet requirements under MIPS through a smaller measure set, requiring ACOs to report through the APP would also eliminate differences in the way ACOs are scored under the Shared Savings Program, as compared to the way their MIPS eligible clinicians are scored under MIPS.

We noted that under the current Shared Savings Program quality scoring methodology, the CAHPS for ACOs survey is counted as ten separate measures, while under the APP, the CAHPS for MIPS survey would be counted as one. We explained that we continue to value the patient voice and believe it should play a significant role in quality scoring. Using the CAHPS for MIPS survey would achieve that goal while further aligning the way in which the quality performance of ACOs and their MIPS eligible clinicians is scored under the Shared Savings Program and under MIPS, respectively. We noted that under the current Shared Savings quality scoring methodology, the 10 CAHPS for ACOs survey measures are scored as one domain, which makes up 25 percent of the Shared Savings Program quality score. In contrast, under the proposed approach, the CAHPS for MIPS survey would be counted as one measure out of the 6 measures that would be included in the calculation of the ACO's quality score under the APP. Both of these approaches have a similar weighting, which would maintain the relevance of patient voice. We also noted that we believed that the proposed approach under the APP of combining the CAHPS survey measures into a single measure for quality scoring purposes would allow Shared Savings Program ACOs to effectively target resources toward improving their assigned beneficiaries' experience of care in the areas for improvement on which they choose to focus, rather than having to track to ten separate survey measures, as is currently required by the CAHPS for ACOs used under the Shared Savings Program. We believed this approach would strike the right balance in reducing burden on ACOs and their participating providers and suppliers while preserving the patient's voice.

Shared Savings Program ACOs are currently required to report on a set of ten measures via the CMS Web Interface. While these measures were appropriate for use in the program in the past because they are primary care focused, we explained that we now recognize that the majority of the measures have highly clustered performance. This means that they cannot meaningfully distinguish quality performance across groups or ACOs. We also noted that we recognize the value in the use of primary care-focused measures and in that developing the proposed measure set for use under the APP, we had sought to preserve the measures we believed most reflect high priority quality measurement areas while also placing more emphasis on outcome-based claims measures, which minimize reporting burden and reflect greater opportunity for improvement.

We received many public comments on the proposed APP quality measure set as applied to Shared Savings Program quality performance scoring. The following is a summary of the comments we received and our responses. Please refer to section IV.A.3.b.(3)a. of this final rule for further discussion of comments and responses on the APP measure set.

Comment: Many commenters were supportive of the overall goal of simplifying reporting and aligning quality measurement approaches across federal programs. Several commenters were supportive of the reduction in the number of measures to reduce burden for healthcare providers, including the reporting burden placed on rural primary care practices. One commenter supported the proposed measure set, stating that it was adequate to address the chronic conditions among Medicare beneficiaries. One commenter indicated that the proposed reduced measure set focused on clinical outcomes and patient experience and is less burdensome for healthcare providers. One commenter supported this proposal and specifically stated that requiring former users of the CMS Web Interface to report all payer data will result in more patients receiving the benefit of services captured in the quality metrics, such as depression screening and pneumococcal vaccination status, rather than practices focusing those wellness measures solely on Medicare patients.

Response: We thank commenters for their positive feedback on the proposed APP quality measure set. The reduced measure set is intended to reduce reporting burden on ACOs and focus on quality measures that address patient outcomes and appreciate hearing that commenters also believe that the proposed measure set is consistent with those goals.

Comment: Several commenters were concerned that the proposed measure set is not appropriate for healthcare providers, such as ACOs, that are responsible for the total cost of care for the populations they serve and will not allow for robust assessment of clinical quality. Some commenters noted that the reduction in measures would significantly increase the impact of each measure on an ACO's overall quality score, which could risk over-emphasizing certain metrics and underlying patient conditions, as well as create more disruption when the measure set is revised. Additionally, several commenters were concerned that reducing the quality measure set would de-emphasize quality and would

not allow for a representative assessment of ACOs' quality improvement efforts, making it more difficult for ACOs to distinguish themselves based on the care they provide. One commenter was concerned that the reduction in measures would limit the ability for consumers to evaluate and compare the quality of providers. Another commenter had concerns that reducing the number of ACO quality measures would make specialists less likely to participate in the Shared Savings Program. Another commenter stated that the proposed measures are not relevant to ophthalmology specialty practices and suggested that the same measure sets used in MIPS be permitted for reporting through the APP or a protocol be put in place to determine if the measures are relevant to the clinicians reporting under the APP.

One commenter expressed concern that the narrower quality measure set would not appropriately protect patients because it would narrow the lens through which quality is assessed. Several commenters recommended that CMS work with stakeholders to refine the current set of measures to make it more appropriate for ACOs, which are responsible for total cost of care for the populations they serve. Another commenter stated that CMS should clarify if the outcome measures selected are representative of all of the different types of populations that ACOs treat and recommended that CMS take patient compliance and case mix into consideration when selecting measures because some patients may take longer to achieve health goals and ACOs may not have the same relative volume of patients with diagnoses such as diabetes and hypertension. One commenter suggested that CMS demonstrate that the proposed measures are of high significance to beneficiaries. Due to the impacts of the PHE for COVID–19, one commenter recommended that measures, such as breast cancer and colorectal cancer screening, be removed or treated as pay-for-reporting for performance year 2021.

Some commenters also expressed concern that the limited measure set would allow little room for random variation in one measure because random variation in one measure will have a larger impact when there are fewer measures to absorb the impact. One commenter stated that the limited measure set puts ACOs at a disadvantage compared to entities that are able to report outside of the APP and who can choose from larger pool of measures. Commenters also expressed concern that the reduction in the number of measures was too drastic and may have unforeseeable impacts on quality scoring for ACOs. One commenter suggested a more gradual, phased reduction where measures would be removed in rounds based on level of priority so that the impact of reducing the size of the measure set could be evaluated before additional measures are removed. Commenters also suggested that CMS monitor the smaller measure set to ensure the measures are not overly sensitive to minor changes in performance, random variation, or risk adjustment methodologies.

Other commenters suggested that CMS consider a broader measure set, and many commenters made recommendations for measures to be added to the measure set. One commenter suggested that a larger set of quality measures would be worth the additional burden because it would protect ACOs against errors in scoring, changes in risk adjustment methodology, and anomalies. Another commenter noted that while reducing the number of measures will reduce burden, ACOs also experience administrative burden due to year-to-year changes in the Shared Savings Program and the lack of alignment in measures between programs.

Response: We appreciate the commenters' concerns and recommendations regarding the narrower set of quality metrics that we proposed for the APP and its appropriateness for assessing the quality of care furnished by ACOs and their ACO participants. The transition to the APP measure set is intended to reduce reporting burden and eliminate differences in the way ACOs are scored compared to their MIPS eligible clinicians, while also moving toward a more outcome-based, primary care focused measure set. Additionally, we selected the measures to be included in the measure set because they are broadly applicable for the primary care population and population health goals that are associated with the Shared Savings Program. These measures align with the Meaningful Measures framework while also being appropriate for assessing ACO quality performance as they focus on prevalent and high priority chronic health conditions. For example, hypertension and diabetes are chronic conditions that are applicable to both primary care practitioners and specialists.

Comment: Several commenters expressed concern that two of the six proposed quality measures (Measure # 479 Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups and Measure # TBD Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs) are focused on utilization even though the Shared Savings Program provides financial incentives for reducing avoidable hospital admissions and readmissions. Additionally, commenters stated that ACOs should be evaluated on quality measures that reflect core ACO competencies, such as care coordination activities and preventative health.

Response: Under the Shared Savings Program, an ACO that lowers growth in Medicare Parts A and B expenditures such that performance year expenditures for the ACO's assigned beneficiary population are below the ACO's updated historical benchmark by an amount that meets or exceeds the applicable minimum savings rate, may be eligible to share in savings. We do not believe that the incentive for ACOs to lower growth in expenditures, in order to generate shared savings, conflicts with assessment of the quality of care furnished by an ACO that includes measures of utilization, such as Measure # 479 Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups and Measure # TBD Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs. We note that section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by the ACO, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization (such as rates of hospital admission for ambulatory sensitive conditions). Additionally, regarding the commenters' concerns about quality measures addressing core ACO competencies, we note that the APP measure set includes measures that address preventive health and care coordination. For example, the All-Cause Readmission (HWR) and All-Cause Unplanned Admissions for Multiple Chronic Condition measures fall into the Meaningful Measure domain of Promoting Effective Communication and Coordination of Care and the Preventive Care and Screening: Screening for Depression and Follow up plan falls into the Meaningful Measure domain of Promoting Effective Prevention & Treatment of Chronic Disease.

Comment: Several commenters expressed concerns about data collection methods in light of the increasing use of telehealth visits, as well as the various measure types (such as eCQM/MIPS CQM measures, CAHPS

for MIPS survey measures, and claims-based measures) used in the APP measure set. Commenters recommended that the measures selected be viewed through the lens of the current PHE environment and that all quality measures allow data to be collected during telehealth visits because many ACO participants have been relying on telehealth visits to continue seeing their patients during the PHE.

Response: We understand commenters' concerns related to the PHE for COVID–19. For the claims-based measures in the APP measure set, telehealth codes are not used to exclude claims from the measure calculation algorithm or the claims used to identify comorbidities as part of the risk adjustment model. Nine out of the ten CMS Web Interface measures, which are in the measure set for performance year 2021, allow the requirements for inclusion in the numerator to be met during a telehealth encounter. Quality ID#: 438 is the only measure that does not allow the quality action required to meet numerator compliance, to occur during a telehealth encounter. Similar to the Web Interface measures, the three eCQM/MIPS CQM measures in the APP measure set allow the requirements for inclusion in the numerator to be met during a telehealth encounter.

Comment: Commenters suggested that further consideration was needed to determine the appropriate composition of the quality measure set by measure type (that is, proportion of clinical, patient experience, and administrative claims measures) and the appropriate balance between clinical outcome measures and preventive care measures. One commenter recommended that, to the extent possible, CMS make use of administrative claims data, including CPT Category II codes, to determine measure performance with an opportunity for ACOs to provide supplementary data to reduce healthcare provider burden. One commenter supported the inclusion of eCQMs because eCQMs tie the use of technology to the Quality performance category by encouraging the proper use of EHRs and increase the reliability of data based upon not having human manipulation or intervention, but did not support the inclusion of administrative claims measures, citing concerns with reliability of the data and the cost to large practices.

Response: In response to comments on the appropriate composition of the quality measure set by measure type (that is, proportion of clinical, patient experience, and administrative claims measures) and the appropriate balance between clinical outcome measures and preventive care measures, we note that the APP measure set is intended to assess a sample of the areas where ACOs should be focused on improving the quality of care; it is expected that ACOs should be working to improve quality in additional areas as well. We appreciate the commenters' concerns regarding the use of administrative claims measures. Administrative claims measures have historically been used successfully to measure ACO quality performance under the Shared Savings Program. CMS calculates the administrative claims measures for ACOs, which minimizes the burden associated with these measures.

Comment: Commenters stated they would like to see more publicly available comparative data on ACO performance on the core quality measures under the Shared Savings Program, such as ACO–14, Influenza Immunization; ACO–19, Colorectal Cancer Screening; ACO–20, Breast Cancer Screening; and the previously used Pneumonia Vaccination measure. The commenters asserted that ACOs cannot be fairly assessed if they are only measured on the proposed APP measures because the measures do not reflect the true purpose of ACOs and the work they do in quality improvement.

Response: Each year when CMS releases the Shared Savings Program Financial and Quality reconciliation results, Public Use files (PUFs) are posted that provide the public with comparative data on the quality results for a given performance year. We note that data on the measures referenced by the commenters are publicly available in these PUF files. We disagree with commenters that ACOs cannot be fairly assessed if they are only measured on the measures in the APP measure set. As discussed above, we believe that the measures in the APP measure set are broadly applicable for the primary care population and population health goals that are associated with the Shared Savings Program. These measures align with the Meaningful Measures framework while also being appropriate for assessing ACO quality performance as they focus on high prevalence, high cost, and high priority chronic health conditions.

Comment: Several commenters expressed concern that half of an ACO's quality score would depend on the CAHPS measure and two administrative claims measures. One commenter asserted that these measures have potential for unpredictability because minor differences in CAHPS scores can cause significant variation in ACOs' overall quality scores and there can be variance in scores on administrative claims measures related to risk adjustment changes. These commenters also expressed concern that CMS does not publish detailed measure specifications for the CAHPS or administrative claims measures. One commenter was concerned that the readmission measure would have a greater impact on the overall quality score under our proposed changes to the quality measure set because the commenter believes that the readmission measure is volatile.

Response: In regard to commenters' concern that the number of CAHPS measures is disproportionately high compared to clinical quality and outcomes measures, we note that under the new APP, the results of the CAHPS survey will account for a smaller proportion of ACOs' total quality score. Under the current scoring methodology, the CAHPS measures make up 1 domain or 25 percent of an ACO's quality score. Under the APP for Shared Savings Program ACOs that we are finalizing in this final rule, the results on the CAHPS measures will be combined to calculate a single composite score that will account for one sixth of the ACO's quality score or 16.7 percent or one tenth of the ACO's quality score or 10.0 percent, depending on which measure set the ACO reports on in 2021. Under both measure sets, patients' experience of care will meaningfully contribute to the overall quality score, while at the same time allowing other important measures of quality to also meaningfully contribute to the overall quality score.

Comment: Some commenters expressed concern that quality measures in the APP quality measure set have narrow performance ranges. One commenter suggested an alternative approach to calculating the benchmarks for quality measures that includes creating expanded percentiles due to concern that the current percentiles result in too narrow of a performance range where variation could be due to a small number of events or beneficiaries.

Response: We appreciate the commenter's recommendations regarding calculating benchmarks. We note that the seven CMS Web Interface measures with benchmarks for performance year 2020 are flat benchmarks that are used in accordance with § 425.502(b)(2)(ii) for measures that have clustered high performance rates. For the measures reported under the CMS Web Interface for performance year 2021, we will continue to use the Shared Savings Program benchmarks developed for the CMS Web Interface for performance year 2020.

We believe this practice addresses commenters' concerns about clustered performance having an adverse effect on ACOs' performance on the web interface measures. We refer readers to the MIPS benchmarking policy as defined at § 414.1380(b)(1)(ii), topped out measure scoring as defined at § 414.1380(b)(1)(iv), and flat percentage benchmark policy as defined at § 414.1380(b)(1)(ii)(C).

Comment: Several commenters suggested that CMS conduct further testing for risk adjustment of outcome measures, including social risk factors. These commenters requested CMS test the measures to ensure that minor changes to the risk adjustment methodology did not have significant impacts on the ACOs' quality scores. One commenter suggested that CMS enhance the risk adjustment of the outcome measures to address the high-risk patient populations of ACOs. Another commenter expressed concern that CMS should not include measures in the quality measure set used to assess ACO quality performance until they have been appropriately risk adjusted for sociodemographic factors, including socioeconomic status. The commenter explained that without appropriate risk adjustment for outcomes measures, such as the proposed readmission measure, the APP measure set could disproportionately impact the quality performance of ACOs that have an assigned beneficiary population served by ''essential hospitals''.

Response: Both of the proposed claims-based measures are risk-adjusted with beneficiary demographic characteristics and a wide range of clinical comorbidities to improve comparison of measure performance between organizations. These measures use a large number of Hierarchical Condition Category (HCC) comorbidity categories that account for many high-risk conditions among beneficiaries, which helps to adjust for differences in patient populations between ACOs. Risk adjusting in this manner is in accordance with best practices for risk adjustment to account for the higher level of risk for certain beneficiaries. We also note that the revised MCC measure has an additional risk adjustment not present in the original MCC measure that is in the current Shared Savings Program measure set. The revised measure adjusts for two area level social risk factors: (1) AHRQ socio-economic status (SES) index; and (2) specialist density. The original MCC measure does not contain any social risk factors in the risk adjustment.

We received several comments regarding the feasibility of using the alternative MIPS reporting options for purposes of quality reporting under the Shared Savings Program, which are summarized below.

Comment: Several commenters requested clarification of whether ACOs would report quality data for all patients regardless of attribution or payer status. Additionally, commenters explained that ACOs often operate using multiple EHR systems and requested clarification of whether ACOs would report separately for each EHR system. Several commenters expressed concern that using the alternative MIPS reporting options would result in ACOs being evaluated on the quality of the care furnished to all of the patients they serve. These commenters were concerned that this data would not be a true reflection of an ACO's quality improvement efforts and objected that it would not be fair to measure ACO quality based on non-attributed patients. Commenters also expressed concern that ACOs may not have the legal ability to access data for patients that are not attributed to the ACO, which may skew any assessment of quality. Additionally, one commenter noted that the differences between community health center populations and private practice populations would be magnified by the requirement to report on all patients served and that unlike the administrative claims measures that use HCC risk adjustment, the three clinical quality measures do not have similar adjustments. The commenter recommended that ''CMS use the same eligibility category definitions used in cost calculations for peer groups that can be assumed to carry forward to the entire patient population.'' The commenter also recommended that CMS further consider whether reporting for all patients will improve or worsen disparities and urged CMS to seek to incentivize improvement of disparities between patients served by community health centers and private practices through clinical quality and claims based measurement and benchmarking. Another commenter noted that current measure specifications would result in patients being eligible for measure denominators regardless of provider specialty designation and recommended that CMS incorporate logic into the measures to require a qualifying visit with a primary care provider. This commenter also recommended that CMS modify the reporting requirements for the eCQM/MIPS CQM measures to exclude patients who are not assigned to the ACO for purposes of reporting under the Medicare Shared Savings Program. The commenter explained that if reporting on the measures is not limited to the ACO's assigned beneficiary population, ACOs that include an Academic Medical Center (AMC) could be particularly negatively impacted because AMCs often care for patients who have primary care providers in other states and patients that are seen for short term destination services.

Some commenters expressed concern that vendors and developers would require additional lead time to update and test systems, configure tools and measurement algorithms to aggregate data at an ACO level, and handle the wave of new entities reporting using eCQMs/MIPS CQMs. Several commenters also noted that some ACOs would need to revise vendor participation agreements and contracts to allow them to access and report on data across all patients served by their ACO participants, which may cause further delays. Additionally, commenters also expressed concern that measure results may be unreliable due to vendors interpreting measure specifications differently.

Although some commenters acknowledged that ACOs would be reporting fewer quality metrics under the proposed APP, these commenters believe the proposal would increase reporting burden because ACOs would be required to report on a larger pool of patients and to become familiar with new data collection and reporting mechanisms. The commenters recommended that if we were to finalize the proposed eCQM/MIPS CQM measures, ACOs should be required to report on a sample population or a maximum of 50 percent of ACO beneficiaries. Alternatively, one commenter suggested that instead of ACOs being responsible for aggregating data for the eCQM/MIPS CQM measures included in the APP to create an ACO-wide score, CMS should be responsible for aggregating data on behalf of the ACO. The commenter stated that this process would reduce burden on the ACOs. Other commenters suggested that ACOs should only be required to report eCQMs for assigned beneficiaries while ACOs are transitioning away from the CMS Web Interface reporting mechanism and that CMS should work with industry leaders to create QRDA III aggregate TIN level reporting for assigned beneficiaries so that each ACO Participant TIN could submit the QRDA III file via the QPP website and CMS would calculate performance scores for the ACO. Additionally, commenters suggested that some ACOs may not have the time or financial capacity to explore other data collection and reporting mechanism workflows, especially due

to constraints caused by the PHE for COVID–19. For example, commenters explained that some ACOs would need to pay fees to modify EHRs, obtain new EHR interfaces and aggregation tools, update performance dashboards, and potentially work with a registry, and that these costs could pose a significant hardship for smaller ACOs.

Response: We acknowledge the concerns raised by the commenters about the change to reporting eCQMs/CQM MIPS measures, the need for time to transition to this new data collection format and collecting data on all-payer data and the time needed to set up new infrastructures for submitting this data to CMS. The CMS Quality Measurement Strategy is continuing to drive towards patient-centered, value-based care through the development, selection, and implementation of measurement that includes accelerating the move to digital measures, promoting the use of all payer data, increasing alignment of measures, and unleashing the voice of the patient through the use of patient reported outcomes. The APP measures include all-payer, patient-centric, and population-based outcome measures that are designed to promote the goals of the CMS Quality Measurement Strategy and align with the Meaningful Measures framework.

While the three eCQM/MIPS CQM measures are based on all payer data, we believe they are appropriate for assessing the quality of care furnished by the ACO as required by section 1899(b)(3) of the Act. These measures focus on the management of chronic health conditions that are a high priority and have high prevalence among Medicare beneficiaries. To the extent that these conditions are also prevalent among other populations of patients that receive services from the eligible clinicians participating in an ACO, we believe it is relevant to consider the quality of care that is furnished by ACO participants across all of their patients as part of assessing the overall quality of care furnished by the ACO. We also note that measuring care delivery to all patients is appropriate because improving care processes and practices is expected to improve care for all patients (for example, improvements to an electronic health record would be expected to improve care for all patients, not just Medicare patients). Additionally, CMS would not want ACOs participating in the Shared Savings Program to improve care for Medicare beneficiaries by reducing care quality for non-Medicare beneficiaries. Thus looking at the overall quality of care furnished to all patients is consistent with the goal of improving care furnished by ACOs by ensuring that care delivery is improving across all patients, rather than encouraging ACOs to focus disproportionately on improving measure performance for Medicare beneficiaries.

In addition, we believe the use of all-payer measures will provide an additional incentive for ACO participants to standardize care processes across all of their patient populations, which should improve the quality of care for all patients, including the ACO's assigned Medicare beneficiaries, while also making it easier to capture and report required data because ACOs would only need to capture and report one set of quality metrics to satisfy the reporting requirements under both MIPS and the Shared Savings Program.

With regard to concerns about reporting the three eCQM/CQM measures, ACOs will need to determine which collection type, either eCQM specifications captured via an EHR or MIPS CQM specifications intended to be used by groups or ACOs submitting measures via qualified registry, they will use to collect and report quality measure data. The ACO will report data in the aggregate on behalf of its ACO participants using the relevant measure specifications and could submit data via the following MIPS submission types using either direct login, such as application program interface or API, or sign in and upload. For example, the ACO could, on behalf of its ACO participants combine the results from all the ACO participant TIN QRDA 3 files, by adding numerators, denominators, etc. and create an aggregate QRDA3 file (or other compliant file format) and submit as an ACO to CMS. ACOs could also contract with a third party intermediary (such as a registry) to submit data on behalf of the ACO. We acknowledge commenters' concerns about the time needed to set up new infrastructures to report all-payer data; therefore, we are finalizing a phase-in approach to the quality reporting requirements under the Shared Savings Program. For performance year 2021, ACOs can opt to report 10 measures via the CMS Web Interface or the three eCQM/CQM measures as part of the APP. If an ACO opts to report via the CMS Web Interface, the requirements for which patients must be included for purposes of quality reporting would remain unchanged, ACOs would report on the provided beneficiary sample.

As discussed earlier in this section, in order to meet the quality reporting requirements under the Shared Savings Program and the MIPS, ACOs must meet the following requirements:

- For performance year 2021, ACOs will be required to report quality data via the APP, and an ACO can choose to actively report either the 10 measures under the CMS Web Interface or the 3 eCQM/MIPS CQM measures. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate 2 measures using administrative claims data.
- For performance year 2022 and subsequent performance years, ACOs will be required to actively report quality data on the 3 eCQM/MIPS CQM measures via the APP. In addition, ACOs will be required to field the CAHPS for MIPS survey, and CMS will calculate two measures using administrative claims data.

As discussed in section III.G.1.c. of this final rule, we are also finalizing policies to phase-in the increase in the quality performance standard over 3 years. We believe that the phase-in policies for applying the APP to Shared Savings Program ACOs and increasing the quality performance standard address the concerns raised by the commenters regarding the proposed timeline for implementing APP and the challenges of reporting on the measures in the APP measure set. The quality reporting requirements described above will provide ACOs with a one-year transition period during performance year 2021 in which they will have the option either to continue to report via the CMS Web Interface or to report on the 3 eCQM/CQM MIPS measures before being required to report on the 3 eCQM/MIPS CQM measures beginning in performance year 2022. This transition period, coupled with the phase-in of the new quality performance standard discussed earlier in this section, will provide ACOs with additional time to set up their systems and educate providers and office staff in order to be prepared report on the 3 eCQM/MIPS CQM measures beginning in performance year 2022 and will also allow ACOs to become familiar with the new quality reporting requirements under the APP and gain experience reporting on the new measures before they are assessed under the higher quality performance standard beginning in performance year 2023.

We received comments on the individual measures in the proposed measure set, which are summarized below.

Comment: We received several comments related to the proposal to include the CAHPS for MIPS measure in the APP for Shared Savings Program ACOs. One commenter noted support for the measures included in the CAHPS for MIPS. Several commenters

expressed concerns related to the CAHPS for MIPS measure. Specifically, the commenters noted that for this measure, small differences in quality can result in large quality score differences. The commenters stated that these differences are not meaningful and recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. Additionally, commenters were concerned that CMS has not detailed how the single composite CAHPS measure score will be calculated and were concerned with how the CAHPS measures are collected. Specifically, several commenters were concerned that the CAHPS measures use a small patient sample and rely on patients to recollect experiences that took place months before. One commenter had concerns about the small sample size for the CAHPS survey, citing previous experience with anomalies and unpredictable measure adjustments. Another commenter was concerned that the CAHPS sample size is the same for all ACOs regardless of ACO size; sampled patients do not represent the full population that ACOs serve; healthcare providers cannot provide supplemental information, such as more accurate contact information, in an effort to reach more patients; and surveys are only administered once annually with results received midway through the following performance year. Commenters recommended that CMS release additional information regarding how the CAHPS measure score will be calculated as soon as possible and recommended that CMS consider using a larger sample and modify the survey so that it is shorter and takes place closer in time to the care that beneficiaries are asked to assess.

Another commenter expressed concern that survey fatigue among patients was leading to declining survey response rates. The commenter recommended that CMS allow providers to use surveys already in place rather than requiring administration of an additional CAHPS for MIPS survey. Another commenter expressed concern over the subjective nature of the survey leading to significant variation in scores over time. Another commenter noted that the methodology of the CAHPS for MIPS and CAHPS for ACO surveys differ, with the CAHPS for MIPS survey having minimum survey size requirements as a function of the Taxpayer Identification Number (TIN) and the CAHPS for ACOs survey having minimum survey size requirements as a function of the ACO. The commenter requested that CMS be explicit if it intends to make any changes in the survey methodology with this proposal because shifting the survey size requirement to be based on TINs rather than the ACO as a whole will result in substantial financial burden to ACOs.

Response: We appreciate the commenters' concerns and recommendations regarding the CAHPS for MIPS measure. The CAHPS for MIPS survey uses the same survey instrument to assess the same patient experience domains as the CAHPS for ACO survey that is currently successfully used to measure ACO quality. The same shortened, streamlined version of the survey was implemented for both CAHPS for ACOs and CAHPS for MIPS in 2018, reflecting efforts by CMS to reduce the number of questions. We conducted analyses to assess the impact of aligning CAHPS scoring and benchmarking using 2019 CAHPS for ACOs and CAHPS for MIPS survey data. In 2019, the two programs used identical survey instruments. Analyses examined the impact of alignment on SSM scores, benchmarks, and quality points by comparing newly calculated SSM scores, benchmarks and quality points under the aligned approach to the official SSM scores, benchmarks, and quality points calculated under the original 2019 approach. The results of these analyses indicate that scoring ACOs using the MIPS methodology resulted in ACOs having a similar distribution of quality points as MIPS groups, which is wider than the distribution of quality points using the ACO scoring methodology. The wider score distribution is largely due to the differences across the two programs in the approach to benchmarking; CAHPS for ACOs uses flat percentage benchmarks for summary survey measures for which the 60th percentile of scores is greater than or equal to 80, or for which the 90th percentile of scores is greater than or equal to 95. CAHPS for MIPS does not use a flat percentage approach. While the shift away from flat percentage benchmarks may have the effect of creating larger differences in quality scores across Shared Savings Program ACOs, we believe that the scores will better reflect small differences in quality performance and will support the goal to improve the Shared Savings Program quality standard over time.

Beneficiaries assigned to an ACO or MIPS group, who are eligible for the CAHPS for MIPS or CAHPS for ACOs survey, are randomly selected for inclusion in the sample. Each ACO or MIPS group sample is therefore representative of the ACO or group population. Sample size requirements for both CAHPS for MIPS and CAHPS for ACOs were established using the results of analyses that sought to establish measures that allowed for meaningful comparisons to be made across ACOs and MIPS groups. Samples are drawn at the ACO level for CAHPS for ACOs, and at the MIPS group TIN level for groups. Target samples for all participating ACOs, groups, and virtual groups is 860; for ACOs, groups, and virtual groups with 860 or more survey-eligible patients, a random sample of 860 patients is drawn. In addition, groups and virtual groups with fewer than 860 survey-eligible patients are eligible to participate if they meet the following minimum sampling thresholds: Large groups or virtual groups with 100 or more eligible clinicians: 416 eligible patients; medium groups or virtual groups with 25–99 eligible clinicians: 255 eligible patients; and small groups or virtual groups with 2–24 eligible clinicians: 125 eligible patients. CMS will continue to draw the CAHPS survey samples for Shared Savings Program ACOs administering the CAHPS for MIPS survey at the Shared Savings Program ACO level, with a target sample size of 860 going forward.

Both surveys ask respondents to provide responses about their experiences of primary care during the previous 6 months. This look back period is used across many CAHPS survey efforts and enables a beneficiary to reflect on multiple care experiences with the focal provider named on the survey. While response rates have declined over time, the CAHPS for MIPS and CAHPS for ACOs surveys still reliably capture important information about the quality of care from patients' perspective, which are not captured via other data sources such as administrative claims data. We refer readers to section IV.A.3.b.3.a. of this final rule for additional details on the CAHPS for MIPS measure. With the alignment of CAHPS for ACOs with CAHPS for MIPS, the benchmarking and scoring methodology used for CAHPS for MIPS will be used. A single set of benchmarks will be calculated using data from all applicable CAHPS for MIPS reporters. The CAHPS for MIPS survey is scored as one quality measure, which is a different scoring approach from the current SSP quality scoring methodology that scores the ten CAHPS for ACOs summary survey measures in one patient/caregiver experience quality domain. As described in the CY 2017 Quality Payment Program final rule, each summary survey measure (SSM)

will have an individual benchmark and each SSM will be scored individually and compared against the benchmark to establish the number of points earned. The CAHPS score will be the average number of points across SSMs (81 FR 77284).

We received comments on the Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups measure, which are summarized below.

Comment: Several commenters expressed concerns related to the Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups measure. One commenter did not support this measure. Another commenter recommended that CMS consider NCQA's Plan All-Cause Readmission (PCR) measure instead because health plans use the PCR measure more widely as it is an NCQA accreditation requirement and the PCR measure is more robust and broader than the HWR measure because it includes patients 18 and older, while the HWR measure only includes patients 65 and older. Another commenter was concerned that the measure was sensitive to risk adjustment and has a narrow range, which negatively impacts ''community health center ACOs''. Another commenter noted that readmissions are low volume and can be influenced by factors outside the control of healthcare providers. Additionally, the commenter explained that an unintended consequence can occur when an ACO's base number of admissions is low compared to other ACOs with high numbers of admissions because it increases the sensitivity of this measure. This commenter suggested that CMS consider the Ambulatory Sensitive Condition Acute Composite measure instead. Other commenters noted that for this measure, small differences in performance can result in large quality score differences. The commenters stated that these differences in performance are not meaningful and recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. One commenter noted concerns about unintended consequences due to the measure not adequately considering the competing risk of mortality. This commenter suggested using an alternative measure, such as risk-adjusted home time.

Response: The proposed Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups measure is a re-specified version of NQF #1789 (Hospital-Wide All-Cause Unplanned Readmission Measure), and an adapted version of NQF #1789 that is currently being used successfully to assess ACO quality performance (ACO–8: Risk-standardized, All Condition Readmission (ACR)). We note that the MIPS HWR is clinically aligned to the ACO ACR measure, with the same cohort inclusion and exclusion criteria, outcome, measurement period, and risk adjustment variables, but the attribution and risk-standardized readmission rate calculation methodologies differ between the two measures. The ACO ACR measure attributes beneficiaries to ACOs prior to measurement, whereas the MIPS HWR measure is attributed to three clinician groups—primary inpatient provider, discharge clinician, and primary outpatient provider—based on measure specifications and care utilization data. In addition, the ACO ACR uses hierarchical logistic regression modeling to calculate risk adjustment while the MIPS HWR cannot use hierarchical logistic regression modeling because of attribution to multiple providers.

We believe that this re-specified version of NQF #1789 will provide a meaningful assessment of ACO quality performance. We will use the MIPS HWR three clinician group attribution method to attribute episodes at the ACO level. However, we will monitor and evaluate the ACOs' performance on the MIPS HWR measure to ensure compatibility including evaluating attribution at the ACO level, as well as refinements to risk adjustment and risk stratification and may revisit the decision to include this measure in the APP measure set for Shared Savings Program ACOs in future rulemaking. Both the MIPS HWR and ACO ACR measures will undergo the NQF endorsement/re-endorsement process during 2021, and we welcome stakeholder feedback on these measures.

We received comments on the three eCQM/CQM MIPS measures and the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs measure. These comments are summarized and responded to in section IV.A.3.B. of this final rule.

Table 40 lists the measures included in the final APP measure set.

TABLE 40: Measures included in the Final APM Performance Pathway Measure Set[1]

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

[1] We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) do not have benchmarks and are therefore not scored; they are, however, required to be reported in order to complete the Web Interface dataset.

* ACOs will have the option to report via Web Interface for the 2021 MIPS Performance year only.

In the CY 2021 PFS proposed rule (85 FR 50234), we noted that in addition to the measures included in the proposed APP measure set, based on recommendations from MedPAC in its 2015 Report to Congress: Medicare and the Health Care Delivery System,[56] we were considering adding a ''Days at Home'' measure that is currently under development, to the APP core measure set in future years, once it has been through the MAP pre-rulemaking process. We explained that any future additions to the measure set, including to add a ''Days at Home'' measure would be proposed and finalized through notice and comment rulemaking.

While CMS is not proposing to incorporate a ''Days at Home'' measure at this time, we received several public comments and recommendations about this measure. We greatly appreciate the commenters' views on a ''Days at Home'' measure, and we will take this feedback into consideration as this measure is developed and considered during future rulemaking cycles.

In addition, in the CY 2021 PFS proposed rule (85 FR 50234), we noted that we have received feedback from a few ACOs, including ACOs that have a significant number of beneficiaries in long-term care facilities or who are chronically ill or high-risk home bound

[56] *http://medpac.gov/docs/default-source/reports/june-2015-report-to-the-congress-medicare-and-the-health-care-delivery-system.pdf.*

patients, that the measures ACOs are required to report are not always applicable to their patient population. Although we proposed to require ACOs to report via the APP, we also sought comment on an alternative approach that could be used in the event the three measures ACOs are required to actively report on are not applicable to their beneficiary population and there are more appropriate measure available under MIPS. Under this alternate approach, ACOs could opt out of the APP and report to MIPS as an APM entity. If the ACO decides to report as an APM entity to MIPS outside of the APP, CAHPS for MIPS would become optional; however, the ACO would be required to report PI and IA and would also be subject to cost under MIPS. In the event an ACO decides to report as an APM entity to MIPS outside the APP, we would use the ACO's MIPS Quality performance category score to determine if the ACO met the Shared Savings Program quality performance standard.

We sought comment on this alternative reporting approach for ACOs in the event the three measures ACOs are required to actively report are not applicable to their beneficiary population.

The following is a summary of the comments we received on this alternative approach and our response.

Comment: One commenter supported this approach as it would allow more flexibility for clinicians to be recognized for the work they are doing inside and outside the context of an ACO. A few commenters stated that they believed all three eCQM/MIPS CQM measures were applicable to all ACOs and expressed concerns that allowing some ACOs to report under this alternative approach would make program evaluation challenging and would not allow for a fair assessment of quality across ACOs because certain organizations would have the opportunity to select measures for which they have the highest historical performance.

Response: We appreciate the commenter's feedback on the alternate approach and CMS will consider the commenters' feedback as part of the development of any future policies in connection with this alternative approach.

c. Shared Savings Program Quality Performance Standard

The quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions. We proposed to increase the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard. As discussed in the CY 2021 PFS proposed rule (85 FR 50234), we explained that we believed the proposed changes would simplify the Shared Savings Program quality performance standard and were also consistent with the statutory requirement that we seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures or both (section 1899(b)(3)(C) of the Act). We proposed to increase the quality performance standard for all ACOs to achievement of a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. We proposed to exclude entities/providers eligible for facility-based scoring from the overall MIPS quality score because facility-based scoring is determined using the Hospital Value Based Purchasing (HVBP) Total Performance Score (TPS), which includes quality and cost.

Given that the statute requires that we seek to increase the quality performance standard over time, we explained our belief that changing the quality performance standard from the 30th percentile on one measure in each domain to a requirement that ACOs achieve a quality performance score equivalent to the 40th percentile or above across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, would be the next incremental step in increasing the quality performance standard. In the CY 2021 PFS proposed rule, we summarized the quality performance results for ACOs participating in the program in performance year 2018. Since the proposed rule was issued, we now have updated 2019 results. Under the current Shared Savings Program quality measurement methodology, 98.71 percent or 534 ACOs participating in the program in 2019 met the quality performance standard of complete and accurate reporting for ACOs in the first year of their first agreement period or the 30th percentile on one measure in each domain, for ACOs in their second or subsequent years of participation in the program. Of these ACOs, 497 were ACOs in second or subsequent years of participation in the program for which most quality measures were scored as pay-for-performance (P4P).

As discussed in the CY 2021 PFS proposed rule (85 FR 50234), eligible clinicians participating in Shared Savings Program ACOs who obtain QP status would continue to be exempt from MIPS, and therefore, would not be subject to MIPS payment adjustments. ACOs participating in a track (or payment model within a track) that is an Advanced APM may elect to report on behalf of their eligible clinicians who do not meet the threshold to earn QP status but do meet the lower payment or patient count threshold to achieve Partial QP status, and these Partial QPs would be subject to a MIPS payment adjustment. Conversely, if an ACO does not elect to report for the Partial QPs, they would not receive a MIPS score or payment adjustment and would have no reporting responsibilities for MIPS. We also explained that utilizing the MIPS Quality performance category scoring methodology to assess the quality performance for purposes of the Shared Savings Program of ACOs participating in tracks (or payment models within a track) that qualify as an Advanced APM would not change whether the eligible clinicians participating in the ACO obtain QP status and are excluded from MIPS, nor would it change the eligible clinicians' eligibility to receive Advanced APM incentive payments.

We received public comments on the proposal to revise the Shared Savings Program quality performance standard. The following is a summary of the comments we received and our responses.

Comment: We received several comments in support of increasing the quality performance standard to the 40th percentile of MIPS Quality performance category scores, all noting that the proposal aligned with CMS' goal of improving quality and reducing cost. We also received many comments opposing the overall approach of changing the quality performance standard to the 40th percentile of all MIPS Quality Performance Category Scores. Several commenters noted the potential uncertainty that ACOs would experience because they would not have a clear indication ahead of the performance year of what standards need to be met to be eligible to receive shared savings. Commenters suggested that CMS set a threshold for the number of measures that must meet the 40th percentile benchmark of at least 50 percent of all measures. Other commenters suggested that the quality performance standard should remain at the current level to allow more time for ACOs to familiarize the new reporting requirements under the APP. One commenter suggested that the MIPS scoring methodology is flawed and introducing a change in the quality performance standard now would cause

instability in the Shared Savings Program. One commenter expressed concerns over ACOs' abilities to meet thresholds on certain measures. One commenter noted that moving the quality performance standard to the 40th percentile would pose difficulties for organizations struggling with the readmission and unplanned admission for multiple chronic condition metrics. One commenter noted that the threshold change is drastic and also noted that with CAHPS data supplied only at the ACO level, not at the individual TIN level, it is hard to provide feedback to each participant TIN, and with ACOs trying to handle the current pandemic, it is difficult to influence performance in this area. In addition, several commenters expressed concerns over the potential impact of the pandemic and other natural disasters on quality performance and the uncertainty ACOs could face and suggested the implementation of a new quality performance standard should be delayed. Commenters expressed concern over the limited time to gain familiarity with the new requirements and difficulty meeting this new quality performance standard for certain measures. Several commenters expressed concerns regarding the shift from a domain-based scoring approach to the proposed approach of requiring an ACO to achieve an overall quality score equivalent to the 40th percentile of all MIPS quality performance category scores. One commenter expressed concerns that such a scoring approach would have major financial implications for the sustainability of the Shared Savings Program as financial implications for ACOs are much higher than MIPS participants.

Response: We appreciate the commenters' feedback on our proposal to revise the Shared Savings Program quality performance standard. In light of the concerns raised by the commenters, we are finalizing a modified version of our original proposal to allow for a gradual phase-in of the increase in the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard. Specifically, we are finalizing that an ACO would meet the quality performance standard if:

- For performance years 2021 and 2022, the ACO achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores; and
- For performance year 2023 and subsequent performance years, the ACO achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores.

Achieving the applicable quality performance standard for a performance year will enable the ACO to share in the maximum amount of savings based on their Track, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions for that performance year.

These policies are summarized in Table 39 in this final rule. The impact on shared savings payments as a result of these final policies is described in section VIII.H.7.a. of this final rule. We are also finalizing our proposal to exclude entities/providers eligible for facility-based scoring from the determination of the overall MIPS Quality performance category score because facility-based scoring is determined using the Hospital Value Based Purchasing (HVBP) Total Performance Score (TPS), which includes quality and cost.

We believe that this phase-in of the quality performance standard, coupled with our decision to phase-in the reporting requirements under the APP for Shared Savings Program ACOs, as described in section III.G.1.b.(1). of this final rule, will alleviate many of the concerns raised by the commenters, especially those related to the PHE for COVID–19 and other natural disasters in 2020. We will monitor ACO performance under the new quality reporting requirements to determine the impact of this measured increase to the quality performance standard and may revisit this policy in future rulemaking if necessary to promote an attainable quality performance standard and degree of improvement. With respect to the concerns raised by commenters regarding the limited time to gain familiarity with the new requirements, the phase-in policies will give ACOs additional time to set up their systems to report all payer data on the three eCQM/MIPS CQM measures under the APP. The phase-in will also allow ACOs additional time to become familiar with the new quality reporting requirements and gain experience reporting on the new measures under the APP before they are assessed under the increased quality performance standard beginning in performance year 2023. We note that the quality performance standard that we are adopting for performance years 2021 and 2022 is analogous to the current quality performance standard, under which ACOs are required to achieve the 30th percentile on one measure in each domain. Therefore, we believe that this approach to phasing in the new, higher quality performance standard is consistent with the statutory requirement in section 1899(b)(3)(C) of the Act that we seek to increase the quality of care furnished by ACOs over time. We also note that ACOs will not be required to meet the 30th or 40th percentile (depending on the performance year) for all measures reported under the APP in order to meet the quality performance standard. If an ACO performs poorly on one measure under the APP, the ACO may still be able to meet the quality performance standard based on its performance across the remainder of the measures set. For commenters that expressed concern that ACOs would not have an indication prior to the start of the performance year of what standards would need to be met to be eligible to receive shared savings, we note that, as discussed in section IV.A.3.d.(1)b.ii. of this final rule, we are not finalizing the proposal to use performance period year benchmarks and instead will continue to use historical benchmarks for quality measures for the CY 2021 MIPS performance period.

Comment: We received several comments related to how the quality performance standard would be assessed and applied. One commenter expressed uncertainty about whether CMS would assess the quality performance standard based on the aggregate score on all quality measures or require a 40th percentile score on each individual measure. Other commenters noted that they were uncertain if the quality performance standard was meant to apply across all domains in the aggregate, or across each individual domain at the 40th percentile.

Response: Under the phase-in we are adopting in this final rule, an ACO's quality performance score must be equivalent to or higher than the 30th or 40th percentile (depending on the performance year) across all MIPS Quality performance category scores in order to meet the quality performance standard. ACOs will not be required to achieve a performance score that is equivalent to or higher than the 30th or the 40th percentile (depending on the performance year) on each individual measure in order to meet the quality performance standard. We are also clarifying that each ACO's quality performance score will be calculated using the ACO's performance on the measures reported under the APP, any applicable MIPS bonus points, and quality improvement points. Please refer to section IV.A.3.b. of this final rule for information on scoring under the APP. Unlike the scoring methodology currently used in the Shared Savings Program, there are no quality domains

under the APP; rather, each measure will be weighted equally.

In the CY 2021 PFS proposed rule (85 FR 50234 and 50235), we proposed to specify in a new section of the Shared Savings Program regulations at § 425.510, policies governing the application of the APP to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021. As proposed, this new section would include a general provision specifying that CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements, and meets all other applicable requirements, the ACO is eligible to receive shared savings. We proposed that this general provision would also indicate that CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. In the proposed new section, we also specified the requirement that ACOs must report quality data via the APP established under § 414.1367 according to the method of submission established by CMS, and that CMS retains the right to audit and validate quality data reported by an ACO according to § 414.1390.

We did not receive any public comments on the proposed regulation at § 425.510. We are finalizing § 425.510 as proposed.

We also proposed to specify in a new section of the Shared Savings Program regulations at § 425.512 provisions for determining the ACO quality performance standard for performance years beginning on or after January 1, 2021. We proposed to specify that the quality performance standard is the overall standard the ACO must meet in order to be eligible to receive shared savings for a performance year, and that an ACO will not qualify to share in savings in any year it fails to meet the quality performance standard. Further, we proposed to specify that for all ACOs, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. In addition, we proposed to specify that if an ACO does not report any of the three measures ACOs are actively required to report and does not field a CAHPS survey, the ACO would not meet the quality performance standard.

We did not receive any public comments on the proposed regulation at § 425.512. However, as a result of our decision to modify our original proposal to provide for a phase-in of the new quality reporting requirements under the APP for Shared Savings Program ACOs, as described in section III.G.1.b.1. of this final rule, and the increase in the quality performance standard, as described earlier in this section, we are finalizing the proposed regulations at § 425.512 with modifications, as described below.

Revising § 425.512(a)(3) to provide that:

- For performance years 2021 and 2022. CMS designates the quality performance standard for all ACOs, with the exception of ACOs in the first performance year of their first agreement period, as the ACO reporting quality data via the APP established under § 414.1367, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.
- For performance year 2021. If an ACO does not report any of the ten CMS Web Interface measures or any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO will not meet the quality performance standard.
- For performance year 2022. If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP the ACO will not meet the quality performance standard.

Adding a new provision at § 425.512(a)(4) to provide that for performance years 2023 and subsequent performances:

- CMS designates the quality performance standard for all ACOs, with the exception of ACOs in the first performance year of their first agreement period, as the ACO reporting quality data via the APP established under § 414.1367, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.
- If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP the ACO will not meet the quality performance standard.

We are also revising § 425.512 to add a new language at § 425.512(a)(2) to provide that for performance year 2022 and subsequent performance years, for the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO meets the data completeness requirement at § 414.1340 and case minimum requirement at § 414.1380 on the three measures it is actively required to report and fields a CAHPS for MIPS survey via the APP, the ACO will meet the quality performance standard. Finally, we are also revising the references to MIPS Quality performance category scores in § 425.512(a)(3) and (4) to make clear that entities/providers eligible for facility-based scoring are excluded.

In addition, we proposed to modify the existing Shared Savings Program regulation at § 425.508, on incorporating quality reporting requirements related to the Quality Payment Program. We proposed to add a provision applicable to 2021 and subsequent performance years, which would specify that ACOs must submit quality data via the APP established under § 414.1367 to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category. We also proposed related technical and conforming modifications to § 425.508.

We did not receive any public comments on the proposed modifications, and related technical and conforming modifications to § 425.508. We are finalizing all of the modifications to § 425.508 as proposed.

d. Use of ACO Quality Performance in Determining Shared Savings and Shared Losses

In section III.G.1.d of the CY 2021 PFS proposed rule (85 FR 50235 and 50236), we proposed modifications to the Shared Savings Program regulations on the use of the ACO quality performance in determining shared savings and shared losses. We explained that section 1899(d)(1)(A) of the Act specifies an ACO is eligible to receive a shared savings payment for a portion of the savings generated for Medicare, provided that the ACO meets both the quality performance standards established by the Secretary and achieves the required level of savings against its historical benchmark. Section 1899(d)(2) of the Act provides the authority for the actual payments for shared savings under the Shared Savings Program. Specifically, if an ACO meets the quality performance standards established by the Secretary (according to section 1899(b)(3) of the

Act), and meets the savings requirements, a percent (as determined appropriate by the Secretary) of the difference between the estimated average per capita Medicare expenditures in the year, adjusted for beneficiary characteristics, and the benchmark for the ACO, may be paid to the ACO as shared savings and the remainder of the difference shall be retained by the Medicare program. The Secretary is required to establish limits on the total amount of shared savings paid to an ACO. We have also incorporated performance-based risk in the form of shared losses into certain financial models using the authority under section 1899(i)(3) of the Act to use other payment models.

The Shared Savings Program's one-sided shared savings only models, and two-sided shared savings and shared losses models are specified in subpart G of the Shared Savings Program regulations. For agreement periods beginning on July 1, 2019, and in subsequent years, eligible ACOs may participate under either: (1) The BASIC track, which includes a glide path consisting of five levels (Levels A through E) that allows eligible ACOs to begin under a one-sided model (Level A or Level B) and incrementally phases-in higher levels of risk and potential reward (Levels C, D, or E) (§ 425.605); or (2) the ENHANCED track, a two-sided model with the highest level of risk and potential reward (§ 425.610). Further, according to the May 8th COVID–19 IFC (85 FR 27574 and 27575), ACOs that entered a first or second agreement period with a start date of January 1, 2018, whose participation agreements expire December 31, 2020, may elect to extend their agreement period for an optional fourth performance year, spanning January 1, 2021, to December 31, 2021. This includes ACOs that entered agreement periods under Track 1 (a one-sided model), Track 2 (a two-sided model), and Track 3 (subsequently renamed the ENHANCED track). Further, this option to elect a 12-month extension of the agreement period also applies to ACOs participating in the Track 1+ Model whose participation agreements expire December 31, 2020.

Under the Shared Savings Program regulations, for both one-sided models and two-sided models, CMS uses the ACO's quality performance to determine the ACO's eligibility to receive shared savings, and the rate at which ACOs share in these savings. We base the final shared savings rate on the ACO's quality performance. For ACOs meeting the quality performance standard, the final shared savings rate is equal to the product of the ACO's quality score and the maximum sharing rate. The maximum sharing rate is specific to the ACO's track/level of participation as follows: 50 percent for ACOs participating in Track 1;[57] 60 percent for ACOs participating in Track 2;[58] 40 percent for ACOs participating in Level A or Level B of the BASIC track;[59] 50 percent for ACOs participating in Levels C, D, or E of the BASIC track;[60] and 75 percent for ACOs participating in the ENHANCED track.[61] The upside of the Track 1+ Model is based on Shared Savings Program Track 1; therefore, a maximum sharing rate of 50 percent applies to Track 1+ Model ACOs.[62]

Depending on the track, the ACO's quality performance may also be used to determine the amount of the ACO's shared losses, for ACOs under two-sided models. ACOs participating in the Track 1+ Model, and Level C, D, or E of the BASIC track are subject to a fixed shared loss rate (also referred to as the loss sharing rate) of 30 percent regardless of quality performance.[63] Under Track 2 and the ENHANCED track, the shared loss rate is calculated as one minus the ACO's final shared savings rate based on quality performance, up to a maximum of 60 percent or 75 percent, respectively, and the shared loss rate may not be less than 40 percent for both tracks.[64] For ENHANCED track ACOs, this 40 percent minimum shared loss rate is expressly stated in the current regulations, whereas for Track 2 ACOs, it is the implicit minimum shared loss rate as calculated based on the inverse of the maximum final shared savings rate for the track. Track 2 and ENHANCED track ACOs that do not meet the quality performance standard for the performance year will be accountable for shared losses based on the highest shared loss rate for their track.

In light of the proposed changes to the Shared Savings Program's quality performance standard, in the CY 2021 PFS proposed rule, we also proposed modifications to the regulations that specify the circumstances under which an ACO will qualify for a shared savings payment based on its quality performance and the determination of the rate at which the ACO will share in savings based on its quality performance.

For all tracks, we proposed to specify, in revisions to the regulations, the requirements that must be met for an ACO to qualify for a shared savings payment for performance years beginning on or after January 1, 2021. We proposed that to qualify for shared savings, an ACO must meet the minimum savings rate requirements established for the track/level, meet the proposed quality performance standard described in section III.G.1.c. of the proposed rule, and otherwise maintain its eligibility to participate in the Shared Savings Program under part 425. We proposed to revise §§ 425.604(c) (Track 1), 425.605(c) (BASIC track), 425.606(c) (Track 2), and 425.610(c) (ENHANCED track) to reflect these requirements.

We also proposed revisions to the provisions establishing the final sharing rate for all tracks. We proposed that for performance years beginning on or after January 1, 2021, if an ACO that is otherwise eligible to share in savings meets the proposed quality performance standard as described in section III.G.1.c. of the proposed rule, the ACO will share in savings at the maximum sharing rate according to the applicable financial model, up to the performance payment limit. We proposed that if the ACO fails to meet the proposed quality performance standard, the ACO would be ineligible to share in savings. We proposed to specify these policies in revisions to the provisions governing Track 1 (§ 425.604(d)), the BASIC track (§ 425.605(d)(1)(i)(A) (Level A), (d)(1)(ii)(A) (Level B), (d)(1)(iii)(A) (Level C), (d)(1)(iv)(A) (Level D), (d)(1)(v)(A) (Level E)), Track 2 (§ 425.606(d)), and the ENHANCED track (§ 425.610(d)).

We also proposed modifications to the methodology for determining shared losses under Track 2 and the ENHANCED track, for performance years beginning on or after January 1, 2021, to account for the proposed revisions to the quality performance standard. If the ACO meets the quality performance standard, we proposed to determine the shared loss rate as follows:

- *Step 1:* Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.
- *Step 2:* Calculate the product of the quotient described in step 1 and the

[57] Refer to § 425.604(d).

[58] Refer to § 425.606(d).

[59] Refer to § 425.605(d)(1)(i)(A), (d)(1)(ii)(A).

[60] Refer to § 425.605(d)(1)(iii)(A), (d)(1)(iv)(A), (d)(1)(v)(A).

[61] Refer to § 425.610(d).

[62] Refer to the Track 1+ Model Participation Agreement, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

[63] Provisions specifying the shared loss rate for two-sided models of the BASIC track are specified in § 425.605(d)(1)(iii)(C), (d)(1)(iv)(C), (d)(1)(v)(C). The shared loss rate applicable to Track 1+ Model ACOs is specified in the Track 1+ Model Participation Agreement.

[64] Refer to §§ 425.606(f), 425.610(f).

sharing rate for the relevant track, either 60 percent for Track 2 or 75 percent for the ENHANCED track.

- *Step 3:* Calculate the shared loss rate as 1 minus the product determined in step 2. Consistent with the existing structure of the financial models: Under Track 2, the shared loss rate may not exceed 60 percent, and may not be less than 40 percent; under the ENHANCED track, the shared loss rate may not exceed 75 percent, and may not be less than 40 percent.

Under the proposed approach, for an ACO that meets the quality performance standard we would take into consideration the ACO's quality score when determining the ACO's share of losses. An ACO with a higher quality score would owe a lower amount of losses compared to an ACO with an equivalent amount of losses but a lower quality score, so long as the ACO's quality score results in a shared loss rate within the range between the minimum shared loss rate (40 percent) and the maximum shared loss rate (60 percent under Track 2, or 75 percent under the ENHANCED track). To the extent the ACO's quality score results in a shared loss rate outside these limits, the shared loss rate is set to the minimum or maximum rate (as applicable). We also proposed to revise the regulation at § 425.606(f) to expressly state both the minimum and maximum shared loss rates for Track 2.

In addition, we also proposed that if the ACO fails to meet the quality performance standard, the shared loss rate would be 60 percent under Track 2 or 75 percent under the ENHANCED track. We explained that we believed this approach would maintain symmetry with the proposed approach to determining shared savings under Track 2 and the ENHANCED track based on quality performance. Thus, an ACO that fails to meet the quality performance standard would be ineligible to share in savings and would owe the maximum amount of shared losses.

We proposed to specify these provisions for determining the shared loss rate under Track 2 and the ENHANCED track, for performance years beginning on or after January 1, 2021, through modifications to the regulations at §§ 425.606(f) and 425.610(f). We also proposed technical and conforming changes to these provisions for clarity, and to specify that the current policy would continue to apply for purposes of determining the shared loss rate for Track 2 ACOs and ENHANCED track ACOs for performance years (or a performance period) beginning on or before January 1, 2020.

We received public comments on the proposed use of ACO quality performance in determining shared savings and shared losses. The following is a summary of the comments we received and our responses.

Comment: Some commenters expressed support for the proposed approach to determining the rate at which ACOs will share in savings based on quality performance, for performance years beginning on or after January 1, 2021. A few commenters expressed support for eliminating the sliding scale for determining shared savings based on quality performance, and allowing ACOs to earn savings at the maximum sharing rate according to the applicable financial model if the quality performance standard is met. One commenter expressed support for making an ACO ineligible to share in savings if it fails to meet the quality performance standard.

Several commenters explained that they supported the proposed approach because it provides a larger reward to ACOs for meeting CMS' increased quality performance standard. One commenter explained the proposed approach would simplify financial calculations.

Some commenters opposed the proposed approach to determining whether an ACO shares in savings at the maximum rate, or not at all, based on whether or not the ACO meets the proposed revised quality performance standard. Commenters suggested instead that CMS use a scoring approach that is more similar to the current domain-based scoring approach rather than an all-or-nothing approach as proposed. In particular, some commenters preferred an approach that differentiates higher quality performers and rewards quality improvement over time with a higher savings percentage.

Some commenters urged CMS to better reward high quality performers, as is done in the Medicare Advantage program by providing bonuses or higher shared savings rates to high quality performers or those that notably improve quality scores over time.

Some commenters suggested that the proposed approach would make it more challenging for ACOs to share in savings, and that may discourage program participation by ACOs. One commenter explained that the change from a quality multiplier on payment, to all-or-nothing savings, adds another significant dimension of risk to the program for ACOs that depend on shared savings to operate. A few commenters expressed concern that the proposed approach may limit participation by ACOs that depend on shared savings to support their participation in the Shared Savings Program, such as to cover ongoing operational costs and infrastructure costs. One commenter suggested that this dynamic could ultimately discourage participation by physician-led ACOs or lead to consolidation of physician-led ACOs with larger entities to manage the ACO, ultimately stifling innovation.

Several commenters expressed concern about an approach that makes the ACO's ability to share in savings an all-or-nothing proposition, particularly as CMS also proposed to increase the quality performance standard for ACOs. One commenter expressed concerns about the proposed approach, suggesting it places the entirety of an ACO's shared savings payment at risk if one measure is missed. This commenter explained that an all-or-nothing approach to determining an ACO's eligibility to share in savings, in combination with higher standards and volatile measures, would negatively impact their decision about continuing their participation in the Shared Savings Program, including whether to enter into a new participation agreement under the Shared Savings Program or take on increased downside risk, and their overall investment in the program.

One commenter supported raising the quality performance standard and allowing ACOs that meet that standard to receive full shared savings, provided that this change accompanies a smaller program measure set and the standard is assessed as an average of the measures. The commenter noted that it would not support a 40th percentile standard applied to each measure given its concerns about several of the measures.

Response: We agree with the comments suggesting that the proposed approach will simplify program calculations going forward. Under the proposed approach, an ACO is eligible to share in the maximum amount of savings if it meets the quality performance standard, and is ineligible to share in savings if it fails to meet the quality performance standard, thereby removing the variation in sharing rates based on the ACO's quality performance score.

We believe a number of factors mitigate commenters' concerns about the determination of shared savings based on the revised quality performance standard for the Shared Savings Program. As discussed elsewhere in section III.G.1 of this final rule, in response to commenters' concerns about the transition to the APP

for Shared Savings Program ACOs, we are finalizing our proposal with certain modifications, including to allow for continued use of the Web Interface as a reporting mechanism for PY 2021, and to allow for a more gradual phase-in of the quality performance standard. We believe this phase-in will give ACOs additional time to prepare to transition to the APP, and thereby to prepare to meet the new quality reporting requirements and quality performance standard, and in turn to meet the requirements for sharing in savings. Further, under the APP (as described in section III.G.1.c of this final rule), we will determine whether the ACO has met the quality performance standard based on the ACO's quality performance score as compared to the relevant percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, that comprises the quality performance standard for the applicable performance year. Therefore, an ACO that performs poorly on one or several measures under the APP may still have the opportunity to share in savings at the maximum sharing rate, if it meets the quality performance standard based on its performance across the remainder of the measure set.

Additionally, we note that while our final policy will require ACOs to meet a higher quality performance standard starting in PY 2023, ACOs that achieve the quality performance standard maximize their upside potential. In contrast, under the existing approach, which is designed to differentiate between higher and lower quality performers, it is rare for ACOs to achieve the maximum sharing rate based on quality performance under the program's pay for performance standards that phase-in after the ACO's first performance year in the Shared Savings Program. Under the existing approach, in an ACO's first performance year in the program, the ACO will receive a quality score of 100 percent, and therefore the maximum sharing rate based on quality performance, if it completely and accurately reports all quality measures. For subsequent performance years, under a pay for performance standard, we multiply an ACO's quality score (as a percentage) by the maximum sharing rate for the track in which the ACO participates to determine the ACO's final sharing rate based on quality performance. Thus, ACOs are effectively limited from maximizing their upside potential since their quality scores are typically below 100 percent. We believe that allowing ACOs to maximize their upside potential year after year, as provided under the policies we are finalizing in this rule, could further facilitate ACOs' participation in the Shared Savings Program and their investments in accountable care activities to meet the program's goals.

We appreciate commenters' concerns that this revised methodology for measuring quality performance and rewarding ACOs with savings based on their quality performance could have the effect of limiting participation by certain types of ACOs. However, we believe commenters' concerns are mitigated by the aforementioned factors, including the gradual phase-in of the quality performance standard and the potential for ACOs to more consistently share savings at the highest sharing rates under the revised approach. We anticipate monitoring to determine if the revised quality performance standard and the approach of determining an ACO's eligibility to share in savings at the maximum sharing rate based on their ability to meet the quality performance standard, disproportionately disadvantage certain ACOs based on composition and experience in the Shared Savings Program, among other factors, and will consider whether any adjustments may be warranted. Any changes to the policies we are adopting in this final rule would be made through notice and comment rulemaking.

In response to commenters' preference that CMS retain an approach that continues to reward quality improvement over time, we note that under the APP, the MIPS quality improvement scoring methodology, as specified under § 414.1370(g)(1)(iv), will be used in determining an ACO's quality performance score. Under this approach, we will consider the improvement in an ACO's quality performance category achievement percent score from the previous performance period in the determination of whether the ACO has met the quality performance standard, and therefore whether the ACO is eligible for sharing savings at the maximum sharing rate. In comparison, the Shared Savings Program's current quality improvement reward as specified in § 425.502(e)(4) rewards ACOs that demonstrate quality improvement with a higher quality score, and therefore a potentially greater share of savings, but the amount of shared savings still would not exceed the maximum sharing rate. Accordingly, given that quality improvement will be factored into determining an ACO's quality performance score under the APP and ACOs that meet the quality performance standard will be eligible to share in savings at the maximum sharing rate for their track, we do not believe it is necessary to provide any additional adjustment to shared savings for ACOs that demonstrate improved quality performance over time.

Further, at this time, we decline commenters' suggestions that we adopt an approach for rewarding higher quality performance, and quality improvement, similar to the approach specified under Medicare Advantage. We note that the focus of the proposed changes was on aligning the Shared Savings Program's quality performance standard with the APP under the Quality Payment Program (as previously described elsewhere in section III.G.1 of this final rule). Further, we believe the approach we are finalizing will be effective in rewarding ACOs that perform well on quality measures and improve quality performance over time. As we have previously described, ACOs that meet the revised quality performance standard, which phases-in a higher performance standard over time, are eligible to share in savings at the maximum sharing rate, and we will factor quality improvement into determining an ACO's quality performance score under the APP.

After considering the comments and the modifications that we are making to phase-in the new quality reporting requirements and quality performance standard under the APP, we are finalizing as proposed our approach to determining an ACO's eligibility for shared savings based on quality performance, for performance years beginning on or after January 1, 2021.

Comment: The few commenters that discussed the proposed approach to determining shared losses based on quality performance were generally supportive of the proposed approach. In particular, commenters expressed support for the proposed approach under which an ACO's shared losses are based on its quality performance such that an ACO with a higher quality score would owe lower shared losses. One commenter supported the proposed modifications to the shared loss calculations for Track 2 and the ENHANCED track, which would still allow an ACO's quality score to be taken into consideration as long as the loss rate stays within the minimum and maximum range, because they would simplify financial calculations.

Response: We are finalizing as proposed the modifications to the methodology for determining shared losses under Track 2 and the ENHANCED track for performance years beginning on or after January 1, 2021, to

account for the revisions to the quality performance standard discussed elsewhere in this section III.G.1 of this final rule.

We did not receive comments on the revisions we proposed to make to the regulations to specify the requirements that must be met for an ACO to qualify for a shared savings payment for performance years beginning on or after January 1, 2021. We are finalizing as proposed the revisions to §§ 425.604(c) (Track 1), 425.605(c) (BASIC track), 425.606(c) (Track 2), and 425.610(c) (ENHANCED track) to reflect these requirements. Specifically, to qualify for shared savings, an ACO must meet the minimum savings rate requirements established for the track/level, meet the quality performance standard established under the new provision at § 425.512 as described in section III.G.1.c. of this final rule, and otherwise maintain its eligibility to participate in the Shared Savings Program under part 425.

After considering the public comments we received, we are finalizing as proposed revisions to the provisions establishing the final sharing rate for all tracks. For performance years beginning on or after January 1, 2021, if an ACO that is otherwise eligible to share in savings meets the quality performance standard established under § 425.512, the ACO will share in savings at the maximum sharing rate according to the applicable financial model, up to the performance payment limit. If the ACO fails to meet the quality performance standard, the ACO will be ineligible to share in savings. These final policies are specified in revisions to the provisions governing Track 1 (§ 425.604(d)), the BASIC track (§ 425.605(d)(1)(i)(A) (Level A), (d)(1)(ii)(A) (Level B), (d)(1)(iii)(A) (Level C), (d)(1)(iv)(A) (Level D), (d)(1)(v)(A) (Level E)), Track 2 (§ 425.606(d)), and the ENHANCED track (§ 425.610(d)).

After considering the public comments we received, we are also finalizing our proposals for determining the shared loss rate under Track 2 and the ENHANCED track, for performance years beginning on or after January 1, 2021, through modifications to the regulations at §§ 425.606(f) and 425.610(f). Specifically, we will determine the shared loss rate as follows:

- *Step 1:* Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.
- *Step 2:* Calculate the product of the quotient described in step 1 and the sharing rate for the relevant track, either 60 percent for Track 2 or 75 percent for the ENHANCED track.
- *Step 3:* Calculate the shared loss rate as 1 minus the product determined in step 2. Consistent with the existing structure of the financial models: Under Track 2, the shared loss rate may not exceed 60 percent, and may not be less than 40 percent; under the ENHANCED track, the shared loss rate may not exceed 75 percent, and may not be less than 40 percent. If the ACO fails to meet the quality performance standard, the shared loss rate will be 60 percent under Track 2 or 75 percent under the ENHANCED track.

We received no comments on our proposed technical and conforming changes to §§ 425.606(f) and 425.610(f), for clarity. We are finalizing these changes as proposed in order to specify the policy that would apply for purposes of determining the shared loss rate for Track 2 ACOs and ENHANCED track ACOs for performance years (or a performance period) beginning on or before January 1, 2020. We are also finalizing our proposed revision to § 425.606(f) to expressly state both the minimum and maximum shared loss rates for Track 2.

e. Compliance With the Quality Performance Standard

(1) Background

As discussed in more detail in section III.G.1.c. of the CY 2021 PFS proposed rule (85 FR 50234), the quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum shared losses under certain payment tracks, and avoid quality-related compliance actions. Section 1899(d)(4) of the Act authorizes the Secretary to terminate an agreement with an ACO that does not meet the established quality performance standards. Through earlier rulemaking we established an approach to enforce ACO compliance with the quality performance standards, as specified in the Shared Savings Program regulations at § 425.316 (see 76 FR 67951, 80 FR 32818 and 32819, 81 FR 80492 through 80494).

To identify ACOs that do not meet the established quality performance standards, we review the ACO's quality data submission. Under our current policies, as specified in § 425.316(c), if an ACO does not meet quality performance standards or fails to report on one or more quality measures, in addition to actions set forth at §§ 425.216 and 425.218, we will take the following actions:

- The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a corrective action plan (CAP). CMS may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.
- The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet the quality performance standards in the following year, the agreement will be terminated.
- An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

Further, according to § 425.224(b), in evaluating the eligibility of a renewing ACO or re-entering ACO to enter a new participation agreement with CMS for participation in the Shared Savings Program, we consider the ACO's history of noncompliance with the program's quality performance standard. For evaluating ACOs that entered into a participation agreement for a 3-year period, we consider whether the ACO failed to meet the quality performance standard during 1 of the first 2 performance years of the previous agreement period. For evaluating ACOs that entered into a participation agreement for a period longer than 3 years, we consider whether the ACO failed to meet the quality performance standard for 2 consecutive performance years and was terminated as specified in § 425.316(c)(2), or whether the ACO failed to meet the quality performance standard for 2 or more performance years of the previous agreement period, regardless of whether the years were consecutive.

The terms ''renewing ACO'' and ''re-entering ACO'' are defined in the regulations at § 425.20. We define renewing ACO to mean an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is either: (1) An ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program; or (2) an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program. We define

re-entering ACO to mean an ACO that does not meet the definition of a renewing ACO and meets either of the following conditions: (1) Is the same legal entity as an ACO that previously participated in the program and is applying to participate in the program after a break in participation, because the ACO's participation agreement expired without having been renewed, or the ACO's participation agreement was terminated under § 425.218 or § 425.220; or (2) is a new legal entity that has never participated in the Shared Savings Program and is applying to participate in the program and more than 50 percent of its ACO participants were included on the ACO participant list under § 425.118, of the same ACO in any of the 5 most recent performance years prior to the agreement start date.

(2) Revisions

In the CY 2021 PFS proposed rule (85 FR 50237), we explained that we had revisited the provisions of § 425.316(c) on monitoring compliance with quality reporting and performance requirements in light of our proposed modifications to the quality performance standard. We proposed to modify the introductory text at § 425.316(c) to state that we will review an ACO's submission of quality measurement data to identify ACOs that are not meeting the applicable quality performance standard under § 425.500 or § 425.512. As proposed, we would retain the discretion to request additional documentation from an ACO, ACO participants, or ACO providers/suppliers. Further, we noted our belief that in conjunction with the proposed changes to the quality performance standard, it would be appropriate to strengthen our policies for compliance with the quality performance standard by broadening the conditions under which CMS may terminate an ACO's participation agreement when the ACO demonstrates a pattern of failure to meet the quality performance standard.

As currently structured, the regulation at § 425.316 does not specify what actions CMS will take when an ACO fails to meet the quality performance standard for multiple, nonconsecutive performance years, or 2 consecutive performance years that span 2 agreement periods (that is, the last performance year of an agreement period and the first performance year of the subsequent agreement period). Accordingly, we proposed a new approach that CMS would follow to monitor for and address an ACO's continued noncompliance with the applicable quality performance standard for performance years beginning on or after January 1, 2021. Noncompliance with the quality performance standard during earlier performance years would continue to be subject to the rules set forth at § 425.316(c)(1) through (3), which we proposed would be consolidated at § 425.316(c)(1). For performance years beginning on or after January 1, 2021, we proposed that when CMS determines an ACO fails to meet the quality performance standard (as described in section III.G.1.c. of the proposed rule), CMS may take the actions prior to termination set forth at § 425.216, and may terminate the ACO's participation agreement according to § 425.218. In addition to the actions set forth at §§ 425.216 and 425.218, we proposed to adopt a specific approach that CMS would follow to monitor for and address an ACO's continued noncompliance with the quality performance standard.

We proposed that ACOs exhibiting a pattern of failure to meet the quality performance standard would be terminated from the program. Specifically, we proposed to terminate an ACO's participation agreement when the ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period or fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order. We also proposed that we would terminate the participation agreement of a renewing ACO or a re-entering ACO if the ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period. In addition, we proposed that we would terminate the participation agreement of a renewing ACO or a re-entering ACO if the ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period. We proposed to amend § 425.316(c)(2) to reflect this new approach.

We explained that the proposal to terminate an ACO if it fails to meet the quality performance standard for 2 consecutive performance years within an agreement period would be consistent with the current approach. However, we also proposed to terminate an ACO's participation agreement if the ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether these years are in consecutive order. In the December 2018 final rule (83 FR 67831), we extended participation agreements from 3-years to 5-years. ACOs participating under a 5-year agreement period may show a pattern of failure to meet the quality performance standard in performance years that are not consecutive. Therefore, we noted that we believe it is important to continue to monitor ACOs throughout their 5-year agreement period and if an ACO fails to meet the quality performance standard for 3 nonconsecutive performance years we proposed to terminate their participation agreement.

Additionally, we noted that we were concerned that a renewing ACO's quality performance results for the last performance year of the current agreement period would not be available for us to consider in reviewing the ACO's application to renew its agreement, as currently provided in § 425.224(b)(1)(ii)(A). We noted that we had a similar concern with respect to some re-entering ACOs (particularly, an ACO that notifies CMS of its decision to terminate its participation agreement and subsequently submits an application to re-enter the program for the next start date following the effective date of its termination). To prevent these ACOs from remaining in the program, despite a pattern of noncompliance with the quality performance standard, we proposed that if we determine that the last performance year of the ACO's previous agreement period was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the prior agreement period, CMS would terminate the ACO's new participation agreement. For example, if an ACO failed to meet the quality performance standard in the first, third and fifth performance years of a 5-year agreement period, or failed to meet the quality performance standard in the fourth and fifth performance years of a 5-year agreement period, results for the fifth performance year would not be available until after the ACO has renewed and entered a new agreement period. We explained that, in both examples, we would anticipate determining during the first performance year of the ACO's new agreement period that the ACO had failed to meet the quality performance standard for the last performance year of

its previous agreement period. Therefore, under the proposal, CMS would terminate the ACO's new participation agreement during the first performance year of that agreement period.

Furthermore, we expressed concern that an ACO could have a pattern of failing to meet the quality performance standard for consecutive years spanning 2 agreement periods. Therefore, if a renewing or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods (the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period), we proposed to terminate the ACO's participation agreement. We noted that we anticipated that quality performance results for the ACO's first performance year of its new agreement period would be available during the second performance year of the ACO's new agreement period. Therefore, CMS would terminate the ACO's new participation agreement during the second performance year of the new agreement period.

We recognized there would be additional complexity in the application of these policies to a new ACO that is identified as a re-entering ACO because of its ACO participants' prior participation in another Shared Savings Program ACO. Under the proposed approach, we would apply to the re-entering ACO the other ACO's quality performance for previous years (prior to the start of the re-entering ACO's agreement period) and would terminate the re-entering ACO if the other ACO is determined to have failed to meet the quality performance standard in 2 consecutive performance years within an agreement period, or if the other ACO is determined to have failed to meet the quality performance standard for 3 performance years (in nonconsecutive order) within an agreement period. We acknowledged that under the proposed approach, this could occur in circumstances when the other ACO's most recent performance year of failed quality performance is determined after the start of the new, re-entering ACO's agreement period. Further, under the proposed approach, we would also consider whether the other ACO failed to meet the quality performance standard in the most recent performance year prior to the start of the new, re-entering ACO's agreement period, and whether the new, re-entering ACO also fails to meet the quality performance standard for its first performance year. Under our proposal, because these 2 performance years of failed quality performance would be consecutive, we would terminate the participation of the new, re-entering ACO.

We noted that because a significant percentage of the ACO participants in the new, re-entering ACO were previously participating in this other ACO, we believed it would be appropriate to hold the new, re-entering ACO accountable for the quality performance of the other ACO. According to the definition of re-entering ACO, more than 50 percent of the entity's ACO participants must have participated together in the same ACO within a 5-performance year lookback period. As a result, over half of the new, re-entering ACO's ACO participants can be considered to have contributed to the failed quality performance of this other ACO. We explained that if we were to disregard the recent failed quality performance of this other ACO, these ACO participants would be allowed to continue participation in the Shared Savings Program as part of the new, re-entering ACO, and potentially take advantage of program flexibilities, despite a pattern of noncompliance with the quality performance standard.

We proposed to implement these policies starting with performance year 2021 and subsequent years. We acknowledged that an ACO currently participating under a performance agreement spanning 5-years could fail the quality performance standard for a performance year starting in 2019 under § 425.502. The same ACO could then again fail the quality performance standard under the proposed new provision at § 425.512 in performance years 2021 and 2023. In this scenario, the ACO would have failed the quality performance standards for 3 nonconsecutive years under the same agreement period, but the ACO would not be terminated in this scenario because the proposed policies would apply starting with performance year 2021. However, we noted that if the ACO decides to apply as a renewing or re-entering ACO, we would review its history of noncompliance with the requirements of the Shared Savings Program as provided under § 425.224(b)(1) when determining whether to approve its application.

We also explained that under the current regulation at § 425.316(c)(3), an ACO will not qualify to share in savings in any year in which it fails to report accurately, completely, and timely on the quality performance measures. Consistent with the proposed revisions to the quality performance standard under the Shared Savings Program discussed in section III.G.1.c. of the proposed rule, we proposed to specify in the proposed new provision at § 425.512 that, for performance years beginning on or after January 1, 2021, an ACO will not qualify to share in savings in any year it fails to meet the quality performance standard.

We noted that the termination of an ACO's participation agreement for failure to meet the quality performance standard under the proposed approach described in the proposed rule, would also make the ACO subject to the payment consequences of early termination as specified in § 425.221(b). Under § 425.221(b)(1)(ii), if the participation agreement is terminated at any time by CMS under § 425.218, the ACO is not eligible to receive shared savings for the performance year during which the termination becomes effective. Under § 425.221(b)(2)(ii)(B), an ACO participating under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. These policies would apply whenever an ACO is terminated for non-compliance with the quality performance standard in accordance with § 425.316(c).

We proposed to revise § 425.316(c) to incorporate the proposed approach for monitoring ACO compliance with the quality performance standard for performance years beginning on or after January 1, 2021. We also proposed to make other technical and conforming changes to the regulations at § 425.316(c). In particular, we proposed to amend the existing provisions for monitoring ACO compliance with the quality performance standards to specify that those provisions are applicable to performance years (or a performance period) beginning on or before January 1, 2020.

We noted that we also continue to believe in the importance of considering an ACO's history of noncompliance with the quality performance standard in evaluating the eligibility of a renewing ACO or a re-entering ACO to enter a new agreement period under the Shared Savings Program. In light of our proposed changes to § 425.316(c), we proposed to make conforming changes to § 425.224(b)(1)(ii)(A), which authorizes CMS to approve or deny a renewing ACO's or re-entering ACO's application to participate in the Shared Savings Program based on an evaluation of the ACO's history of non-compliance with the quality performance standard. Specifically, we proposed to revise § 425.224(b)(1)(ii)(A) to state that as part

of its evaluation of a renewing or re-entering ACO's history of noncompliance with the requirements of the Shared Savings Program, we will evaluate whether the ACO demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under § 425.316(c)(1)(ii) or (c)(2)(ii).

We received public comments on the proposals concerning monitoring compliance with the quality performance standard. The following is a summary of the comments we received and our responses.

Comment: We received a few comments supporting our proposals to modify our policies for monitoring ACOs for compliance with the quality performance standard. Two commenters suggested we modify the proposed approach to provide that an ACO's participation agreement will be terminated after 3 consecutive years of failing to meet the quality performance standard. One commenter noted this approach would align with policies used in Medicare Advantage where plans' contracts may be terminated after three consecutive years of failing to achieve an overall quality rating of at least 3 stars. One of the commenters further suggested we terminate an ACO's participation agreement for failure to meet the quality performance standard after 4 non-consecutive years of failing to meet the quality performance standard.

Response: We appreciate the additional suggestions for modifying our approach for monitoring and enforcing compliance with the quality performance standard. Since the beginning of the Shared Savings Program, we have terminated 3 ACOs for failure to report quality for two consecutive years. We decline to modify the proposed changes to our policies for monitoring compliance with the quality performance standard to provide for termination only after 3 consecutive years or 4 non-consecutive years of noncompliance. We believe the policies as proposed, under which an ACO will be terminated following 2 consecutive years or 3 non-consecutive years of non-compliance, provide ACOs enough time to implement processes and procedures that will allow them to meet the quality performance standard. If an ACO repeatedly fails to meet the quality performance standard the ACO should not continue participating in the Shared Savings Program. The Shared Savings Program seeks to both improve quality performance and reward high quality, while reducing the growth in Medicare spending. We believe these requirements for enforcing compliance with the quality performance standard help to hold ACOs accountable for the quality of the care they furnish to their beneficiaries and further encourage ACOs to demonstrate consistently that they are providing high quality of care to their beneficiary populations year over year.

Comment: We received a few comments opposing our proposed policies for terminating an ACO's participation agreement for a pattern of failure to meet the quality performance standard. One commenter suggested we develop a compliance standard that includes educating ACOs and issuing corrective action plans. The commenter suggested that we should terminate an ACO's participation agreement only if the ACO's failure to meet the quality performance standard was due to ''gross negligence.''

Response: We appreciate the commenter's suggestions; however, we note that we already incorporate education and outreach activities and compliance activities into our management and operations of the Shared Savings Program. We encourage and support ACOs in sharing their best practices and lessons learned from their experiences participating in the Shared Savings Program. We have hosted in-person learning collaboratives where ACOs can meet one another and listen to case study presentations about their experiences. We have also hosted webinars where ACOs present case studies on providing value-based care, including sharing lessons learned and best practices in quality reporting. Recordings of these webinars and supporting materials remain available for ACOs participating in the Shared Savings Program to access. Additionally, as proposed, if the ACO fails to meet the quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216, which may include requesting a corrective action plan from the ACO. Lastly, we disagree with the commenter's suggestion that CMS should not terminate an ACO's participation agreement unless the ACO's failure to meet the quality performance standard was due to ''gross negligence.'' Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both. The gross negligence standard advocated by the commenter would set far too high a bar for enforcement of the quality performance requirements and thereby do little to encourage improvement in quality of care over time. We believe it is important for ACOs to meet the quality performance standard and that ACOs that repeatedly fail to meet the quality performance standard should not be able to continue their participation in the program.

We did not receive comments concerning our proposal to make conforming changes to § 425.224(b)(1)(ii)(A). After considering the comments received, we are finalizing our proposed policies without modifications. We are revising § 425.316(c) to modify our approach for monitoring ACO compliance with the quality performance standard for performance years beginning on or after January 1, 2021. We are also making technical and conforming changes to amend the existing provisions on monitoring ACO compliance with the quality performance standards to specify that those provisions are applicable to performance years (or a performance period) beginning on or before January 1, 2020. Lastly, we are making conforming changes to § 425.224(b)(1)(ii)(A) to provide that as part of evaluating a renewing or re-entering ACO's application to participate in the Shared Savings Program, CMS will consider whether the ACO has demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under § 425.316(c)(1)(ii) or (c)(2)(ii).

f. Updating the Process Used To Validate ACO Quality Data Reporting

In the CY 2017 PFS final rule, we finalized modifications to the quality measures validation audit process. These modifications changed the overall audit process from a 3-phased medical record review to an audit conducted in a single phase. Under our current process, if selected for an audit, an ACO must provide beneficiary medical records data to substantiate the quality data reported by the ACO. As part of the audit, CMS calculates an overall audit match rate, which is derived by dividing the total number of audited records that match the information reported in the CMS Web Interface by the total number of the medical records audited. For example: (1) If the ACO has an audit match rate of 90 percent or above it will pass the audit; (2) if the ACO has an audit match rate of less than 90 percent, but greater than 80 percent, the ACO may be required to submit a CAP under § 425.216 for CMS approval; (3) if the ACO has an audit match rate of less than 80 percent, absent unusual circumstances, we will adjust the ACO's

overall quality score proportional to the ACO's audit match rate, which may have implications for the ACO's financial reconciliation.

We stated in the CY 2021 PFS proposed rule (85 FR 50239) that under our proposal to align the quality reporting requirements under the Shared Savings Program with quality reporting under the APP, we believed it would be appropriate to also align with the MIPS Data Validation and Audit (DVA) process (§ 414.1390). Rather than continuing to validate ACO quality data reporting under the Shared Savings Program, we noted that we believed it would be more appropriate for MIPS to validate the data submitted by ACOs for the three measures in the APP, as ACOs will be able to select the submission method for these measures and the MIPS DVA is based on submission method. We also noted that we believed streamlining the approach to data validation and audit would minimize administrative burden associated with the audit for ACOs as they would only need to track to one validation process, and for ACOs in a track (or payment model within a track) that does not meet the definition of an Advanced APM, the results of the audit would be applicable for purposes of both the Shared Savings Program and MIPS.

We proposed to address the audit and validation of data used to determine the ACO's quality performance in a new provision we proposed to add to the Shared Savings Program regulations at § 425.510(c). Specifically, we proposed that CMS would retain the right to audit and validate the quality data reported by an ACO under § 425.510(b) according to § 414.1390.

We received public comments on the proposed updates to the process used to validate ACO quality data reporting. The following is a summary of the comments we received and our response.

Comment: We received comments that supported our proposal. One commenter indicated that the proposed approach would allow for the continued oversight of quality performance, while reducing administrative burden on ACOs as they ensure audit readiness.

Response: We are finalizing the updates to the process used to validate ACO quality data reporting and the conforming changes to § 425.510(c) as proposed. Specifically, we are finalizing that CMS retains the right to audit and validate quality data reported by an ACO via the APP according to the MIPS DVA process for performance years beginning on or after January 1, 2021. We believe that this updated process will reduce administrative burden on ACOs by allowing them to track only one validation process that will be applicable for both the Shared Savings Program and MIPS. We note that in section III.G.1.e. of this final rule, we are finalizing our proposals related to ACOs' compliance with the quality performance standard, including the proposed approach to terminating ACOs that exhibit a pattern of failure to meet the quality performance standard.

g. Changes to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2021 and Subsequent Performance Years

As discussed in section III.G.1.c. of the CY 2021 PFS proposed rule, we proposed to make changes to the quality performance standard for the Shared Savings Program for the performance year beginning on January 1, 2021, and subsequent performance years. We explained that we continue to believe it is appropriate to adjust the quality performance scores for ACOs affected by extreme and uncontrollable circumstances. Therefore, we proposed to update the extreme and uncontrollable circumstances policy under the Shared Savings Program consistent with the proposal to align the quality reporting requirements for the Shared Savings Program with the proposed APP. Specifically, for performance year (PY) 2021 and subsequent performance years, we proposed to set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, to equal the 40th percentile MIPS Quality performance category score. If the ACO is able to report quality data and meet the MIPS data completeness and case minimum requirements, we would use the higher of the ACO's MIPS Quality performance category score or the 40th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we would apply the 40th percentile MIPS Quality performance category score. We noted that we believed this approach would be appropriate as it aligns with the proposed threshold for meeting the quality performance standard allowing impacted ACOs to share in savings at their maximum sharing rate. We acknowledged that using the 40th percentile may not offer the same level of protection for ACOs incurring losses that would receive the higher of their ACO quality score or the mean ACO score under the current policy. However, we noted that for ACOs in Track 2 and the ENHANCED track, under which shared losses are determined based in part on an ACO's quality performance, ACOs are also afforded relief from shared losses through the application of the extreme and uncontrollable circumstances policy under which shared losses are reduced based on the percentage of the year and percentage of assigned beneficiaries impacted by an extreme and uncontrollable circumstance.

In the CY 2021 PFS proposed rule (85 FR 50240), we explained that under the proposed revisions to the quality reporting requirements, we would no longer generate a CMS Web Interface quality reporting sample for ACOs because ACOs would no longer be reporting measures via the Web Interface; therefore, we proposed to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries, rather than the list of assigned beneficiaries used to generate the Web Interface quality reporting sample, which is currently used. We explained that using the quarter four list of assigned beneficiaries would be an appropriate alternative because the file is generated after the end of the fourth quarter and would offer a more complete representation of the population of assigned beneficiaries that reside in an area that is impacted by an extreme and uncontrollable circumstance during the performance year. Accordingly, we solicited comment on our proposed revisions to the extreme and uncontrollable circumstances policy for performance year 2021 and subsequent performance years.

We proposed to specify our proposed policies for addressing the effect of extreme and uncontrollable circumstances on ACO quality performance for performance year 2021 and subsequent performance years in the proposed new provision at § 425.512. In addition, we proposed to include policies that parallel the existing policies, as specified in § 425.502(f), for determining when an extreme and uncontrollable circumstance has occurred and identifying affected ACOs. In particular, we proposed to include a provision, similar to the current provision at § 425.502(f)(1), to establish our policies for determining whether an ACO has been affected by an extreme and uncontrollable circumstance. We also

proposed to include a provision, similar to the provision at § 425.502(f)(2), to establish the policies that would apply for calculating an affected ACO's quality performance score. Similar to the existing provision at § 425.502(f)(3), we proposed to specify that we would apply determinations made under the Quality Payment Program with respect to whether an extreme and uncontrollable circumstance has occurred, and the affected areas. Consistent with the existing policy under § 425.502(f)(4), this new provision would also specify that we have sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

We received public comments on the proposed changes to the extreme and uncontrollable circumstances policy for PY 2021 and subsequent performance years. The following is a summary of the comments we received and our response.

Comment: Several commenters supported our proposal to set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, to equal the 40th percentile MIPS Quality performance category score in performance year 2021. Two commenters did not support the proposed changes to the extreme and uncontrollable policy for performance year 2021. One commenter explained that ACO participants tend to have higher MIPS Quality performance category scores than non-ACO participants; therefore, setting the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance to equal the 40th percentile MIPS Quality performance would be lower than what the ACO may have earned. The other commenter stated that our proposal would effectively lower the protections for impacted ACOs and comes at a particularly tumultuous time due to the PHE for COVID–19. The commenter noted that they would support a similar policy if CMS maintained a baseline level of protection, such as the affected ACO's mean quality performance score, because this would maintain current levels of protection, which is particularly critical in the midst of the PHE for COVID–19, while also incentivizing ACOs to report data to improve their quality scores.

Several commenters encouraged CMS to apply the alternative extreme and uncontrollable circumstances policy discussed in the CY 2021 PFS proposed rule for performance year 2020 to performance year 2021. These commenters cited their concerns that the effects of the PHE for COVID–19 would extend into 2021 and urged CMS to extend this alternative policy to performance year 2021.

Other commenters urged us to refrain from making further changes to the extreme and uncontrollable circumstances policy for other performance years at this time, given that all ACOs are currently subject to the existing policy due to the PHE for COVID–19. These commenters explained that numerous changes to the extreme and uncontrollable circumstances policy were made in performance years 2019 and 2020, including additional modifications due to the PHE for COVID–19, and therefore CMS should refrain from making further changes to the policy at this time. Commenters noted that abrupt changes in policy, like changing the reporting requirements during the PHE for COVID–19, have been difficult for healthcare providers to adjust to and that these policy changes should take place only after the end of the PHE for COVID–19, once the totality of information and learnings can be assessed. The commenters suggested that we allow more time to examine the impacts of the PHE for COVID–19 and gather further stakeholder input before proceeding with any changes to the policy for performance year 2021 and subsequent years.

Response: We acknowledge that we have made multiple changes to the extreme and uncontrollable circumstances policy over the past few years in order to provide relief to ACOs impacted by extreme and uncontrollable circumstances. We also agree with the commenter that ACOs typically have higher MIPS Quality performance category scores than non-ACO MIPS participants, based on their performance on the measures reported via the CMS Web Interface and the CAHPS for ACOs; however, given that the APP measure set is smaller and includes a combination of eCQMs/CQM MIPS measures, CAHPS for MIPS and 2 claims-based measures, we have no comparisons to determine how ACOs will perform in relation to non-ACO groups under the APP. Accordingly, we believe setting the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year to equal the MIPS Quality performance category score that will satisfy the quality performance standard is appropriate and aligns with the policies regarding for the quality performance standard as discussed in section III.G.1.b.(1) of this final rule.

We note that as discussed in section III.G.1.c. of this final rule, we are finalizing a gradual phase-in of the increase in the level of quality performance standard that would be required for all ACOs to meet the Shared Savings Program quality performance standard to allow time for ACOs to gain experience. For performance years 2021 and 2022, the threshold for the quality performance standard will be set at a quality performance score equivalent to or above the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring, and for performance year 2023 and subsequent performance years, the threshold for the quality performance standard will be set at a quality score equivalent to or above the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring. This gradual phase-in is designed to allow ACOs to gain experience under the new standard. We agree that the extreme and uncontrollable circumstances policy should offer an appropriate level of protection for ACOs that are impacted by an extreme and uncontrollable circumstance while still incentivizing quality reporting. We believe that aligning the extreme and uncontrollable circumstances policy with the gradual phase in of the quality performance standard will offer protection for ACOs, while still incentivizing reporting. Moreover, this policy enables ACOs impacted by an extreme and uncontrollable circumstance to share in savings at their maximum sharing rate. We acknowledge that this policy change will potentially affect ACOs in Track 2 and the ENHANCED track, for whom shared losses are determined based in part on an ACO's quality performance. These ACOs, however, will have relief from shared losses through the application of the extreme and uncontrollable circumstances policy under which shared losses are reduced based on the percentage of the year and percentage of assigned beneficiaries impacted by an extreme and uncontrollable circumstance.

Although several commenters encouraged CMS to apply the alternative extreme and uncontrollable circumstances policy we sought comment on in the CY 2021 PFS

proposed rule for performance year 2020 to performance year 2021, we do not believe applying the same policy we sought comment on for performance year 2020, as described in section III.I.2 of this final rule would be appropriate for performance year 2021. We do not believe assigning the higher of an ACO's 2019 or 2021 quality score to determine an ACO's quality performance score for performance year 2021 would be an effective way to mitigate the concerns related to the PHE for COVID–19 because there would be a mismatch in the datasets and the scoring methodologies between the 2 years. One score would be based on a one to 100 scale while the other would be based on a percentile range. As a result, the scores for the 2 years would not be comparable across years. However, in this final rule, we are lowering the threshold for the quality performance standard to the 30th percentile from the initially proposed 40th percentile for performance years 2021 and 2022, and we believe this change will help to alleviate and mitigate the impact of COVID–19.

We received no comments on our proposal to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries.

For these reasons, we are finalizing our proposed changes to the extreme and uncontrollable circumstances policy for performance year 2021 and subsequent performance years with modifications and conforming changes as follows:

For PY 2021 and PY 2022, consistent with the modifications to the quality performance standard described in section III.G.1.b.(1). of this final rule, the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, will be set equal to the 30th percentile MIPS Quality performance category score as determined under § 425.512(a)(3). If the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's quality performance score or the 30th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 30th percentile MIPS Quality performance category score.

For PY 2023, we will set the minimum quality performance score for an ACO affected by an extreme and uncontrollable circumstance during the performance year, including the applicable quality data reporting period for the performance year, to equal the 40th percentile MIPS Quality performance category score as determined under § 425.512(a)(4). If the ACO is able to report quality data and meets the MIPS data completeness and case minimum requirements, we will use the higher of the ACO's quality performance score or the 40th percentile MIPS Quality performance category score. If an ACO is unable to report quality data and meet the MIPS Quality data completeness and case minimum requirements due to an extreme and uncontrollable circumstance, we will apply the 40th percentile MIPS Quality performance category score.

For additional information, we refer readers to Table 39, in section III.G.1.b.(1) above, which shows the Shared Savings Program quality performance standard for PY 2021, PY 2022, and PY 2023.

We are finalizing our proposal to determine the percentage of the ACO's performance year assigned beneficiary population that was affected by an extreme and uncontrollable circumstances based on the quarter four list of assigned beneficiaries as proposed. We are also finalizing our proposal to specify the policies for addressing the effect of extreme and uncontrollable circumstances on ACO quality performance for performance year 2021 and subsequent performance years with the modifications and conforming changes described previously, in the new provision at § 425.512(b).

In the CY 2021 PFS proposed rule (85 FR 50240 and 50241), we also solicited comment on a potential alternative extreme and uncontrollable circumstances policy for PY 2022 and subsequent years that would continue to incentivize reporting but also acknowledge the challenges presented by extreme and uncontrollable circumstances. We explained that we were considering creating an extreme and uncontrollable circumstances methodology that would adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting. This methodology would be similar to the methodology currently used to adjust for extreme and uncontrollable circumstances when calculating the amount of shared losses for impacted ACOs. Under this alternative approach, instead of determining that ACOs are affected by an extreme and uncontrollable circumstances if 20 percent of their beneficiaries or their legal entity are located in an area impacted by an extreme and uncontrollable circumstance and determining shared savings using the higher of the ACO's own quality score and the mean ACO quality score, we would determine shared savings for an affected ACO by multiplying the maximum possible shared savings the ACO would be eligible to receive based on its financial performance and track (or payment model within a track) by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance.

If an ACO impacted by an extreme and uncontrollable circumstance does not report quality or reports quality, but does not meet the quality performance standard of a quality performance score equivalent to a MIPS Quality performance category score at or above the 40th percentile and owes shared losses, we noted that the existing extreme and uncontrollable circumstances methodology that applies when calculating the amount of shared losses would help to mitigate those losses.

We received public comments on this potential alternative extreme and uncontrollable circumstances policy for PY 2022 and subsequent years. The following is a summary of the comments we received and our responses.

Comment: We received two comments in support of the potential alternative extreme and uncontrollable circumstances policy for performance year 2022 and subsequent years. One commenter noted that the proposed methodology to adjust the amount of shared savings determined for affected ACOs that complete quality reporting but do not meet the quality performance standard or that are unable to complete quality reporting would provide affected ACOs with flexibility in reporting. The commenter emphasized that this would help ACOs continue participating in the Shared Savings Program.

Several other commenters stated that they did not support CMS making additional changes to the extreme and uncontrollable circumstances policy at this time. These commenters urged CMS to refrain from making any significant changes to the extreme and uncontrollable policy at this time and to continue to assess the impact of the PHE

for COVID–19 before making any further changes to the established policy.

Response: As we plan for future updates and changes to the extreme and uncontrollable circumstances policy for performance year 2022 and subsequent years, we will consider this feedback in the development of our proposals.

h. Technical Changes To Incorporate References To Revised Quality Performance Standard

In section III.G.1.h of the CY 2021 PFS proposed rule (85 FR 50241), we proposed to make certain technical, conforming changes to provisions of the Shared Savings Program regulations to reflect the proposal to add new sections of the regulations at § 425.510 on the application of the APP to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021, and § 425.512 on determining the ACO quality performance standard for performance years beginning on or after January 1, 2021. We did not receive comments directly addressing our proposed technical changes to incorporate references to the proposed new regulations. In this section, we specify the technical changes we are finalizing either as proposed, or with additional revisions to account for the modifications we are making to phase in the new quality performance standard for performance years beginning on or after January 1, 2021, as discussed elsewhere in section III.G.1 of this final rule.

- Under subpart A, which specifies general provisions governing the Shared Savings Program:

++ In § 425.100(b), the general description of ACOs that are eligible to receive payments for shared savings under the program, we are finalizing our proposed revisions for clarity and to add a reference to § 425.512. In the description of the quality performance standard that must be met for the ACO to be receive payment for shared savings, we are finalizing our proposal to specify that the quality performance standards established under § 425.500 are applicable for performance years (or a performance period) beginning on or before January 1, 2020, and that the quality performance standard under § 425.512 is applicable for performance years beginning on or after January 1, 2021.

++ In § 425.112(b)(2)(i), the provision specifying the ACO must have processes to promote patient engagement including to address compliance with patient experience of care survey requirements, we are finalizing our proposal to add a reference to § 425.510.

- Under subpart C, which governs application procedures and the participation agreement, we are finalizing our proposed addition of a reference to § 425.510 in the provision at § 425.200(d) specifying that ACOs must submit measures in the form and manner required by CMS.

- Under subpart D, which specifies program requirements and beneficiary protections, we are finalizing our proposed addition of a reference to § 425.510 in § 425.302(a)(1) specifying requirements for data submission and certification.

- Under subpart G, which specifies the program's financial models for determining shared savings and shared losses (as applicable), we proposed to revise the description of program requirements that phase-in over multiple agreement periods in § 425.600(f)(4). We are finalizing our proposal to revise this provision with modifications to account for the phase-in of the revised quality performance standard that we describe in section III.G.1.b and section III.G.1.c of this final rule with modifications. Specifically, we are revising this provision to account for the approach we are finalizing under § 425.512(a), which differentiates the quality performance standard applicable to ACOs in the first performance year of their first agreement period from the standard that is applicable to ACOs in subsequent years. This aspect of the phase-in of the quality performance standard applies to ACOs entering their first agreement period in the Shared Savings Program beginning on January 1, 2022, and in subsequent years, consistent with CMS' decision to forgo an application cycle for a January 1, 2021 agreement start date in the Shared Savings Program. Therefore, we are finalizing revisions to § 425.600(f)(4)(i) to add a reference to the quality performance standard as described in § 425.512(a), which will be applicable for the performance year starting on January 1, 2021, and subsequent performance years.

- Under subpart I, which governs the reconsideration review process, we are finalizing our proposed addition of references to § 425.510, § 425.512, or both to § 425.800(a)(1), (2), and (6).

2. Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

a. Healthcare Common Procedure Coding System (HCPCS) and Current Procedural Terminology (CPT) Codes Used in Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by a physician who is an ACO professional and all services furnished by Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs). However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by CPT and HCPCS codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services, if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking to reflect additions or modifications to the codes that have been recognized for payment under the Medicare PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program.

In the June 2015 final rule (80 FR 32746 through 32748), we expanded the definition of primary care services to include two transitional care management (TCM) codes (CPT codes 99495 and 99496), and one chronic care management (CCM) code (CPT 99490). As discussed in the final rule, the TCM codes were established to pay a patient's physician or practitioner to coordinate the patient's care in the 30 days following a hospital or SNF stay. Including these codes in the definition of primary care services reflects our belief that the work of community physicians and practitioners in managing a patient's care following discharge from a hospital or nursing facility (NF) to ensure better continuity of care for these patients and help

reduce avoidable readmissions is a key aspect of primary care.

In the CY 2016 PFS final rule (80 FR 71270 through 71273), we revised the definition of primary care services to exclude services billed under CPT codes 99304 through 99318, containing the place of service 31 modifier specifying that the service was furnished in a SNF. We also revised the definition of primary care services to include claims submitted by Electing Teaching Amendment (ETA) hospitals.

In the CY 2018 PFS final rule, we revised the definition of primary care services to include three additional CCM service codes, 99487, 99489, and G0506, and four behavioral health integration (BHI) service codes, G0502, G0503, G0504 and G0507 (82 FR 53212 and 53213). We further revised the definition of primary care services in the November 2018 final rule. In the November 2018 final rule, we added new codes to the definition of primary care services (CPT codes 99497, 99498, 96160, 96161, 99354, and 99355, and HCPCS codes G0444, G0442, and G0443), and revised how we determine whether services identified by CPT codes 99304 through 99318 were furnished in a SNF (83 FR 59964 through 59968).

For performance years beginning on January 1, 2019, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(iv) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

(1) 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient).

(2) 99304 through 99318 (codes for professional services furnished in a NF; services identified by these codes furnished in a SNF are excluded).

(3) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(4) 99341 through 99350 (codes for E/M services furnished in a patients' home for claims identified by place of service modifier 12).

(5) 99487, 99489 and 99490 (codes for chronic care management).

(6) 99495 and 99496 (codes for transitional care management services).

(7) 99497 and 99498 (codes for advance care planning).

(8) 96160 and 96161 (codes for administration of health risk assessment).

(9) 99354 and 99355 (add-on codes, for prolonged E/M or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code).

(10) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

HCPCS codes:

(1) G0402 (the code for the Welcome to Medicare visit).

(2) G0438 and G0439 (codes for the annual wellness visits).

(3) G0463 (for services furnished in ETA hospitals).

(4) G0506 (code for chronic care management).

(5) G0444 (codes for annual depression screening service).

(6) G0442 (code for alcohol misuse screening service).

(7) G0443 (code for alcohol misuse counseling service).

In the May 8th COVID–19 IFC (85 FR 27582 through 27586), we revised the regulations to add § 425.400(c)(2), specifying the definition of primary care services for purposes of beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19 defined in § 400.200, to include the foregoing codes specified in § 425.400(c)(1)(iv), as well as specified codes for remote evaluations, virtual check-ins, e-visits, and telephone E/M services. In section III.G.5.e of this final rule, we discuss the final policies regarding the definition of primary care services during the PHE for COVID–19.

(2) Revisions

Based on feedback from ACOs and our further review of the HCPCS and CPT codes currently recognized for payment under the PFS, we discussed in the CY 2021 PFS proposed rule (85 FR 50242 through 50248) our belief that it would be appropriate to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes and make other technical changes to the definition of primary care services, for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years.

We proposed to revise the definition of primary care services in the Shared Savings Program regulations to include the following additions: (1) Online digital E/M CPT codes 99421, 99422, and 99423; (2) assessment of and care planning for patients with cognitive impairment CPT code 99483; (3) chronic care management code CPT code 99491; (4) non-complex chronic care management HCPCS code G2058 and its proposed replacement CPT code, if finalized through the CY 2021 PFS rulemaking; (5) principal care management HCPCS codes G2064 and G2065; and (6) psychiatric collaborative care model HCPCS code GCOL1, if finalized through the CY 2021 PFS rulemaking.

The following provides additional information about the CPT and HCPCS codes that we proposed to add to the definition of primary care services used in assignment:

- *Online Digital Evaluation and Management Services (CPT codes 99421, 99422, and 99423):* In the CY 2020 PFS final rule (84 FR 62797), we finalized payment for new online digital assessment services, also referred to as ''E-Visits,'' beginning in CY 2020 for practitioners billing under the PFS. These services are non-face-to-face, patient-initiated communications using online patient portals. These digital assessment services are for established patients who require a clinical decision that otherwise typically would have been provided in the office. Practitioners who may independently bill Medicare for E/M services (for instance, physicians and NPs) can bill the following codes:

++ *99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.)*

++ *99422 (Online digital evaluation and management service, for an established patient, for up to 7 days cumulative time during the 7 days; 11–20 minutes.)*

++ *99423 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes.)*

In the May 8th COVID–19 IFC (85 FR 27583), we stated that we believe it is appropriate to include these CPT and HCPCS codes in the definition of primary care services used for assignment for PY 2020 and any subsequent performance year that starts during the PHE for COVID–19 because the services represented by these codes are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. We also explained our belief that it is important to include these services in our assignment methodology because we determine assignment to ACOs based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting

assigned beneficiary population. Subsequent to the publication of the May 8th COVID–19 IFC, we have determined, based on the justification above, that these codes should be included in the definition of primary care services under § 425.400(c) permanently for purposes of determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years, and should not be linked to the duration of the PHE for COVID–19.

• *Assessment of and care planning for patients with cognitive impairment (CPT code 99483):* In the CY 2017 PFS final rule (81 FR 80252–54), we finalized a G-code that would provide separate payment to recognize the work of a physician (or other appropriate billing practitioner) in assessing and creating a care plan for beneficiaries with cognitive impairment, such as from Alzheimer's disease or dementia, at any stage of impairment, G0505 (*Cognition and functional assessment using standardized instruments with development of recorded care plan for the patient with cognitive impairment, history obtained from patient and/or caregiver, in office or other outpatient setting or home or domiciliary or rest home*). In the CY 2018 PFS final rule (82 FR 53077), we deleted the interim HCPCS code G0505 and replaced it with CPT code 99483 (*Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (e.g., Basic and Instrumental Activities of Daily Living), including decision-making capacity; Use of standardized instruments for staging of dementia (e.g., Functional Assessment Staging Test [FAST], Clinical Dementia Rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (e.g., home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (e.g., rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family caregiver*).

CPT code 99483 includes the same elements included in the Level 5 E/M service CPT code 99215, such as, a comprehensive history, comprehensive exam, and high complexity medical decision-making. CPT code 99215 is included in the definition of primary care services used for assignment. Accordingly, we noted in the proposed rule that we believe it would be appropriate to also include CPT code 99483 in the definition of primary care services used for assignment under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years.

• *Chronic Care Management (CPT code 99491):* In the CY 2019 PFS final rule (83 FR 59577), we finalized CPT code 99491 (*Chronic care management services, provided personally by a physician or other qualified healthcare professional, at least 30 minutes of physician or other qualified health care professional time, per calendar month, with the following required elements: Multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored*). This code requires two or more chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, and that a comprehensive care plan has been established, implemented, revised or monitored by the billing practitioner for such patient. In earlier rulemaking, we finalized the inclusion of CCM CPT codes 99487, 99489, and 99490 (codes for chronic care management) in the definition of primary care services for the Shared Savings Program. Refer to the June 2015 final rule (80 FR 32746 through 32748), and CY 2018 PFS final rule (82 FR 53212 through 53213). ''Non-complex'' CCM services (CPT codes 99490 and 99491), and ''complex'' CCM services (CPT codes 99487 and 99489) share a common set of service elements, including the following: (1) Initiating visit, (2) structured recording of patient information using certified electronic health record technology (EHR), (3) 24/7 access to physicians or other qualified health care professionals or clinical staff and continuity of care, (4) comprehensive care management including systematic assessment of the patient's medical, functional, and psychosocial needs, (5) comprehensive care plan including a comprehensive care plan for all health issues with particular focus on the chronic conditions being managed, and (6) management of care transitions. They differ in the amount of clinical staff service time provided, the involvement and work of the billing practitioner, and the extent of care planning performed.[65] CPT code 99491 includes only time that is spent personally by the billing practitioner. Clinical staff time is not counted towards the required time threshold for reporting this code, whereas CPT codes 99487, 99489, and 99490 include time spent directly by the billing practitioner and by other clinical staff that counts toward the threshold clinical staff time required to be spent during a given month. Accordingly, CPT code 99491 cannot be reported for a beneficiary by a billing practitioner in the same month as CCM codes 99487, 99489, or 99490. Therefore, we noted in the proposed rule that we believe it would be appropriate to propose to include CCM CPT code 99491 in the definition of primary care services under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years, in order to capture these CCM services when attributing beneficiaries to an ACO.

• *Non-Complex CCM (HCPCS code G2058 and its proposed replacement CPT code):* In the CY 2020 PFS final rule (84 FR 62690), we finalized the creation of HCPCS code G2058 *(Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure). (Do not report G2058 for care management services of less than 20 minutes additional to the first 20 minutes of chronic care management services during a calendar month). (Use G2058 in conjunction with 99490). (Do not report 99490, G2058 in the same calendar month as 99487, 99489, 99491))* for additional time spent beyond the initial 20 minutes included in the current coding for CCM services. As described in the CY 2021 PFS proposed rule, we proposed the

[65] Refer to CMS Medicare Learning Network, MLN Booklet ''Chronic Care Management Services'' (ICN MLN909188, July 2019); available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ChronicCareManagement.pdf*.

adoption of the permanent CPT code to replace HCPCS code G2058. As described in previous rulemaking, practitioners who choose to use G2058 can report the initial 20 minutes of non-complex CCM under CPT code 99490 and receive increased payment for their work under HCPCS code G2058 (84 FR 62690). Since CPT code 99490 is currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(1)(iv), we proposed to add G2058 to the definition, effective for performance years starting on or after January 1, 2021, because the services furnished during the additional time billed under HCPCS code G2058, would be expected to be substantially similar to the services furnished under CPT code 99490, and thus should also be considered for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years. In the CY 2021 PFS proposed rule, we stated that, if the proposal to adopt the permanent CPT code to replace HCPCS code G2058 is finalized, we would instead include that CPT code in the definition of primary care services used for purposes of assignment under § 425.400(c) for the performance year starting on January 1, 2021, and subsequent performance years. Elsewhere in this rule, we discuss the finalization of 99439 (*Chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*) as the permanent CPT code to replace G2058.

- *Principal Care Management (HCPCS codes G2064 and G2065):* The CY 2020 PFS final rule (84 FR 62692 through 62697) introduced two new HCPCS codes (G2064 and G2065) for Principal Care Management (PCM) services. G2064 *(Comprehensive care management services for a single high-risk disease, e.g., principal care management, at least 30 minutes of physician or other qualified health care professional time per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been the cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities),* for use by physicians and NPPs, and G2065 *(Comprehensive care management for a single high-risk disease services, e.g. principal care management, at least 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month with the following elements: One complex chronic condition lasting at least 3 months, which is the focus of the care plan, the condition is of sufficient severity to place patient at risk of hospitalization or have been cause of a recent hospitalization, the condition requires development or revision of disease-specific care plan, the condition requires frequent adjustments in the medication regimen, and/or the management of the condition is unusually complex due to comorbidities),* for use by clinical staff.

As discussed in the proposed rule, we expect that most services billed under these codes will be billed by specialists who are focused on managing patients with a single complex chronic condition requiring substantial care management. HCPCS code G2064 would be reported when, during the calendar month, at least 30 minutes of physician or other qualified health care professional time is spent on comprehensive care management for a single high-risk disease or complex chronic condition. HCPCS code G2065 would be reported when, during the calendar month, at least 30 minutes of clinical staff time is spent on comprehensive management for a single high-risk disease or complex chronic condition. Comprehensive care management codes require patients to have two or more chronic conditions and are primarily billed by practitioners who are managing a patient's total care over a month, including primary care practitioners and some specialists, such as cardiologists or nephrologists. By contrast, PCM services involve care management services for one serious chronic condition, typically expected to last between 3 months and a year, or until the death of the patient, that may have led to a recent hospitalization, and/or places the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. Specifically, we stated in the CY 2020 PFS final rule (84 FR 62693 through 62697) that we agree that the relativity between CCM CPT codes 99490 and 99491 should be preserved in PCM HCPCS codes G2064 and G2065 and crosswalked the RVUs for G2064 and G2065 to 99491 and 99490, respectively. Due to the similarity between the description of the PCM and CCM services, both of which involve non-face-to-face care management services, we finalized that the full CCM scope of service requirements apply to PCM, including documenting the patient's verbal consent in the medical record. CCM services billed under code 99490 are currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(1)(iv), and as discussed previously, we proposed to include CCM services billed under code 99491 for performance years starting on or after January 1, 2021; therefore, for the foregoing reasons, we also proposed to add G2064 and G2065 to the definition of primary care services for the performance year starting on January 1, 2021, and subsequent performance years.

- *Psychiatric collaborative care model HCPCS code GCOL1:* In the CY 2017 PFS final rule (81 FR 80230–36), we established G-codes used to bill for monthly services furnished using the Psychiatric Collaborative Care Model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. These G-codes were replaced by CPT codes 99484, 99492, 99493, and 99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077 and 53078).

As discussed in the proposed rule, we proposed to add a new HCPCS code GCOL1 *(Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional)* in response to stakeholders who have requested additional coding to capture shorter increments of time spent, for example, when a patient is seen for services, but is then hospitalized or referred for specialized care, and the number of minutes required to bill for services using the current coding is not met. Specifically, we proposed to establish a G-code to describe 30 minutes of behavioral health care manager time. This code would describe one-half of the time described by the existing code that describes subsequent months of CoCM services, CPT code 99493 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified*

health care professional, with the following required elements:

- *Tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant;*
- *Ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers;*
- *Additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant;*
- *Provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies;*
- *Monitoring of patient outcomes using validated rating scales; and*
- *Relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment*).

Because CPT code 99493 is currently included in the Shared Savings Program's definition of primary care services under § 425.400(c)(iv), we believe it is appropriate to add GCOL1 to the definition since the services furnished under the proposed new code would be expected to be substantially similar to the services furnished under CPT code 99493. Accordingly, contingent upon its finalization, we proposed to add HCPCS code GCOL1 to the definition of primary care services for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years. HCPCS code GCOL1 is being finalized as HCPCS code G2214 (*Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional*), as discussed elsewhere in this final rule.

In the May 8th COVID–19 IFC (85 FR 27583), we revised the definition of primary care services used in the Shared Savings Program assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19, as defined in § 400.200, to include the following additions: (1) HCPCS code G2010 (*remote evaluation of patient video/images*); (2) HCPCS code G2012 (*virtual check-in*); and (3) CPT codes 99441, 99442, and 99443 (*telephone evaluation and management services*).

We considered adding HCPCS codes G2010 *(Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment)* and G2012 *(Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion)* to the definition of primary care services for purposes of assignment under § 425.400 for the performance year starting on January 1, 2021, and subsequent performance years; however, while we recognized the importance of the flexibility these HCPCS codes provide during the PHE for COVID–19, we explained in the proposed rule that we do not believe they should be added to definition of primary care services for purposes of assignment under § 425.400 on a permanent basis. In the context of the PHE for COVID–19, when brief communications with practitioners and other non-face-to-face services could mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, healthcare providers, and individuals in the community, we concluded that it was appropriate to include HCPCS codes G2010 and G2012 in the definition of primary care services used in assignment. However, outside the context of the PHE for COVID–19, we expect that these monitoring/check-in services for established patients will no longer replace primary care services because these separately billable brief communication-technology based services describe a check-in directly with the billing practitioner to assess whether an office visit is needed. When the PHE for COVID–19 ends, these services would likely be replaced by an in-person primary care visit on which assignment would be based.

We sought comment on this issue and on the alternative approach of permanently including HCPCS codes G2010 and G2012 in the definition of primary care services used in assignment. We noted that we would consider the comments received in developing the policies for the final rule.

We noted that we did not consider including CPT codes 99441, 99442, and 99443 in the definition of primary care services at § 425.400(c) on a permanent basis. Telephone E/M services CPT codes 99441 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion.*); 99442 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion.*); and 99443 (*Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion.*) are non-covered services when not provided during the PHE for COVID–19, as defined in § 400.200, and so could not be included in the definition of primary care services for purposes of assignment outside the context of the PHE.

We also proposed to modify the definition of primary care services for purposes of assignment in the Shared Savings Program regulations to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting, for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. In the November 2018 final rule (83 FR 59964 through 59968), we finalized the inclusion of CPT code 99497 and the add-on code 99498 in the definition of primary care services. We did not propose any exceptions to place of service or provider type because there

are no facility setting limitations or provider specialty limitations on these codes.[66] In the CY 2021 PFS proposed rule (85 FR 50245), we explained that since adding these codes to the definition of primary care services we have received feedback from an ACO that, by not restricting place of service when using advance care planning codes in assignment, our methodology may inappropriately assign beneficiaries. Specifically, we described our concern that the inclusion of these CPT codes when the services are provided in an inpatient care setting may result in beneficiaries being assigned based on inpatient care rather than based on primary care by their regular healthcare providers. Based on an initial analysis using calendar year 2019 claims data, we observed the following frequencies for occurrence of place of service code 21, which identifies the place of service as an inpatient hospital, with CPT codes 99497 and 99498 in Part B claims: Over 13 percent of approximately 1.6 million Part B claims for CPT code 99497 had place of service code 21; over 48 percent of approximately 43,000 Part B claims for CPT code 99498 had place of service code 21. We explained that operationally we would exclude advanced care planning services claims billed under CPT codes 99497 and 99498 from use in the assignment methodology when there is an inpatient facility claim in our claims files with dates of service that overlap with the date of service for the professional service billed under CPT code 99497 or add-on code 99498. A similar operational approach is currently used to exclude certain codes for professional services furnished in a SNF pursuant to § 425.400(c)(1)(iv)(A)(*2*), as described in the proposed rule.

We also sought comment on an alternative method for determining operationally whether advance care planning services are provided in an inpatient care setting. Specifically, we sought comment on whether to exclude advance care planning services identified by CPT code 99497 or add-on code 99498, or both, reported on claims with place of service code 21, which identifies the place of service as an inpatient hospital.[67] We explained that based on initial analysis, we had determined that this alternative approach would capture slightly fewer claims for advance care planning, compared to the proposed approach. We noted that we would consider any comments received on this alternative approach in developing our policies for the final rule.

We proposed to specify a revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(v) to include the list of HCPCS and CPT codes specified in § 425.400(c)(1)(iv) with the proposed additional CPT and HCPCS codes, and reflecting the proposal to exclude advance care planning codes when provided in an inpatient setting in the new provision at § 425.400(c)(1)(v)(A)(*12*). We also proposed that the new provision in § 425.400(c)(1)(v) would reflect technical modifications to the previously finalized descriptions of the CPT and HCPCS codes for consistency and clarity, including grammatical updates and ordering the codes sequentially. We proposed the new provision at § 425.400(c)(1)(v) would be applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. Further, we proposed technical modifications to the introductory text in § 425.400(c)(1)(iv) to specify the applicability of this provision for determining beneficiary assignment for performance years (or a performance period) during 2019 and performance year 2020.

We sought comment on the proposed changes to the definition of primary care services used for assigning beneficiaries to Shared Savings Program ACOs for the performance year starting on January 1, 2021, and subsequent performance years. We also sought comments on any other existing HCPCS or CPT codes, and new HCPCS or CPT codes proposed in the CY 2021 PFS proposed rule, that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

We noted that, under § 425.212, an ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless otherwise required by statute: (1) Eligibility requirements concerning the structure and governance of ACOs; and (2) calculation of sharing rate. As we have explained in earlier rulemaking, consistent with our authority under section 1899(d)(1)(B)(ii) of the Act to adjust the benchmark for beneficiary characteristics and other factors as the Secretary determines appropriate, CMS adjusts an ACO's historical benchmark to account for any regulatory changes affecting assignment during the agreement period (80 FR 32730 through 32732). Accordingly, we stated in the proposed rule that, if we finalized any of the proposed changes to the definition of primary care services discussed in section III.G.2. of the CY 2021 PFS proposed rule for purposes of beneficiary assignment applicable for the performance year starting on January 1, 2021, and subsequent performance years, we would adjust ACOs' historical benchmarks to account for these changes. Although it has been our historical practice to make these adjustments, the regulations establishing our benchmarking methodology do not explicitly describe these adjustments. Accordingly as discussed in the CY 2021 PFS proposed rule, we proposed conforming revisions to the regulations in §§ 425.601(a)(9), 425.602(a)(8), and 425.603(c)(8), to specify that CMS will adjust the ACO's historical benchmark to reflect any changes to the beneficiary assignment methodology specified in part 425, subpart E during an ACO's agreement period including revisions to the definition of primary care services in § 425.400(c). Further, in light of the proposed changes, we proposed to make certain other technical changes to §§ 425.601, 425.602, and 425.603 for clarity and internal consistency.

We received public comments on the proposed revisions to HCPCS and CPT codes used for purposes of assignment in the Shared Savings Program regulations. The following is a summary of the comments we received and our responses.

Comment: Most commenters were generally supportive of our proposals regarding the expansion of the definition of primary care services for purposes of assignment in the Shared Savings Program regulations. Many comments indicated that the PHE for COVID–19 has led healthcare providers to expand their provision of services via telehealth, which has allowed beneficiaries to access to many services that otherwise might have been foregone due to the PHE. Furthermore, some commenters suggested that increased delivery of services via telehealth is likely to continue after the PHE, as healthcare providers and patients are increasingly accustomed to this service delivery modality and have found it to be a convenient and appropriate means for delivery of certain healthcare services. A few commenters noted it is vital that ACOs are held responsible for the correct cohort of patients, and these

[66] Refer to CMS, Medicare Learning Network, ''Advance Care Planning'' (ICN MLN909289, August 2019); available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AdvanceCarePlanning.pdf*.

[67] See for example, *CMS.gov*, Place of Service Code Set (updated October 2019); available at *https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set*.

changes to the definition of primary care services would help to 'move the needle' in that direction. One commenter stated that it has increased its provision of telehealth services exponentially due to the PHE and expects that the volume of these types of visits will remain elevated even after the PHE ends. This commenter stated its belief that these changes will be necessary to accurately reflect the Medicare patient population's health care utilization patterns going forward.

While most commenters supported the addition of Principal Care Management (PCM) codes G2064 and G2065 to the list of primary care services, a few commenters did not support adding the PCM codes. These commenters noted that these codes will primarily be used by specialists and while the scope and description of services for CCM and PCM may be similar, it does not necessarily follow that both services should be considered primary care services.

Response: We appreciate the commenters' support for our proposal to revise the definition of primary care services used for assignment under the Shared Savings Program regulations to include the following additions: (1) Online digital E/M CPT codes 99421, 99422, and 99423; (2) assessment of and care planning for patients with cognitive impairment CPT code 99483; (3) chronic care management code CPT code 99491; (4) non-complex chronic care management HCPCS code G2058 and its replacement CPT code 99439; (5) principal care management services HCPCS codes G2064 and G2065; and (6) psychiatric collaborative care model HCPCS code GCOL1, which is being finalized as HCPCS code G2214, as discussed elsewhere in this final rule. We agree that expanding the definition of primary care services used for beneficiary assignment will allow for more accurate assignment. While we appreciate the concerns raised by commenters regarding the addition of PCM codes G2064 and G2065, due to the similarity between the description of the PCM and CCM services, we continue to believe that these codes are a valuable addition to the definition of primary care services used for beneficiary assignment, because the full CCM scope of service requirements apply to PCM, and the CCM services are included in the Shared Savings Program's current definition of primary care services under § 425.400(c)(1)(iv). Additionally, consistent with our current methodology, if services billed under these codes are provided by specialists not used in the Shared Savings Program beneficiary assignment methodology, then they will not be included in beneficiary assignment. Therefore, we are finalizing our proposal to incorporate the aforementioned codes into the definition of primary care services that will be used in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. We are also finalizing our proposal to specify the updated definition of primary care services in a new provision of the regulations at § 425.400(c)(1)(v).

Comment: Several commenters supported the permanent addition of the remote evaluation of patient video/images (G2010) and virtual check-in (G2012) HCPCS codes to the Shared Savings Program definition of primary care services used for assignment, beginning with performance year 2021. These commenters indicated that virtual check-ins and remote evaluation of patient video/images are communications-based technology services that have proven their value across the disease spectrum and care continuum and should continue to be included in the definition of primary care services used for assignment after the PHE ends.

Response: We appreciate the comments in support of the permanent addition of the remote evaluation of patient video/images (G2010) and virtual check-in (G2012) HCPCS codes to the Shared Savings Program definition of primary care services used for assignment, beginning with performance year 2021. In the CY 2021 PFS proposed rule (85 FR 50245), we stated that, outside the context of the PHE for COVID–19, we did not expect these monitoring/check-in services for established patients to replace primary care services. This was because these separately billable brief communication-technology based services describe a check-in directly with the billing practitioner to assess whether an office visit is needed; and we believed that when the PHE for COVID–19 ends, these services would likely be replaced by an in-person primary care visit on which assignment would be based. However, based on comments received anticipating that healthcare providers will continue to provide the services identified by G2010 and G2012 and that there will continue to be an uptake of services identified by these codes in lieu of an in-person primary care visit by the beneficiary even following the end of the PHE for COVID–19, we are persuaded that including G2010 and G2012 in the Shared Savings Program definition of primary care services used for assignment, beginning with performance year 2021, would result in more accurate assignment of beneficiaries based on where they receive the plurality of their primary care services. We are therefore adding HCPCS codes G2010 and G2012 to the definition of primary care services for purposes of beneficiary assignment in the Shared Savings Program for the performance year starting on January 1, 2021, and subsequent performance years, as specified in the regulations at § 425.400(c)(1)(v).

Comment: Several commenters supported our proposal to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting. These commenters appreciated the concern that codes billed in an inpatient setting in the beneficiary assignment methodology may result in beneficiaries being assigned to an ACO based on inpatient care, rather than on primary care. However, one commenter was concerned that removing these services from the definition of primary care services used for assignment may inadvertently discourage healthcare provider from furnishing these services in inpatient settings. This commenter stated that evidence shows that usage of these billing codes is low, even though most Americans do not have advance directives. Therefore, the commenter suggested that advance care planning should be promoted, not in any way discouraged. Commenters also appreciated CMS' desire to ensure that beneficiaries are attributed to the ACOs from whom they receive their primary care services.

Response: We appreciate the support from commenters regarding our proposal to exclude advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting, for purposes of determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. Although we do not want to discourage the provision of advance care planning services or the appropriate use of the associated advance care planning codes, we do not believe that these services, when provided in an inpatient setting represent primary care services that should be used in assignment. In particular, we continue to have concerns that including these codes when billed in an inpatient setting may result in beneficiaries being assigned to an ACO based on inpatient care, rather than on primary care. By this, we mean that a beneficiary could be assigned to the ACO with which the physician providing inpatient care is associated,

which may be different from the ACO in which the physician from which the beneficiary typically receives primary care services in the community is participating, which could be disruptive to the beneficiary's overall care management. Therefore, we are finalizing our proposal to specify in § 425.400(c)(1)(v)(A)(*12*) that advance care planning services identified by CPT code 99497 and add-on code 99498 are excluded when furnished in an inpatient setting.

We did not receive comments regarding our proposal to exclude advanced care planning services claims billed under CPT codes 99497 and 99498 from use in the assignment methodology when there is an inpatient facility claim in our claims files with dates of service that overlap with the date of service for the professional service billed under CPT code 99497 or add-on code 99498. We also did not receive comments regarding the potential alternative method for determining whether advance care planning services are provided in an inpatient care setting. Specifically, we sought comment on whether to exclude advance care planning services identified by CPT code 99497 or add-on code 99498, or both, reported on claims with place of service code 21, which identifies the place of service as an inpatient hospital. Accordingly, we are finalizing as proposed the operational approach of excluding advanced care planning services claims billed under CPT codes 99497 and 99498 from use in the assignment methodology when there is an inpatient facility claim in our claims files with dates of service that overlap with the date of service for the professional service billed under CPT code 99497 or add-on code 99498. This operational approach is similar to the operational approach currently used to exclude certain codes for professional services furnished in a SNF under § 425.400(c)(1)(iv)(A)(*2*) and, as we discussed in the CY 2021 PFS proposed rule (85 FR 50246) captures slightly more claims than the alternative proposed approach We believe this more inclusive approach is appropriate in order to ensure that beneficiaries are assigned based on primary care services, not inpatient care services.

Comment: We received a couple of comments suggesting that CMS add the Primary Care Add-on HCPCS Code GPC1X, which is being finalized as HCPCS code G2211, as discussed elsewhere in this final rule, and the new Prolonged Services Add-on CPT Code 99417 (when the base code is also a primary care service code) to the list of primary care services used for assignment.

Response: We appreciate the feedback from commenters on our comment solicitation regarding any existing HCPCS or CPT codes and new HCPCS or CPT codes proposed in the CY 2021 PFS proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking. HCPCS G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious, or complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*) and prolonged visit add-on CPT code 99417 (*Prolonged office or other outpatient evaluation and management service(s) (beyond the total time of the primary procedure which has been selected using total time), requiring total time with or without direct patient contact beyond the usual service, on the date of the primary service; each additional 15 minutes (List separately in addition to CPT codes 99205, 99215 for office or other outpatient evaluation and management services)*) are used to report prolonged care provided to beneficiaries as an add-on to an E/M service. Under Medicare FFS payment policy, G2211 may be used in combination with certain E/M codes for new or established patients, including CPT codes 99201 through 99215, which are included within the definition of primary care services used for beneficiary assignment as specified under § 425.400(c).

Because we did not discuss adding add-on HCPCS Code G2211 and the prolonged services add-on CPT Code 99417, formerly CPT code 99XXX, to the list of primary care services used for assignment in the CY 2021 PFS proposed rule, we cannot finalize the inclusion of these codes in the definition of primary care services used for beneficiary assignment as specified under § 425.400(c), for the performance year beginning January 1, 2021, and subsequent performance years. We agree with commenters that G2211 and 99417 seem to fit within the definition of primary care services used for beneficiary assignment as specified under § 425.400(c). We will continue to evaluate and may consider the addition of these codes in future rulemaking.

In summary, after considering comments we received, we are finalizing the proposed definition of primary care services for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years, with a modification to include G2010 and G2012 in the definition of primary care services used in assignment. We are finalizing this definition in a new provision of the regulations at § 425.400(c)(1)(v), which includes the HCPCS and CPT codes specified in § 425.400(c)(1)(iv), as well as the following additional codes, and limitations on the use of certain codes:

- Online digital E/M CPT codes 99421, 99422, and 99423;
- Assessment of and care planning for patients with cognitive impairment CPT code 99483;
- Chronic care management code CPT code 99491;
- Exclusion of advance care planning CPT code 99497 and the add-on code 99498 when billed in an inpatient care setting;
- Remote evaluation of patient video/images HCPCS codes G2010;
- Virtual check-in HCPCS code G2012;
- Non-complex chronic care management HCPCS code G2058 and its replacement CPT code 99439 as finalized elsewhere in this final rule;
- Principal care management HCPCS codes G2064 and G2065; and
- Psychiatric collaborative care model HCPCS code GCOL1, which is being finalized as HCPCS code G2214, as discussed elsewhere in this final rule.

We did not receive comments specifically addressing our proposals for technical modifications, which we are finalizing without modification. Specifically, we are finalizing as proposed the technical modifications to the introductory text in § 425.400(c)(1)(iv) to specify the applicability of this provision for determining beneficiary assignment for performance years (or a performance period) during 2019 and performance year 2020. We are also finalizing the proposal to include technical modifications to the previously finalized descriptions of the CPT and HCPCS codes for consistency and clarity, including grammatical updates and ordering the codes sequentially, in the new provision at § 425.400(c)(1)(v).

We did not receive comments on our proposed conforming revisions to the regulations at §§ 425.601(a)(9), 425.602(a)(8), and 425.603(c)(8), to specify that CMS will adjust the ACO's historical benchmark to reflect any changes to the beneficiary assignment methodology specified in part 425, subpart E during an ACO's agreement period including revisions to the

definition of primary care services in § 425.400(c). Further, we did not receive comments on our proposed technical changes to §§ 425.601, 425.602, and 425.603 for clarity and internal consistency. We are finalizing these proposals without modification.

b. Exclusion From Assignment of Certain Services Reported by FQHCs or RHCs When Furnished in Skilled Nursing Facilities (SNFs)

(1) Background

As we described in section III.G.2.a.(1) of the proposed rule, under the Shared Savings Program, we define primary care services in § 425.400(c)(1) and (2) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the specified HCPCS and CPT codes. In the November 2018 final rule (83 FR 59965 through 59968), we finalized a policy, specified in the regulation at § 425.400(c)(1)(iv)(A)(*2*) and effective for performance years starting on January 1, 2019, and subsequent performance years, to exclude services billed under CPT codes 99304 through 99318 when such services are furnished in a SNF. As described in the earlier rulemaking, CPT codes 99304 through 99318 are used for reporting E/M services furnished by physicians and other practitioners in a SNF or NF (83 FR 59964).

In the November 2018 final rule, we explained our operational approach to excluding CPT codes 99304 through 99318 from use in the assignment methodology when such services are furnished in a SNF. We explained that we would exclude professional services claims billed under CPT codes 99304 through 99318 from use in the assignment methodology when there is a SNF facility claim in our claims files with dates of service that overlap with the date of service for the professional service (83 FR 59967). This exclusion methodology replaced the prior approach, established through earlier rulemaking (80 FR 71271 and 71272), which excluded from the definition of primary care services claims billed under CPT codes 99304 through 99318 when the claim included the place of service code 31 modifier, specifying that the service was furnished in a SNF.

In earlier rulemaking (see for example, 83 FR 59964 and 59965), we have explained our belief that excluding from assignment certain services rendered to beneficiaries during a SNF stay is appropriate because it helps to ensure that beneficiaries who receive care in a SNF are assigned to ACOs based on care received from primary care professionals in the community (including nursing facilities), who are typically responsible for providing care to meet the primary care needs of these beneficiaries. We previously explained that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. Although their care may be coordinated during their time in the SNF, they are then transitioned back into the community to the primary care professionals who are typically responsible for providing care to meet their primary care needs.

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, requires the Secretary to assign beneficiaries to ACOs participating in the Shared Savings Program based not only on their utilization of primary care services furnished by ACO professionals who are physicians but also on their utilization of services furnished by FQHCs and RHCs, effective for performance years beginning on or after January 1, 2019. The statute provides the Secretary with broad discretion to determine how to incorporate services provided by FQHCs and RHCs into the Shared Savings Program beneficiary assignment methodology.

In earlier rulemaking, we established and modified special assignment conditions for FQHCs and RHCs (see for example, 82 FR 53210 through 53212). According to § 425.404(b), for performance years starting on January 1, 2019, and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC or RHC claim as a primary care service performed by a primary care physician. Therefore, according to the Shared Savings Program's step-wise claims-based assignment methodology, as specified in § 425.402(b), all services furnished by an FQHC or RHC to a beneficiary eligible for assignment to an ACO are considered in the first step of the assignment methodology. As specified in § 425.402(b)(3), under this first step, a beneficiary eligible for assignment is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

Currently, the exclusion from beneficiary assignment of professional services claims with CPT codes 99304 through 99318, when there is an overlapping SNF stay, does not apply to services billed through FQHCs/RHCs. Because FQHC/RHC claims are submitted to CMS using institutional claim forms, we currently do not exclude these FQHC/RHC claims from assignment when a service billed under CPT codes 99304 through 99318 is provided concurrently with a SNF stay, as when claims for services billed under these codes are submitted by physicians and other practitioners. Rather, consistent with the requirement in § 425.404(b), we consider all FQHC/RHC claims for purposes of beneficiary assignment.

(2) Revisions

As discussed in the CY 2021 PFS proposed rule (85 FR 50247), an ACO has raised concerns that our methodology for excluding primary care services billed under CPT codes 99304 through 99318 from use in beneficiary assignment when provided during a beneficiary's stay in a SNF does not apply to these services when billed by FQHCs. The ACO described a circumstance where ACO professionals, billing through ACO participant FQHCs, submitted claims using CPT codes 99304 through 99318 for services provided to patients in SNFs. Specifically, the ACO participant FQHCs' physicians provided services billed under these codes to beneficiaries in community SNFs. Following discharge from the SNF, these beneficiaries returned to receiving care from their regular primary care physicians (outside the ACO). However, because the SNF exclusion for services billed under CPT codes 99304 through 99318 does not apply to services furnished by FQHCs/RHCs, these beneficiaries were assigned to the ACO in which the FQHC was an ACO participant based on the services rendered in the SNF. We believe this result is contrary to the original intention of our policy of excluding claims billed under CPT codes 99304 through 99318 for professional services furnished during a SNF stay from consideration in the assignment methodology, as described in the background for this section.

Section 1899(c)(1) of the Act provides discretion for the Secretary to determine the appropriate method to utilize services provided by FQHCs and RHCs in conducting assignment for performance years beginning on or after January 1, 2019. As discussed in the proposed rule, we believe it is important

to exclude claims for FQHC and RHC services that include CPT codes 99304 through 99318 from use in assignment when there is a SNF facility claim in our claims files with a date of service that overlaps with the date of FQHC or RHC services. Consistent with the previously established exclusion for claims billed under these codes when the services are provided to beneficiaries with an overlapping SNF stay, we believe it is important to exclude the same services from use in assignment when they are furnished by physicians and NPPs billing through an FQHC or RHC to beneficiaries in a SNF. As we explained in the CY 2021 PFS proposed rule, this approach would better recognize that beneficiaries who receive care from physicians and NPPs billing through an FQHC or RHC during a SNF stay are expected to return to receiving primary care from the health care professionals typically responsible for meeting their primary care needs when they transition back into the community.

Therefore, we proposed to revise the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF. Operationally, the exclusion would occur when the following conditions are met:

(1) Either a professional service is billed under CPT codes 99304 through 99318, or an FQHC/RHC submits a claim including a qualifier CPT code 99304 through 99318; and

(2) A SNF facility claim is in our claims files with dates of service that overlap with the date of service for the professional service or FQHC/RHC service.

As discussed in section III.G.2.a.(2) of the proposed rule, we proposed to incorporate the revised definition of primary care services in a new provision of the Shared Savings Program regulations at § 425.400(c)(1)(v), applicable for use in determining beneficiary assignment for the performance year starting on January 1, 2021, and subsequent performance years. As part of this revised definition, we proposed to incorporate the proposed revisions to the exclusion for CPT codes 99304 through 99318 when services are furnished in a SNF at § 425.400(c)(1)(v)(A)(*3*) to extend the exclusion to services identified by these codes reported on an FQHC or RHC claim when furnished in a SNF. We proposed that this revision would also be applicable to determining assignment for the performance year starting on January 1, 2021, and subsequent performance years.

As we explained in section III.G.2.a.(2) of the proposed rule, we adjust the ACO's historical benchmark for changes in the program's assignment methodology occurring during the ACO's agreement period. We stated in the proposed rule that, if we finalized the proposed exclusion from beneficiary assignment of services reported by FQHCs or RHCs on claims that include CPT codes 99304 through 99318, when furnished in a SNF, we would adjust ACOs' historical benchmarks to account for these changes.

Further, we noted that we believe the existing process is appropriately excluding from assignment professional services billed under CPT codes 99304 through 99318 when these services are provided to beneficiaries receiving SNF services in swing beds in Critical Access Hospitals (CAHs) or Electing Teaching Amendment (ETA) hospitals. Based on our operational experience:

- We exclude professional services billed under CPT codes 99304 through 99318 when such services are furnished for care of a beneficiary in a CAH swing bed; however, relatively few claims are identified for exclusion on this basis.
- We do not believe that ETA hospitals are billing for services furnished to beneficiaries in a SNF or swing bed setting by physicians and other practitioners that have reassigned their billing rights to ETA hospitals.

However, we solicited comment on whether additional exceptions are needed to ensure that all claims for services that include CPT codes 99304 through 99318 are excluded from assignment when those services are furnished to a beneficiary receiving SNF care, including when these professional services are billed by a Method II CAH or ETA hospital.

We received public comments on the proposed revisions to exclude from assignment certain services reported by FQHCs or RHCs when furnished in SNFs. We received no comments regarding additional exceptions that may be needed to ensure that all claims for services that include CPT codes 99304 through 99318 are excluded from assignment when those services are furnished to a beneficiary receiving SNF care, including when these professional services are billed by a Method II CAH or ETA hospital.

The following is a summary of the comments we received and our responses.

Comment: Commenters were overwhelmingly supportive of CMS' proposal to exclude professional services furnished by FQHCs or RHCs when delivered in a SNF, for purposes of assignment. Several commenters stated that this policy would ensure parity between FQHC practitioners, including physicians, and practitioners who practice in other settings, with respect to this issue. One commenter stated that, because FQHCs do not use place of service codes or other indicators that would demonstrate that a claim is eligible for exclusion, their claims are always considered primary care claims under current policy, even when the services are furnished in a SNF. These claims are then used for ACO beneficiary attribution, to the disadvantage of ACOs that include FQHCs as participants. Commenters noted that the proposed change, while technical in nature, would result in more accurate beneficiary assignment lists for ACOs.

Response: We agree with commenters that this policy will allow for more accurate assignment of beneficiaries. Accordingly, we are finalizing our proposal to revise the existing exclusion for professional services billed under CPT codes 99304 through 99318 that are furnished in a SNF to include services reported on an FQHC or RHC claim that includes CPT codes 99304 through 99318, when those services are furnished in a SNF. By finalizing this policy, we will have a more consistent and accurate assignment approach. We are finalizing the definition of primary care services for use in beneficiary assignment for performance years starting on January 1, 2021, and subsequent performance years in the regulations at § 425.400(c)(1)(v), which includes the codes for professional services furnished in a nursing facility (CPT codes 99304 through 99318) at § 425.400(c)(1)(v)(A)(*3*). The provision at § 425.400(c)(1)(v)(A)(*3*) specifies that professional services or services reported on an FQHC or RHC claim identified by these codes are excluded from the definition of primary care services when furnished in a SNF.

3. Reducing the Amount of Repayment Mechanisms for Eligible ACOs

a. Background

An ACO that will participate in a two-sided model must demonstrate that it has established an adequate repayment mechanism to provide CMS assurance of its ability to repay shared losses for which the ACO may be liable upon reconciliation for each performance year. The requirements for an ACO to establish and maintain an adequate repayment mechanism are described in § 425.204(f), and we have provided additional program guidance on

repayment mechanism arrangements.[68] We established the repayment mechanism requirements through earlier rulemaking,[69] and recently modified the repayment mechanism requirements in the December 2018 final rule (83 FR 67928 through 67938).

According to § 425.204(f)(4)(iv), in the case of an ACO that has submitted a request to renew its participation agreement and wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to the greater of the following: (1) The amount calculated by CMS in accordance with § 425.204(f)(4)(ii) at the time of renewal application; or (2) the repayment mechanism amount that the ACO was required to maintain during the last performance year of the participation agreement it seeks to renew. This approach ensures that a renewing ACO would remain capable of repaying losses incurred under its old agreement period (83 FR 67931). Based on our operational experience with implementing these policies, of 55 renewing two-sided model ACOs for a July 1, 2019, or January 1, 2020 start date, 43 ACOs (or 78.2 percent) elected to continue use of their existing repayment mechanism, and 22 (or 51.2 percent) of these ACOs had a higher existing repayment mechanism amount compared to the amount calculated for the new agreement period (determined at the time of renewal application).

Alternatively, to meet the requirements of § 425.204(f), a renewing ACO could establish a new repayment mechanism arrangement to support its participation in its new agreement period, in addition to maintaining its existing repayment mechanism. This option allows an ACO to establish a repayment mechanism to support its new agreement period at a potentially different amount (determined according to § 425.204(f)(4)(ii)) than the amount of the existing arrangement. However, under this approach there is a period of time during which the ACO must maintain multiple repayment mechanisms. The ACO must maintain the repayment mechanism established to support the ACO's previous agreement period until the term of the repayment mechanism arrangement expires, or conditions arise to allow for termination of the repayment mechanism according to § 425.204(f)(6)(iv) (see 83 FR 67933 through 67936). Once the repayment mechanism for the previous agreement period is closed, the ACO would be required to maintain only the repayment mechanism arrangement applicable to its current agreement period. An ACO could use this option to establish a repayment mechanism at a relatively lower amount (if applicable) for its current agreement period, while maintaining and eventually closing-out a repayment mechanism at a relatively higher amount needed for its previous agreement period.

As specified under § 425.204(f)(4)(iii), for agreement periods beginning on or after July 1, 2019, CMS recalculates the ACO's repayment mechanism amount before the second and each subsequent performance year in the agreement period based on the certified ACO participant list for the relevant performance year. We require an increase in the repayment mechanism amount if the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least 50 percent or $1,000,000, whichever is the lesser value. Under § 425.204(f)(4)(iii), an ACO cannot decrease the amount of its repayment mechanism during its agreement period as a result of changes in its composition.

In implementing the revised repayment mechanism rules, we have discovered some unintended consequences. Specifically, under § 425.204(f)(4), a renewing ACO that chooses to retain its higher repayment mechanism for a new agreement period might never be able to reduce its repayment mechanism even after the ACO has paid any shared losses incurred for performance years in the previous agreement period. Moreover, the ACO would have to maintain the higher repayment mechanism amount in future agreement periods unless the ACO opts to establish a new repayment mechanism. We did not intend this result.

More generally, based on our operational experience, many ACOs fully repay shared losses without use of their repayment mechanism arrangement. For example, of the eleven ACOs that owed shared losses for performance year 2018, CMS used the repayment mechanism for one ACO to support recoupment. Considering this experience, which suggests there may be low risk to the Shared Savings Program by allowing lower repayment mechanism amounts, and the potential reduction in burden on ACOs by lower repayment mechanism amounts, we revisited in the CY 2021 PFS proposed rule the policies requiring renewing ACOs to retain higher repayment mechanism amounts when these amounts may no longer be needed to support their continued participation.

b. Revisions

In the CY 2021 PFS proposed rule (85 FR 50248 through 50251), we proposed to establish two policies that would allow certain ACOs to benefit from a lower repayment mechanism amount than would otherwise be required under the current regulations. Under the first proposed policy, a renewing ACO that uses an existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in its new agreement period may reduce its existing repayment mechanism amount if the repayment mechanism amount calculated for the new agreement period is less than the amount of the existing repayment mechanism. The second proposed policy would permit certain ACOs whose agreement periods began July 1, 2019 or January 1, 2020 to elect to reduce the amount of their repayment mechanisms.

Under § 425.204(f)(4)(iv), a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period must maintain its existing repayment mechanism amount if it is higher than the repayment mechanism amount calculated for the new agreement period in accordance with § 425.204(f)(4)(ii). We proposed to discontinue this policy by revising the regulations to specify that we will determine the repayment mechanism amount for such a renewing ACO only according to the methodology currently specified in § 425.204(f)(4)(ii). Under the proposed approach, a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period would be required to have a repayment mechanism amount equal to the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS

[68] Medicare Shared Savings Program, Repayment Mechanism Arrangements, Guidance Document, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Repayment-Mechanism-Guidance.pdf* (herein Repayment Mechanism Arrangements Guidance).

[69] See 76 FR 67937 through 67940 (establishing the requirement for Track 2 ACOs). See 80 FR 32781 through 32785 (adopting the same general requirements for Track 3 ACOs with respect to the repayment mechanism and discussing modifications to reduce burden of the repayment requirements on ACOs).

revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

As specified in the May 8th COVID–19 IFC (85 FR 27574 and 27575), we are forgoing the application cycle for the January 1, 2021 start date. Therefore, the proposed policy for determining the repayment mechanism amount for renewing ACOs would apply with the application cycle for an agreement period starting on January 1, 2022, and in subsequent years.

As discussed in the CY 2021 PFS proposed rule (85 FR 50249), a renewing ACO could still choose to establish a new repayment mechanism arrangement for the amount calculated at the time of the renewal application to support its participation in its new agreement period and maintain its existing repayment mechanism at the previously required amount. Once the conditions arise for termination of the repayment mechanism arrangement supporting the ACO's previous agreement period, according to § 425.204(f)(6)(iv), only the arrangement supporting the ACO's current agreement period would remain.

In the CY 2021 PFS proposed rule (85 FR 50249), we explained our belief that the proposed approach would reduce burden by allowing renewing ACOs that wish to continue use of their existing repayment mechanism to decrease their repayment mechanism amount if a higher amount is not needed to support their new agreement period. As discussed in the CY 2021 PFS proposed rule, the proposal would prevent a higher repayment mechanism amount from following the ACO from one agreement period to the next, as is the case with the current approach. Further, an ACO would no longer need to establish another repayment mechanism for the ACO's new agreement period to ultimately get relief from the higher amount of its existing repayment mechanism arrangement, which the ACO would need to maintain until the conditions arise allowing for termination.

As discussed in the CY 2021 PFS proposed rule, we recognize that the proposal would reduce the amount available to support repayment of shared losses. The typical timing of issuance to ACOs of financial reconciliation, which includes performance results and written notification from CMS of the amount of shared losses owed (if any), is in the summer following the conclusion of the performance year. Renewing ACOs permitted to reduce the amount of their existing repayment mechanism may be notified of shared losses owed for their most recent prior performance year during the application review period and would be in the process of paying shared losses within 90 days of written notification from CMS of the amount owed (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)). Further, at the time of renewal application, the ACO would be completing the last performance year of its existing agreement period, and financial reconciliation results for this performance year would likely be available during the summer of the ACO's first performance year of its new agreement period.

However, as discussed in the CY 2021 PFS proposed rule, we believe this risk to CMS noted above is mitigated for a number of reasons. The Shared Savings Program's existing policies require ACOs to pay shared losses, in full, within 90 days of written notification from CMS of the amount owed (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)). ACOs have an interest in fully paying the amount of shared losses owed within the 90-day payment window to remain in compliance with the Shared Savings Program's requirements and avoid compliance actions including involuntary termination from the program. CMS may terminate an ACO's participation agreement for reasons including, but not limited to, non-compliance with requirements in part 425 (§ 425.218(b)(1)), such as failure to repay shared losses owed according to the program's regulations and may take pre-termination actions as described in § 425.216. Under § 425.221(b)(2)(ii)(B), an ACO under a two-sided model whose participation agreement is terminated by CMS under § 425.218 is liable for a pro-rated share of any shared losses determined for the performance year during which the termination becomes effective. ACOs must also repay shared losses owed to avoid accruing interest on any amount that remains unpaid after the 90-day payment window, and referral of an unpaid debt to the Department of Treasury for collection. Based on our operational experience, nearly all ACOs fully repay shared losses without use of their repayment mechanism arrangement.

Nevertheless, in the CY 2021 PFS proposed rule we considered finalizing a policy that would require a renewing ACO to maintain its existing, higher repayment mechanism amount until the ACO has fully repaid the amount of shared losses determined to be owed for the most recent performance year for which financial reconciliation results are available. Under this approach, for instance, § 425.204(f)(4)(iv) would remain unchanged, and we would amend § 425.204(f)(4)(iii) to add a provision permitting a renewing ACO to reduce the amount of its repayment mechanism.

As discussed in the CY 2021 PFS proposed rule, the Shared Savings Program regulations do not address the opportunity for a re-entering ACO, defined according to § 425.20, to use a repayment mechanism arrangement established to support its participation in an earlier agreement period to also support its participation in a new agreement period. As defined at § 425.20, a ''re-entering ACO'' may or may not be the same legal entity that previously participated in the Shared Savings Program. Specifically, a ''re-entering ACO'' is defined to include the following: (1) An ACO that is the same legal entity as an ACO that previously participated in the program and is applying to participate in the program after a break in participation due to early termination of its participation agreement or the expiration and non-renewal of its participation agreement; and (2) a new legal entity that has never participated in the Shared Savings Program, provided that more than 50 percent of its ACO participants were included on the ACO participant list of the same ACO in any of the 5 most recent performance years prior to the agreement start date for the new legal entity.

In the CY 2021 PFS proposed rule, we stated that we were considering finalizing provisions specifying the conditions under which a re-entering ACO may use an existing repayment mechanism arrangement to support its participation in a subsequent agreement period in the Shared Savings Program. Specifically, because a repayment mechanism is valid only with respect to amounts owed by the legal entity to whom or on whose behalf it was issued, we stated that we were considering specifying in the final rule that a re-entering ACO may use its existing repayment mechanism only if it is the same legal entity as the ACO that previously participated in the program. We stated that this option for continued use of an existing repayment mechanism would not be feasible for (and therefore would not be applicable to) a re-entering ACO that is not the same legal entity as the ACO that previously participated in the program and is identified on the repayment mechanism documentation (that is, the proposed policy would not apply to an ACO identified as a re-entering ACO because more than 50 percent of its ACO participants were included on the ACO participant list for a single ACO in

any of the 5 most recent performance years prior to the agreement start date).

We also proposed to establish a second policy that would allow certain ACOs a one-time opportunity to decrease the amount of their repayment mechanisms. Under this proposal, an ACO that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism if (1) upon renewal, it elected to use an existing repayment mechanism to establish its ability to repay any shared losses incurred in its new agreement period and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated for the ACO's new agreement period; and (2) the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount. We noted that the proposal would not be finalized if we finalized our alternate proposal described above to modify § 425.204(f)(4)(iii) to permit a renewing ACO to reduce the amount of its repayment mechanism after the ACO fully repaid the amount of shared losses determined to be owed for the final performance year of its prior agreement period. We explained that the purpose of this second proposal is to let any ACO that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, to decrease its repayment mechanism amount before it seeks to renew its current agreement under the first proposed policy, which if finalized, would otherwise be the earliest opportunity for the ACO to reduce its repayment mechanism amount.

To determine if an ACO that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, is eligible for the one-time opportunity to lower its repayment mechanism amount, we proposed to compare the recalculated amount of the ACO's repayment mechanism based on its certified ACO participant list for performance year 2021, calculated according to § 425.204(f)(4)(iii), to the ACO's existing repayment mechanism amount. If the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount, the ACO would be eligible to decrease the amount of its repayment mechanism to the recalculated amount. Under this approach, we would permit a decrease in the repayment mechanism amount even for relatively small differences in dollar amounts. However, an ACO may wish to maintain the existing amount of its repayment mechanism arrangement, particularly if the cost to the ACO of amending the arrangement outweighs the potential benefit of a nominal decrease in the amount of the repayment mechanism.

We proposed that CMS would notify the ACO in writing that the ACO may elect to decrease the amount of its repayment mechanism. We explained that if we finalized our proposal to allow a one-time opportunity for a repayment mechanism decrease by eligible ACOs that renewed for an agreement period beginning on July 1, 2019, or beginning on January 1, 2020, we would notify an ACO that it may elect to reduce its repayment mechanism amount after the start of performance year 2021. We also proposed that an ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS would review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of § 425.204(f).

Regarding the timeframe for an ACO to elect to decrease the amount of its repayment mechanism, we indicated that we might require an ACO to submit its election, together with revised repayment mechanism documentation, within 30 days from the date of the written notice from CMS, particularly if prompt election is needed to ensure compliance with other program requirements. For instance, CMS may notify the ACO that it may elect to decrease the amount of its repayment mechanism after using the ACO's existing repayment mechanism to support repayment of shared losses. In this case, prompt notification by the ACO of its election to decrease the amount of its repayment mechanism may be necessary if the ACO seeks to replenish the amount of its repayment mechanism to the permitted lower amount within the 90-day replenishment period according to § 425.204(f)(5). However, we recognized that there may be circumstances that necessitate a longer timeframe.

We proposed to amend § 425.204(f)(4)(iv) by removing the introductory text and specifying in paragraph (f)(4)(iv)(A) the revised methodology for determining the repayment mechanism amount for renewing ACOs that seek to use their existing repayment mechanism to support their continued participation in their new agreement period. We proposed to revise § 425.204(f)(4)(iv)(B) to establish the policy and relevant procedure for allowing eligible ACOs with July 1, 2019, or January 1, 2020 start dates to elect to lower the amount of their repayment mechanism arrangements.

We proposed to amend § 425.204(f)(5), which requires an ACO to replenish the amount of funds available through the repayment mechanism within 90 days of use of the arrangement to repay any portion of shared losses. Specifically, we proposed to specify that the resulting amount available through the repayment mechanism after replenishment must be at least the amount specified by CMS in accordance with § 425.204(f)(4). For example, these revisions would allow an eligible ACO, that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, to replenish the repayment mechanism to the lower amount determined by CMS, according to the proposed approach described in the CY 2021 PFS proposed rule. As proposed, the revision may also be relevant to a renewing ACO that is seeking to use its existing repayment mechanism to support its participation in its new agreement period. Specifically, if the renewing ACO's existing repayment mechanism is used to support payment of shared losses, based on financial reconciliation results available at the time of renewal application, CMS may permit the renewing ACO to replenish the amount of its existing repayment mechanism to the lower amount determined to be applicable for the ACO's new agreement period.

We also proposed technical changes to § 425.204(f)(3)(iv) for clarity. This provision specifies that an ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period, and describes the conditions under which an ACO may use its current repayment mechanism to apply to the new agreement period. For clarity, we proposed to specify under this provision that the duration of the existing repayment mechanism must be revised to comply with § 425.204(f)(6)(ii), and the amount of the repayment mechanism must comply with § 425.204(f)(4).

Further, we proposed that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism. Based on our operational experience, ACOs periodically request to close-out their

existing repayment mechanisms and establish new repayment mechanisms to support their continued participation under a two-sided model. We have typically permitted these requests, under the following circumstances: We first ensure the ACO's new repayment mechanism meets the program's requirements and is fully executed; and then we permit cancellation of the repayment mechanism arrangement(s) being replaced. Further, when reviewing requested modifications to repayment mechanism documentation it is our practice to ensure that all the terms of the repayment mechanism are compliant with the program's policies. Therefore, we proposed to revise the regulations in § 425.204(f)(3)(i) through (iii) to further specify that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism.

We received public comments on the proposals for reducing the amount of repayment mechanisms for eligible ACOs. The following is a summary of the comments we received and our responses.

Comment: Many commenters addressing the program's repayment mechanism policies expressed their support for CMS' proposal to eliminate the requirement that renewing ACOs that wish to continue use of their existing repayment mechanism maintain the higher repayment mechanism amount in their subsequent agreement period, when a lower amount is calculated at the time of renewal application.

One commenter commended CMS for addressing the unintended consequences of ACOs having to maintain a higher-than-required repayment mechanism as they transition to new agreement periods.

One commenter acknowledged CMS' consideration of an alternative that would require renewing ACOs to maintain existing, higher repayment mechanism amounts until they have fully repaid any shared losses owed for the most recent performance year. This commenter stated its belief that other enforcement mechanisms, such as possible pre-termination actions and accruing interest for not repaying shared losses, are sufficient to warrant timely repayment of shared losses.

Response: We are finalizing the proposed changes to determining the amount for repayment mechanisms for renewing ACOs that elect to continue use of their existing repayment mechanism to support their continued participation in a new agreement period, to permit the amount of these arrangements to be reduced.

Under this final policy, specified in revisions to § 425.204(f)(4)(iv)(A), a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period will be required to have a repayment mechanism amount equal to the lesser of the following, as currently specified in § 425.204(f)(4)(ii): (1) 1 Percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available. As we described in the CY 2021 PFS proposed rule, and restated in this section of this final rule, these modifications apply to the application cycle for an agreement period starting on January 1, 2022, and in subsequent years.

We are not adopting the alternative we described in the CY 2021 PFS proposed rule, under which we would require a renewing ACO to maintain its existing, higher repayment mechanism amount until the ACO has fully repaid the amount of shared losses determined to be owed for the most recent performance year for which financial reconciliation results are available. Although the policy changes we are finalizing for determining the amount for repayment mechanisms for renewing ACOs may reduce the amount available to CMS to support repayment of shared losses in some cases, we believe the potential burden reduction for ACOs outweighs the risk to CMS. We continue to believe the risk to CMS of reduced repayment amounts for supporting repayment of shared losses is mitigated because the effect of other policies is to encourage compliance with the requirement that ACOs timely repay shared losses in full. As described in the proposed rule and reiterated in this section of the this final rule, ACOs have an interest in fully paying the amount of shared losses owed within the 90-day payment window (according to §§ 425.605(e)(3), 425.606(h)(3), 425.610(h)(3)); timely payment in full allows the ACO to remain in compliance with the Shared Savings Program's requirements and to avoid compliance actions, including involuntary termination from the program and related payment consequences of early termination. Also, timely payment in full of shared losses allows an ACO to avoid accruing interest charges on any unpaid shared losses and referral of an unpaid debt to the Department of Treasury for collection.

Comment: One commenter generally supported the approach that CMS sought comment on for allowing a re-entering ACO identified as the same legal entity as an ACO that previously participated in the program to use that ACO's existing repayment mechanism to support its participation in a new agreement period.

Response: We appreciate the commenter's support for this consideration. We are finalizing this approach by amending § 425.204(f)(4)(iv)(A) to specify that the requirements regarding use of an existing repayment mechanism arrangement to support the ACO's participation in a new agreement period in the Shared Savings Program will apply to both a renewing ACO, and a re-entering ACO that is the same legal entity that previously participated in the Shared Savings Program (either an ACO whose participation agreement expired without having been renewed, or an ACO whose participation agreement was terminated under § 425.218 or § 425.220). Specifically, if a renewing ACO or re-entering ACO that is the same legal entity as an ACO that previously participated in the program wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to at least the amount calculated by CMS in accordance with § 425.204(f)(4)(ii), which is the lesser of the following: (1) 1 percent of the total per capita Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available; or (2) 2 percent of the total Medicare Parts A and B FFS revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available.

Section 425.204(f)(3)(iv), as amended by this final rule, describes repayment mechanism documentation requirements, and specifies the condition under which a renewing ACO may use its existing repayment mechanism to support its continued participation under a new agreement period. To apply similar requirements to eligible, re-entering ACOs, we are revising the regulations to add a new paragraph (f)(3)(v) to § 425.204 to specify that an ACO that has submitted

an application to the program after a break in participation must submit as part of its application, documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the re-entering ACO, provided that the ACO is the same legal entity as an ACO that previously participated in the program, and the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with § 425.204(f)(6)(ii) and the amount of the repayment mechanism complies with § 425.204(f)(4).

We are revising § 425.204(f)(6)(ii), which specifies the required duration for repayment mechanisms for a renewing ACO that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period. Specifically, we are revising paragraph (ii) to make it applicable to re-entering ACOs that are the same legal entity as an ACO that previously participated in the program. With these modifications, the provision specifies that a renewing ACO, or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, must amend its existing repayment mechanism to meet either § 425.204(f)(6)(ii)(A) or (B). Respectively, these provisions specify the following:

- The duration of the existing repayment mechanism is extended by an amount of time that covers the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.
- The duration of the existing repayment mechanism is extended, if necessary, to cover a term of at least the first two performance years of the new agreement period and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the new agreement period plus 12 months following the conclusion of the new agreement period.

Comment: Commenters expressed support for CMS' proposed approach that provides a one-time opportunity for eligible ACOs that renewed their agreement periods beginning on July 1, 2019 or January 1, 2020, and elected to continue use of their existing repayment mechanism at a higher amount, to decrease their repayment mechanism amount if the recalculated amount for performance year 2021 is less than the existing amount.

Some commenters expressed support for an approach that would allow any ACO the option to decrease its repayment mechanism amount if the recalculated amount for the performance year is less than the current repayment mechanism amount and requested that CMS finalize this policy.

Response: We are finalizing the proposed policy at § 425.204(f)(4)(iv)(B), which grants a one-time opportunity for an ACO that renewed its agreement period beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of its repayment mechanism if (1) upon renewal, it elected to use an existing repayment mechanism to establish its ability to repay any shared losses incurred in its new agreement period and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated for the ACO's new agreement period; and (2) the recalculated repayment mechanism amount for performance year 2021 is less than the existing repayment mechanism amount.

At this time, we decline commenters' suggestions to establish a policy to allow for annual repayment mechanism decreases by all two-sided model ACOs, if the recalculated amount for the performance year is lower than their existing repayment mechanism amount. This alternative goes beyond the scope of the modifications we proposed to the program's repayment mechanism requirements. However, we will consider commenters' suggestions and we may revisit this issue in future notice and comment rulemaking.

Comment: One commenter addressing the proposed one-time opportunity for eligible renewing ACOs with a July 1, 2019 and January 1, 2020 start date, to elect to decrease their repayment mechanism amount, urged CMS to consider allowing these ACOs longer than 30 days to submit elections to reduce their repayment mechanism amounts, particularly given the circumstances of COVID–19. However, the commenter did not provide additional details on an alternative timeframe for this election.

Response: We proposed that such elections must be submitted ''by a deadline specified by CMS'' and noted that the deadline might be 30 days from the date of CMS' written notification to the ACO, of its one-time opportunity to decrease its repayment mechanism amount. We appreciate the commenter's concern that an ACO may need more than 30 days to submit its election and the revised repayment mechanism documentation. We are not finalizing a 30-day deadline in regulation text, although such a deadline may ultimately be necessary depending on the circumstances. We continue to believe it is important for ACOs to promptly elect the option for a repayment mechanism decrease, particularly when prompt election is needed to ensure compliance with other program requirements. Consistent with our existing approach to supporting ACOs in meeting repayment mechanism requirements, we anticipate working closing with ACOs to ensure the documentation they provide is sufficient.

We are finalizing the proposed policy by revising § 425.204(f)(4)(iv)(B) to specify that CMS will notify an eligible ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism. We are also finalizing as proposed the policy that the ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of § 425.204(f).

Comment: Some commenters explained that securing a repayment mechanism is a regulatory burden, which is time consuming and costly for ACOs. While some commenters expressed their appreciation for CMS' efforts to minimize burdens associated with the repayment mechanism through the changes proposed with the CY 2021 PFS proposed rule, they also urged CMS to take additional steps to minimize burdens on ACOs associated with repayment mechanism requirements.

Some commenters explained that many ACOs cite the burden and cost of securing a repayment mechanism as reasons not to move to a performance-based risk model. Commenters urged CMS to remove the repayment mechanism requirement when an ACO can prove that it has an investor or financial backer with a demonstrated high credit rating, instead of requiring the ACO to incur the costs of obtaining a repayment mechanism, and thereby direct the ACO's resources away from its core mission of improving patient

care. As suggested by the commenters, financial backers could include outside investors, insurers or hospitals or health systems that are aligned with the ACO and committed to providing financial support, which would be available should losses occur. These commenters noted that this assurance would protect the Medicare Trust Funds in the event the ACO has losses while avoiding the financial inefficiency and regulatory burden of involving outside financial institutions.

These commenters also noted that this alternative approach would also eliminate the need to have a 24-month ''tail period''. Although not specifically stated, we believe commenters are referring to a requirement that ACOs maintain their repayment mechanism for a period of time following the conclusion of the ACO's agreement period. Commenters explained that the additional burden of a 24-month tail period heightens concerns, and increases financial requirements for ACOs. Should CMS maintain requirements for a repayment mechanism, commenters requested that CMS minimize this regulatory and financial burden by removing the requirement for tail period coverage. Commenters indicated this was especially important considering longer agreement periods.

Response: We note that commenters' alternative suggestions, for removing or significantly revising the repayment mechanism requirements, go beyond the scope of the proposals to revise the repayment mechanism requirements discussed in the CY 2021 PFS proposed rule. We decline the commenters' suggestions, including to establish alternative pathways for ACOs to demonstrate their ability to repay shared losses or to shorten the duration for which a repayment mechanism must be available.

We are concerned that commenters' references to a 24-month ''tail period'' requirement suggest a misunderstanding of the existing requirements for the duration of a repayment mechanism. Although in recent rulemaking (83 FR 67933 through 67937) we proposed requiring repayment mechanisms to be in effect for the duration of the ACO's participation in a two-sided model plus 24 months after the conclusion of the agreement period, we ultimately finalized an approach (taking into consideration public comments on our proposals) that requires the repayment mechanism to be available for 12 months following the conclusion of the ACO's agreement period. In brief, as specified under § 425.204(f)(6), the repayment mechanism must be in effect for the duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period, and this can be demonstrated by either of the following: (1) The repayment mechanism covers the entire duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period; or (2) the repayment mechanism covers a term of at least the first 2 performance years in which the ACO is participating under a two-sided model and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in effect for the duration of the agreement period plus 12 months following the conclusion of the agreement period.

As we have explained in previous rulemaking (see for example, 83 FR 67933, and 80 FR 32783), this tail period must be sufficient to permit CMS to calculate the amount of any shared losses that may be owed by the ACO and to collect this amount from the ACO. This is necessary, in part, because financial reconciliation results are not available until the summer following the conclusion of the performance year, and ACOs have 90 days to make payment in full once they are notified of shared losses based on financial reconciliation (see §§ 425.605(e), 425.606(h), and 425.610(h)). Therefore, we continue to believe that a requirement that an ACO's repayment mechanism be available for 12 months following the conclusion of its agreement period is critical to ensuring the availability of the repayment mechanism to support collection of shared losses that may be owed for the final performance year of the agreement period. As we explained in previous rulemaking, in allowing for a shorter tail period of 12-months, we believed the importance of reducing burden on ACOs outweighed the possible risk to the Trust Funds (83 FR 67934). We would also note that the program's policies under § 425.204(f)(6)(iv) specify the conditions upon which we permit early termination of a repayment mechanism and release of the arrangement's remaining funds to the ACO. This allows us to terminate repayment mechanism arrangements that are no longer needed to support ACOs' participation in the Shared Savings Program, which may free up capital for ACOs.

We appreciate the continued engagement of ACOs and other program stakeholders in suggesting policy alternatives to reducing the burdens of the repayment mechanism requirements on ACOs. We will consider commenters' suggestions, and we may revisit this issue in future notice and comment rulemaking.

As a result of the comments received, we are amending § 425.204(f)(4)(iv) to specify in paragraph (f)(4)(iv)(A) that a renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program may use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreements period. That provision also sets forth the revised methodology for determining the repayment mechanism amount for such ACOs. These modifications apply to the application cycle for an agreement period starting on January 1, 2022, and in subsequent years. We are also adding provisions in § 425.204(f)(4)(iv)(B) establishing policies and procedures that allow certain ACOs that renewed for an agreement period beginning on July 1, 2019, or January 1, 2020, to elect to decrease the amount of their existing repayment mechanisms.

We are adding new paragraph (f)(3)(v) to § 425.204 to allow a re-entering ACO to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, provided that the ACO is the same legal entity as an ACO that previously participated in the Shared Savings Program and the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with § 425.204(f)(6)(ii) and the amount of the repayment mechanism complies with § 425.204(f)(4). We are also revising § 425.204(f)(6)(ii) (describing the required duration of the repayment mechanism) to make it applicable to a renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, that wishes to use its existing repayment mechanism to support its participation in its new agreement period.

Additionally, we received no public comments on the following proposals, which we are finalizing as proposed:

We are amending § 425.204(f)(5) (regarding the replenishment of funds available through the repayment mechanism) to specify that the resulting amount available through the repayment mechanism after replenishment must be at least the amount specified by CMS in accordance with § 425.204(f)(4).

We are finalizing as proposed certain technical changes to § 425.204(f)(3)(iv). This provision specifies that an ACO that has submitted a request to renew its

participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period, and describes the conditions under which an ACO may use its current repayment mechanism to apply to the new agreement period. For clarity, we are finalizing our proposed modification to specify under this provision that the duration of the existing repayment mechanism must be revised to comply with § 425.204(f)(6)(ii), and the amount of the repayment mechanism must comply with § 425.204(f)(4).

Lastly, we are finalizing the proposal to revise § 425.204(f)(3)(i) through (iii) to further specify that an ACO must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism.

4. Applicability of Policies to Track 1+ Model ACOs

In the CY 2021 PFS proposed rule (85 FR 50251 and 50252), we provided a comprehensive discussion of the applicability of the proposed policies specified in section III.G and section III.I of the proposed rule to Track 1+ Model ACOs. We explained which of the proposed policies would become applicable to Track 1+ Model ACOs either through revisions to existing Shared Savings Program regulations that currently apply to Track 1+ Model ACOs or through the addition of new provisions that would apply to Track 1+ ACOs in the same way that they apply to ACOs in Track 1. However, we also explained the circumstances under which certain changes in policies would become applicable through an amendment to the ACO's Track 1+ Model Participation Agreement.

We received no public comments directly addressing the applicability of the policies proposed in the CY 2021 PFS proposed rule to Track 1+ Model ACOs. However, a few commenters expressed their support for applying the voluntary 1-year extension, for ACOs whose agreement periods would otherwise expire on December 31, 2020, to Track 1+ Model ACOs. Although this policy was established in the May 8th COVID–19 IFC (85 FR 27574 and 27575, see also 85 FR 27586 and 27587), we explained in the CY 2021 PFS proposed rule (85 FR 50251) that Track 1+ Model ACOs, among other ACOs whose agreement periods would otherwise expire on December 31, 2020, were eligible to voluntarily elect a 1-year extension of their agreement period for a fourth performance year from January 1, 2021, to December 31, 2021.

However, we believe it would be helpful to summarize how the policies we are finalizing in sections III.G and III.I of this final rule apply to Track 1+ Model ACOs. Unless specified otherwise, the changes to the program's regulations finalized in this final rule that are applicable to Shared Savings Program ACOs within a current agreement period will apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 1, so long as the applicable regulation has not been waived under the Track 1+ Model. Similarly, to the extent that certain requirements of the regulations that apply to ACOs under Track 2 or the ENHANCED track have been incorporated for ACOs in the Track 1+ Model under the terms of the Track 1+ Model Participation Agreement, any changes to those regulations that are finalized in this final rule will also apply to ACOs in the Track 1+ Model in the same way that they apply to ACOs in Track 2 or the ENHANCED track. For example, the following final policies will apply to Track 1+ Model ACOs:

- The application of the APP to determine the quality performance of Shared Savings Program ACOs (section III.G.1.c. of this final rule).
- The revisions to the Shared Savings Program quality performance standard. Specifically, under the modified approach we are finalizing, the quality performance standard for Track 1+ Model ACOs will be set at a quality score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, for performance year 2021 (section III.G.1.c. of this final rule).
- The modifications to the regulations under § 425.604(c) specifying the circumstances under which a Track 1 ACO will qualify to receive a shared savings payment (section III.G.1.d. of this final rule).
- The modifications to the regulations under § 425.604(d) governing the determination of the final sharing rate for Track 1 ACOs (section III.G.1.d. of this final rule).
- The modifications to § 425.316 to allow CMS to identify ACOs that are not meeting the revised quality performance standard finalized this final rule, and to require these ACOs to take actions to address their poor quality performance or face termination of their Shared Savings Program participation agreement (section III.G.1.e. of this final rule).
- The modifications to the policies governing the audit and validation of data used to determine the ACO's quality performance. Specifically, under the new provision of the regulations at § 425.510(c), CMS retains the right to audit and validate the quality data reported by an ACO according to § 414.1390 (section III.G.1.f. of this final rule).
- The new provision of the regulations at § 425.512(b) to address the effect of extreme and uncontrollable circumstances on ACOs' quality performance for performance year 2021 and subsequent performance years (section III.G.1.g. of this final rule).
- The revisions to the definition of primary care services used in beneficiary assignment. The revised definition is applicable to Track 1+ Model ACOs for the performance year starting on January 1, 2021, and we will adjust the Track 1+ ACO's historical benchmark to reflect these policies (section III.G.2 of this final rule).
- The changes to the CAHPS for ACOs reporting requirements for performance year 2020 (section III.I.1 of this final rule).

5. Medicare Shared Savings Program Provisions From the May 8th COVID–19 IFC

In the May 8th COVID–19 IFC, we noted that, as of January 1, 2020, there were 517 Medicare Shared Savings Program (Shared Savings Program) Accountable Care Organizations (ACOs) serving approximately 11.2 million Medicare FFS beneficiaries across the country: 37 percent of ACOs (192 of 517) were participating under two-sided shared savings and shared losses models; and 160 ACOs had agreements ending December 31, 2020, and would be required to renew under the BASIC track or ENHANCED track to continue in the Shared Savings Program, including 20 ACOs participating in the Medicare ACO Track 1+ Model (Track 1+ Model).

In the May 8th COVID–19 IFC, we expressed our belief that the COVID–19 pandemic, and the resulting PHE as defined in § 400.200, have created a lack of predictability for many ACOs regarding the impact of expenditure and utilization changes on historical benchmarks and performance year expenditures, and for those under performance-based risk, the potential liability for shared losses, as well as disrupting population health activities, as clinicians, care coordinators and financial and other resources are diverted to address immediate acute care needs. We explained that ACOs and other program stakeholders have advocated for CMS to modify Shared Savings Program policies to address the

impact of the COVID–19 pandemic including to:

- Adjust the methodology for determining shared savings and shared losses, such as by: Reducing or eliminating liability for ACOs under performance-based risk for shared losses for PY 2020; not sharing savings or losses with ACOs for PY 2020; or adjusting program calculations to address the impact of COVID–19 on benchmark and PY expenditures, particularly for calendar year 2020.
- Eliminate or extend the deadline for ACOs to voluntarily terminate from the program without being financially reconciled for PY 2020, which under § 425.221(b)(2)(ii)(A) is June 30, 2020, with notification 30 days prior (no later than June 1).
- Maintain or ''freeze'' ACOs in their current participation options so that ACOs otherwise required to renew their participation for a new agreement period starting on January 1, 2021, to continue their participation in the Shared Savings Program, are not burdened with meeting application deadlines, and forgo the requirement that ACOs participating in the BASIC track's glide path advance to the next level for PY 2021.
- Account for changes in billing and care patterns in determining beneficiary assignment.

In the May 8th COVID–19 IFC (85 FR 27574), we explained that ACOs and other program stakeholders had indicated that there was an urgent need to address these concerns because ACOs needed to make participation decisions for PY 2020 and PY 2021 and may choose to terminate their participation in the Shared Savings Program on or before June 30th, rather than face the potential of pro-rated losses for PY 2020 if the PHE for COVID–19 does not extend for the entire year or the program's policies do not adequately mitigate liability for shared losses.

We expressed our belief that it is vital to the stability of the Shared Savings Program to encourage continued participation by ACOs by adjusting program policies as necessary to address the impact of the COVID–19 pandemic, including by offering certain flexibilities in program participation options to currently participating ACOs and addressing potential distortions in expenditures resulting from the pandemic to ensure that ACOs are treated equitably regardless of the degree to which their assigned beneficiary populations are affected by the pandemic. We explained that the changes we were making in the May 8th COVID–19 IFC would help to ensure a more equitable comparison between ACOs' expenditures for PY 2020 and ACOs' updated historical benchmarks and that ACOs are not rewarded or penalized for having higher/lower COVID–19 spread in their patient populations which, in turn, would help to protect ACOs from owing excessive shared losses and the Medicare Trust Funds from paying out windfall shared savings. As described in the May 8th COVID–19 IFC (85 FR 27573 through 27587), we modified Shared Savings Program policies to: (1) Allow ACOs whose current agreement periods expire on December 31, 2020, the option to extend their existing agreement period by one year, and allow ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for PY 2021; (2) clarify the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19; (3) adjust program calculations to mitigate the impact of COVID–19 on ACOs; and (4) expand the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also addressed how these adjustments to program policies would apply to ACOs participating in the Track 1+ Model.

In response to the May 8th COVID–19 IFC, CMS received 57 timely pieces of correspondence addressing Shared Savings Program policies. We thank commenters for their thoughtful consideration of the modifications to and clarifications of Shared Savings Program policies included in the May 8th COVID–19 IFC. Within section III.G.5. of this final rule, we summarize and respond to public comments, and discuss our final policies after taking into consideration the public comments we received on the May 8th COVID–19 IFC. Some commenters' suggestions for modifications to Shared Savings Program policies went beyond the scope of the policies addressed in the May 8th COVID–19 IFC, and will not be addressed in this section of this final rule.

Comment: Generally, some commenters expressed their appreciation for CMS' call for a renewed national commitment to value-based care.[70] These commenters generally underscored the importance of value-based healthcare as a stabilizing force during the COVID–19 pandemic. A few commenters explained that alternative payment models like the Shared Savings Program have enabled healthcare providers and ACOs to more effectively adapt to the challenges of delivering care during the PHE compared to their counterparts that are more reliant on reimbursement under traditional FFS. Another commenter described value-based healthcare initiatives, of which the Shared Savings Program is Medicare's flagship program, as proving to be ''a port in the storm during COVID–19'' offering both infrastructure and expertise unavailable in traditional FFS and predictable revenue during unpredictable times. One commenter explained that ACOs represent a viable path for a further step away from volume-focused medicine and its problematic incentives.

Some commenters specifically described ACOs' efforts to meet the Shared Savings Program's goals and provide for the health and safety of their patients during the COVID–19 pandemic, as in any other performance year. Some commenters described ACOs' agility in responding to disruptions in their routine monitoring of and care for patients, for example by rapidly deploying, or implementing, strategies to respond to the COVID–19 pandemic, including coordinating with local healthcare providers, expanding telehealth services, and diverting care coordinators to help manage patient outcomes. One commenter described ACOs' efforts to ''double down on existing risk targeting and care coordination efforts'' which helped support vulnerable patients to shelter safely in their homes with needed medications, food and other essentials. As another commenter described, many program participants have transitioned care to virtual platforms and/or provided care on porches or in parking lots or other outdoor settings as appropriate. This commenter explained that program participants are also working to establish long-term plans for triaging and treating patients with chronic conditions who are currently not seeking care because of the COVID–19 pandemic.

Some commenters detailed the challenges ACOs face in implementing their business operations within the pandemic. As described by one

[70] Although not specifically described in the May 8th COVID–19 IFC, CMS' commitment to value-based care has been announced in recent publications. See for example, Verma S. New CMS Payment Model Flexibilities for COVID–19. *Health Affairs.* June 3, 2020. Available at *https://www.healthaffairs.org/do/10.1377/hblog20200602.80889/full/.* See also, CMS Press Release, ''Trump Administration Issues Call to Action Based on New Data Detailing COVID–19 Impacts on Medicare Beneficiaries'' (June 22, 2020), available at *https://www.cms.gov/newsroom/press-releases/trump-administration-issues-call-action-based-new-data-detailing-covid-19-impacts-medicare.*

commenter, ACOs are procuring the personal protective equipment (PPE) needed to treat patients in person, applying for loans, keeping track of new guidance and policy changes, and making financial decisions related to their business. As another illustration, some commenters explained that while their commitment to value-based care was unwavering, the financial strains and uncertainty of the COVID–19 pandemic presents a difficult choice for ACOs' future.

Response: As we described in a recent publication,[71] we recognize beneficiaries and healthcare providers have been facing unprecedented challenges due the COVID–19 pandemic. The pandemic has underscored the need for a resilient healthcare system where reimbursement is not tied to the volume of services provided, but rather to value-based incentives to keep patients healthy. The Shared Savings Program is one of the country's largest initiatives on value-based care, equipping healthcare providers with the flexibility to innovate and focus on health outcomes that can help them respond to the pandemic. We appreciate ACOs' continued commitment to meeting the goals of the Shared Savings Program while facing challenges in caring for Medicare FFS beneficiaries and operating their organizations during the COVID–19 pandemic.

a. Application Cycle for January 1, 2021 Start Date and Extension of Agreement Periods Expiring on December 31, 2020

As we explained in the May 8th COVID–19 IFC (85 FR 27574), a renewing ACO is defined as an ACO that continues its participation in the program for a consecutive agreement period, without a break in participation, because it is an ACO whose participation agreement expired and that immediately enters a new agreement period to continue its participation in the program, or an ACO that terminated its current participation agreement under § 425.220 and immediately enters a new agreement period to continue its participation in the program (see § 425.20). Section 425.224 specifies application procedures for a renewing ACO applying to enter a new participation agreement with CMS for participation in the Shared Savings Program. In the May 8th COVID–19 IFC, we explained that we were seeking to reduce operational burden for ACOs and their healthcare providers while they respond to the serious health threats posed by the spread of the COVID–19. We described that we had received feedback from ACO stakeholders requesting that CMS delay the Shared Savings Program application cycle for a January 1, 2021 start date (occurring in CY 2020), since they had reassigned staff and care coordinators to respond to the current pandemic. Stakeholders expressed concern about focusing resources on applying to the Shared Savings Program rather than on patient care during the PHE for COVID–19. Additionally, stakeholders expressed uncertainty over their continued participation in the Shared Savings Program in 2021 given the lack of predictability of the impact of COVID–19 on the expenditures used to establish an ACO's historical benchmark.

In response to stakeholder feedback, in the May 8th COVID–19 IFC (85 FR 27574), we announced we were forgoing the application cycle for a January 1, 2021 start date (herein referred to as the 2021 application cycle). We explained our belief that it is appropriate to forgo the 2021 application cycle as the PHE for COVID–19 continues because this would allow ACOs and their ACO providers/suppliers currently participating in the Shared Savings Program to continue focusing on treating patients during the pandemic. We explained there were 160 Medicare Shared Savings Program ACO participation agreements that would end on December 31, 2020, including 20 ACOs participating in the Track 1+ Model. These ACOs would have been required to apply to renew their participation agreement to continue participating in the Shared Savings Program effective January 1, 2021. To reduce burden and allow these ACOs to continue participating in the program without a 2021 application cycle, we allowed ACOs that entered a first or second agreement period with a start date of January 1, 2018, the opportunity to elect to extend their agreement period for an optional fourth performance year. The fourth performance year would span 12 months from January 1, 2021, to December 31, 2021. This election to extend the agreement period would be voluntary and an ACO could choose not to make this election, and therefore, conclude its participation in the program with the expiration of its current agreement period on December 31, 2020. Under this approach, eligible ACOs would be able to remain under their existing historical benchmark for an additional year, which would increase stability and predictability given the potential impact of the pandemic on beneficiary expenditures under FFS Medicare and help provide greater certainty for ACOs making determinations regarding their future participation in the Shared Savings Program.

Additionally, we explained that by forgoing the 2021 application cycle for new applicants, CY 2020 will not serve as benchmark year 3 for a cohort of ACOs that would otherwise be January 1, 2021 starters (85 FR 27574 and 27575). An ACO's historical benchmark is determined based on the 3 most recent years prior to the start of its agreement period. For ACOs in a first agreement period, benchmark year 3 is given the highest weight of the 3 benchmark years and, because we expected CY 2020 to be an anomalous year, we explained our belief that it could be disadvantageous to include CY 2020 expenditures as the third benchmark year for this cohort of ACOs. Cancelling the 2021 application cycle would provide us with additional time to consider and develop approaches to further mitigate the role of 2020 as a benchmark year given the unusual expenditure and utilization trends likely to result from the pandemic.

As established in the May 8th COVID–19 IFC (85 FR 27575), the ACO's voluntary election to extend its agreement period must be made in the form and manner and by a deadline established by CMS, and an ACO executive who has the authority to legally bind the ACO must certify the election. We noted that this optional 12-month agreement period extension was a one-time exception for all ACOs with agreements expiring on December 31, 2020; it would not be available to other ACOs or to future program entrants. Eligible ACOs were able to notify CMS of their decision to elect to extend their agreement starting June 18, 2020 and ending September 22, 2020.

We explained that under the existing provision at § 425.210(a), the ACO must provide a copy of its participation agreement with CMS to all ACO participants, ACO providers/suppliers, and other individuals and entities involved in ACO governance. In the case of an ACO that elects to extend its agreement period pursuant to the May 8th COVID–19 IFC, we indicated that we would consider the ACO to be in compliance with § 425.210(a) if it notifies these parties that it will continue to participate in the program for an additional year. Further, under § 425.210(b), all contracts or arrangements between or among the

[71] Verma S. 2019 Medicare Shared Savings Program ACO Performance: Lower Costs And Promising Results Under 'Pathways To Success.' *Health Affairs.* September 14, 2020. Available at *https://www.healthaffairs.org/do/10.1377/hblog20200914.598838/full/.*

ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities must require compliance with the requirements and conditions of the program's regulations, including, but not limited to, those specified in the participation agreement with CMS (see also § 425.116(a)(3) (as to agreements with ACO participants) and (b)(3) (as to agreements with ACO providers/suppliers)). Thus, as we explained in the May 8th COVID–19 IFC (85 FR 27575), an ACO that elects to extend its participation agreement pursuant to the policy established by the IFC must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities during PY 2021 to comply with the program's requirements through December 31, 2021. We noted that to remain in compliance with § 425.116, an ACO may need to extend the duration of its agreements with ACO participants and ACO providers/suppliers.

We revised § 425.200(b)(3)(ii) to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, to elect to extend their agreement period for an optional fourth performance year (85 FR 27575). We explained that while we were forgoing the application cycle for ACOs to apply to enter an agreement period beginning on January 1, 2021, eligible, currently participating ACOs would be able to apply for a SNF 3-day rule waiver (§ 425.612(a)(1)(i)), apply to establish a beneficiary incentive program (§ 425.304(c)(2)), modify ACO participant (§ 425.118(b)) and/or SNF affiliate lists (§ 425.612(a)(1)(i)(B)), and elect to change their assignment methodology (§ 425.226(a)(1)) for PY 2021 (85 FR 27575). Also, an ACO participating under the BASIC track's glide path could still elect to transition to a higher level of risk and potential reward within the BASIC track's glide path other than the level of risk and potential reward that the ACO would be automatically transitioned to for PY 2021, absent the ACO's election to maintain its current participation level for one year as described in section II.L.2. of the May 8th COVID–19 IFC (85 FR 27575 and 27576). For example, an ACO participating in BASIC track Level B in PY 2020 could still elect to transition to BASIC track level D or E in PY 2021.

We received public comments on the approach we established in the May 8th COVID–19 IFC under which ACOs whose participation agreements were scheduled to expire on December 31, 2020, could elect to extend their agreement period for an optional fourth performance year. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported CMS' decision to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, the opportunity to extend their agreement period for an optional fourth performance year, spanning 12 months, from January 1, 2021, to December 31, 2021.

Response: We appreciate commenters' support for providing eligible ACOs the opportunity to extend their agreement period for an optional fourth performance year. Eligible ACOs had until September 22, 2020, to notify us of their election to extend their participation agreement. Of the Shared Savings Program ACOs with an agreement set to expire on December 31, 2020, 89 percent have elected to extend their agreement period for an additional performance year.

Comment: Most commenters urged CMS to reconsider its decision to forgo the Shared Savings Program 2021 application cycle, and a few commenters noted that the decision to cancel the application cycle would impede participation in Alternative Payment Models (APMs) during 2021. Several organizations commented on CMS' commitment to reducing administrative burdens on applicants, given the strain on resources as a result of the PHE for COVID–19, expressing appreciation for the added flexibility, but strongly believed that the decision whether it is too burdensome to apply to enter a new agreement period should be left up to the ACO. A number of commenters suggested that CMS reverse its decision to forgo a 2021 application cycle, and allow (for example) agreement period start dates of either April 1, 2021, or July 1, 2021. In urging CMS to allow for an agreement period start date in 2021, one commenter suggested an alternative approach to identifying the benchmark years, which included using 2017, 2018, and 2019 as benchmark years, and thereby avoiding the use of 2020 as a benchmark year.

A few commenters requested that CMS consider making opportunities available for Track 1 ACOs whose agreement periods expire on December 31, 2020, to elect to transition to a two-sided model for performance year 2021, or to enter a new agreement period under a two-sided model beginning on January 1, 2021, such as by allowing these ACOs to enter the ENHANCED track or the BASIC track's glide path.

Response: While we appreciate commenters' support for an agreement period start date in 2021, we decline at this time to establish such an option. At the time of this final rule, we do not believe that we have enough time to develop policies for a mid-year start date in 2021, because the program's rules and regulations are generally based on the calendar year from January 1 through December 31, and significant modifications would be needed to accommodate a start date other than January 1 during 2021. Such regulatory changes would require notice and comment rulemaking, and we would then require time to implement an application process. We would also need to allow ACOs enough time to review the regulation and apply for the program; allow for CMS' review of applications, including vetting of ACO participants through program integrity and law enforcement screening; allow for both parties to sign participation agreements; and allow time for CMS to deliver assignment list reports prior to the start date of the agreement period. Further, there would be complexities with establishing a mid-year start date in 2021, which would require additional analysis and policy development, followed by further consideration of those policies by prospective applicants and existing ACOs. These complexities, as described in previous rulemaking (see, for example, 83 FR 67944 through 67967), include policies for determining the ACO's assigned population, determining shared savings and shared losses, and quality reporting for a short performance year, among other factors. A further consideration would be the use of 2020 as benchmark year 3 in establishing historical benchmarks for agreement periods starting in 2021. While we appreciate the commenter's suggestion that we use alternative benchmark years in order to avoid using 2020 as a benchmark year, we decline at this time to make any additional modifications to the Shared Savings Program's benchmarking methodology. As discussed in section III.G.5.d.(2) of this final rule, we anticipate continuing to monitor and evaluate the impact of the PHE for COVID–19 on Medicare FFS expenditures and Shared Savings Program payment calculations, to help inform potential future policy modifications to the Shared Savings Program. We believe it is premature to undertake such policy modifications at the time of this final rule.

We appreciate commenters' support for APM participation through participation in a Shared Savings Program ACO. We note that existing

ACOs had the opportunity to make ACO participant list modifications that will be effective for performance year 2021, which we believe provided an opportunity for additional TINs, and thereby the providers and suppliers that have assigned their billing rights to these TINs, to begin participating in the Shared Savings Program, or for existing ACO participant TINs to participate under a different Shared Savings Program ACO.

We decline at this time to adopt the commenters' suggestions to allow ACOs that elect the 1-year extension of their participation agreement to also elect a different track of participation for performance year 2021 or to allow these ACOs to enter a new agreement period under a two-sided model, beginning on January 1, 2021, such as allowing Track 1 ACOs to elect to transition to performance-based risk on the BASIC track's glide path or to enter the ENHANCED track. The approach we established in the May 8th COVID–19 IFC contemplates an extension of the ACO's existing agreement period, not entry into a new agreement period, which would include (for instance) rebasing the ACO's historical benchmark. Such an approach would also raise the same concerns as allowing ACOs to enter the Shared Savings Program for a start date in 2021, in particular around the use of 2020 as a benchmark year. Similarly, the approach adopted in the May 8th COVID–19 IFC does not contemplate that ACOs would be permitted to elect to participate under a different track during the optional fourth performance year under their current participation agreement. We encourage ACOs interested in transitioning to performance-based risk, or entering higher levels of risk and potential reward, to apply to do so at the next opportunity, which will be the application cycle for an agreement period beginning on January 1, 2022.

After considering the comments received, we are finalizing without modification the revisions to the provision at § 425.200(b)(3)(ii) to allow ACOs that entered a first or second agreement period with a start date of January 1, 2018, to elect to extend their agreement period for an optional fourth performance year.

b. Allow BASIC Track ACOs To Elect To Maintain Their Participation Level for One Year

We finalized a redesign of Shared Savings Program's participation options in the final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'', which appeared in the **Federal Register** on December 31, 2018 (83 FR 67816). We finalized the BASIC track, added as a new provision at § 425.605, which includes an option for eligible ACOs to begin participation under a one-sided model and incrementally phase-in risk (calculated based on ACO participant revenue and capped at a percentage of the ACO's updated benchmark) and potential reward over the course of a single agreement period, an approach referred to as the glide path (83 FR 67841). The glide path includes five levels: A one-sided model available only for the first 2 consecutive performance years of a 5-year agreement period, each year of which is identified as a separate level (Levels A and B); and three levels of progressively higher risk and potential reward in performance years 3 through 5 of the agreement period (Levels C, D, and E). ACOs are automatically advanced along the progression of risk/reward levels at the start of each participation year, over the course of a 5-year agreement period, unless the ACO elects to advance more quickly, until ACOs reach the BASIC track's maximum level of risk/reward (Level E) (83 FR 67844). For ACOs that entered the BASIC track's glide path for an agreement period beginning on July 1, 2019, the progression through the levels of risk and potential reward spans 6 performance years, including the ACO's first performance year from July 1, 2019, through December 31, 2019; these ACOs were not automatically advanced to the next risk/reward level at the start of PY 2020 (§ 425.200(b)(4)(ii), (c)(3); § 425.600(a)(4)(i)(B)(*2*)(*i*)).

As explained in the May 8th COVID–19 IFC (85 FR 27575 and 27576), stakeholders have expressed concerns that due to the unpredictable impact of COVID–19 during PY 2020, and the uncertainty as to their ability to secure a repayment mechanism for PY 2021, ACOs are uncertain they will continue participating in the program if they are automatically transitioned to downside risk or a higher level of downside risk in PY 2021. Specifically, stakeholders requested we ''freeze,'' or forgo the automatic advancement of BASIC track ACOs and allow them to remain at their current level of participation for PY 2021. Additionally, per § 425.204(f)(3)(iii), an ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to a two-sided model of the BASIC track, including Level C, Level D, or Level E. We noted our concern whether some ACOs, particularly those that would automatically transition to Level C of the BASIC track, would be able to establish a repayment mechanism prior to the start of PY 2021 because the source of capital to cover potential losses may be uncertain for some ACOs given the resource intensity of responding to the pandemic. We noted that 136 ACOs participating under Level B of the BASIC track were scheduled to automatically advance to Level C on January 1, 2021. As discussed in the May 8th COVID–19 IFC (85 FR 27576), some stakeholders indicated that they may be unable to secure a letter of credit, while other stakeholders indicated that their discretionary funds were fully committed to responding to the PHE for COVID–19.

We also expressed concern that some of the care coordination processes ACOs have been developing may be interrupted by the pandemic. For example, ACOs may have reallocated funding and staff resources to respond to the PHE for COVID–19, thereby temporarily disrupting their ability to implement redesigned care processes that would support their transition to risk. We agreed with stakeholders that most ACOs did not know the impact that COVID–19 would have on their expenditures or beneficiary population and the potential for losses under risk arrangements. Therefore, we permitted ACOs participating in the BASIC track's glide path to elect to maintain their current level of participation under the BASIC track for PY 2021. During the summer of 2020, applicable ACOs were able to elect to remain in the same level of the BASIC track's glide path that the ACO entered for PY 2020. For PY 2022, an ACO that elected this advancement deferral option will be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2022 if it had advanced automatically to the next level for PY 2021 (unless the ACO elects to advance more quickly before the start of PY 2022). For example, if an ACO participating in the BASIC track, Level B, in PY 2020 elected to maintain its current level of participation for PY 2021, it will participate under Level B for PY 2021 and then will automatically advance to Level D for PY 2022, since the ACO would have moved automatically to Level C for PY 2021 under current program rules, absent this

change. The ACO could also elect to advance more quickly by opting to move to Level E instead of Level D for PY 2022, in which case the ACO would participate under Level E for the remainder of its agreement period.

In the May 8th COVID–19 IFC, we redesignated § 425.600(a)(4)(i)(B)(*2*)(*iii*) as § 425.600(a)(4)(i)(B)(*2*)(*iv*) and added a new § 425.600(a)(4)(i)(B)(*2*)(*iii*) to allow ACOs currently participating in the BASIC track's glide path to elect to maintain their current participation level for PY 2021.

We received public comments on the advancement deferral option we established in the May 8th COVID–19 IFC. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed support for CMS' decision to permit ACOs participating in the BASIC track's glide path the option to voluntarily elect to maintain their current participation level under the BASIC track for PY 2021.

Response: We appreciate commenters' support for allowing ACOs participating in the BASIC track the opportunity to elect to remain in the same level of the BASIC track's glide path for PY 2021 as they entered for PY 2020.

Comment: Several commenters urged CMS to reconsider its decision to move ACOs to the level of risk they would have been in for 2022, absent the freeze. Commenters noted that skipping a level would be challenging under normal circumstances. However, under the extenuating circumstances of the PHE for COVID–19, they believed this requirement would not allow them the opportunity to focus on recovering financially and would take attention away from providing the best patient care, serving only to drive ACOs from the Shared Savings Program. Some commenters suggested that CMS allow ACOs to freeze their current risk level as proposed, but then resume the glide path in performance year 2022 at the risk level they would have been automatically advanced to for performance year 2021, absent their election to freeze their participation level for that performance year.

Response: Of the BASIC track ACOs that participated in PY 2020, 77 percent of these ACOs began the agreement period that includes that performance year as renewing or re-entering ACOs, as defined at § 425.20. These ACOs all have prior experience participating in the Shared Savings Program; some of these ACOs have continuously participated in the program since 2012. We believe that entering an agreement period under the BASIC track's glide path suggests that these ACOs should already have been taking steps to prepare to enter performance-based risk and to progress to higher levels of risk and potential reward in order to continue their participation in the Shared Savings Program. We believe that by enabling these ACOs to gain additional experience in meeting the Shared Savings Program's goals within the context of the PHE for COVID–19 by allowing them to maintain their current participation level for performance year 2021, these ACOs will be further prepared to progress to higher levels of risk and potential reward within the BASIC track's glide path in PY 2022. Additionally, we note that some ACOs are currently ready to take on increasing levels of performance-based risk, as 9 percent of the ACOs participating in the BASIC track's glide path in PY 2020 have elected to advance along the glide path more quickly than required. Therefore, at this time, we decline commenters' suggestions to further slow ACOs' progression along the BASIC track's glide path by allowing ACOs that have elected to maintain their position on the glide path for PY 2021 to resume their progression at the level they would have entered for PY 2021, absent the freeze.

Comment: Many commenters suggested that CMS allow additional participation options under which ACOs would be protected from shared losses (such as options to allow ACOs to select no downside risk), with some commenters suggesting that these alternatives include reduced (lower) shared savings rates. For example, commenters suggested that we allow ACOs to elect the level of risk/reward currently available under the one-sided models of the BASIC track, under which ACOs take on no downside risk and share in savings at a rate of up to 40 percent, based on quality performance. While some commenters suggested making this alternative available for PY 2020, other commenters' suggestions for such an option seemed to be more open-ended, without specifying which cohorts of ACOs should be eligible or for how long this option should continue to be available. A number of commenters conveyed their belief that, absent this protection, and given the uncertainty around the end date of the PHE for COVID–19, ACOs may choose to leave the program rather than be at risk for shared losses under a two-sided model. One commenter explained that, at a minimum, CMS should allow ACOs to opt for lower shared savings rates in exchange for reduced downside risk, given that, due to the PHE for COVID–19, circumstances have drastically changed since ACOs performed their original cost-benefit calculations and signed their participation agreements. Another commenter explained that many clinicians are concerned about their ability to assume financial risk during this unprecedented time. Allowing ACOs the option to be protected from shared losses, along with existing policies in the Shared Savings Program to address extreme and uncontrollable circumstances, would support participants as they weigh continued participation in the program. Finally, some commenters conveyed their belief that it is very important to protect ACOs that are harmed by the PHE for COVID–19 from shared losses, and that it is also critical to allow eligible ACOs to still earn shared savings for PY 2020. These commenters explained that ACOs make significant investments to enhance quality, address chronic disease, and improve patient care, and shared savings are instrumental to continuing those initiatives.

Response: At this time, we do not believe it is necessary to provide alternative participation options for future performance years, and note that any new participation options would need to be established through additional notice and comment rulemaking. We believe a combination of policies will encourage continued participation by ACOs under the Shared Savings Program's existing financial models, in particular: The program's extreme and uncontrollable circumstances policies for mitigating shared losses, which will reduce ACOs' liability for losses for months covered by the PHE for COVID–19, including any applicable months within performance year 2021 (refer to section III.G.5.c of this final rule); the adjustment to program calculations for episodes of care for treatment of COVID–19, triggered by inpatient services (as discussed in section III.G.5.d.(2) of this final rule); and the policies to address the effect of extreme and uncontrollable circumstances on ACO quality performance (as discussed in section III.G.1.g and section III.I of this final rule).

At the time of this final rule, the PHE for COVID–19 has been renewed with an effective date of October 23, 2020, and, unless terminated early, will remain in effect for 90 days from the effective date. Under the Shared Savings Program's extreme and uncontrollable circumstances policies for mitigating shared losses (described in section III.G.5.c of this final rule), shared losses will be mitigated for all ACOs

participating in a performance-based risk track, including: Track 2, the ENHANCED track, Levels C, D and E of the BASIC track, and the Track 1+ Model, for the duration of the PHE for COVID–19 as specified in § 400.200, which started in January 2020. If the PHE covers the full year (January through December 2020) any shared losses an ACO incurs for performance year 2020 would be reduced completely, and the ACO would not owe any shared losses. Under the Shared Savings Program's existing policies, ACOs will continue to be eligible to share in savings if they meet the criteria for doing so, as specified in the regulations at §§ 425.604(c), 425.605(c), 425.606(c), 425.610(c). As described in section III.G.5.d. of this final rule, we will adjust certain Shared Savings Program calculations, including the determination of benchmark and performance year expenditures, to remove payment amounts for episodes of care for treatment of COVID–19, triggered by an inpatient service. These adjustments will help protect CMS and ACOs against distortions in expenditures resulting from the COVID–19 pandemic that could affect shared savings and shared losses calculations. We believe these policies mitigate commenters' concerns about the availability of shared savings and the risk of shared losses under the existing participation options.

After considering the comments received, we are finalizing without modification the redesignation of § 425.600(a)(4)(i)(B)(*2*)(*iii*) as § 425.600(a)(4)(i)(B)(*2*)(*iv*) and the addition of a new § 425.600(a)(4)(i)(B)(*2*)(*iii*) to allow ACOs currently participating in the BASIC track's glide path to elect to maintain their current participation level for PY 2021.

c. Applicability of Extreme and Uncontrollable Circumstances Policies to the PHE for COVID–19

In the May 8th COVID–19 IFC (85 FR 27576 and 27577), we clarified, for purposes of the Shared Savings Program, that the months affected by an extreme and uncontrollable circumstance would begin with January 2020, consistent with the PHE for COVID–19 determined to exist nationwide as of January 27, 2020, by the Secretary on January 31, 2020, and continue through the end of the PHE, as defined in § 400.200, which includes any subsequent renewals.

We explained in the May 8th COVID–19 IFC (85 FR 27577) that catastrophic events outside the ACO's control could also increase the difficulty of coordinating care for patient populations, and due to the unpredictability of changes in utilization and cost of services furnished to beneficiaries, may have a significant impact on expenditures for the applicable performance year and the ACO's benchmark in the subsequent agreement period. We explained these factors could jeopardize the ACO's ability to succeed in the Shared Savings Program, and ACOs, especially those in performance-based risk tracks, may reconsider whether they are able to continue their participation in the program.

Therefore, as explained in the May 8th COVID–19 IFC (85 FR 27577), we believed it was important to make clear that, under the existing extreme and uncontrollable circumstances policies for the Shared Savings Program, the timeframe for the extreme and uncontrollable circumstance of the COVID–19 pandemic for purposes of mitigating shared losses will extend for the duration of the PHE for COVID–19 as specified in § 400.200, which begins in January 2020. We explained that if the PHE for COVID–19 extends through all of CY 2020, all shared losses for PY 2020 will be mitigated for all ACOs participating in a performance-based risk track: Including Track 2, the ENHANCED track, Levels C, D and E of the BASIC track, and the Track 1+ Model. At the time of the May 8th COVID–19 IFC, the PHE for COVID–19 had covered 4 months (January through April 2020) meaning any shared losses an ACO incurred for PY 2020 would be reduced by at least one-third. We explained that if the PHE for COVID–19 extends for a large portion, if not all of the year, the existing extreme and uncontrollable circumstances policy under the Shared Savings Program would mitigate a significant portion of, if not all, shared losses an ACO may owe for PY 2020. For example, if the PHE for COVID–19 were to cover 6 months (January through June 2020) any shared losses an ACO incurs for PY 2020 would be reduced by one-half; if the PHE for COVID–19 were to cover 9 months (January through September 2020) any shared losses an ACO incurs for PY 2020 would be reduced by three-fourths; and if the PHE for COVID–19 were to cover the full year (January through December 2020) any shared losses an ACO incurs for PY 2020 would be reduced completely, and the ACO would not owe any shared losses.

We received public comments on our clarification of the applicability of the extreme and uncontrollable circumstances policies to the COVID–19 pandemic for purposes of mitigating shared losses under the Shared Savings Program. The following is a summary of the comments we received and our responses.

Comment: Commenters discussing this topic generally welcomed the clarification that the PHE for COVID–19 constituted an extreme and uncontrollable circumstance for purposes of mitigating shared losses, beginning in January 2020. While one commenter expressed support for the approach specified in the May 8th COVID–19 IFC, under which the extreme and uncontrollable circumstances policy would mitigate shared losses based on the duration of the PHE, many other commenters addressing this issue tended to express concern that mitigation of shared losses would cease with the end of the PHE. In particular, commenters expressed concern about the extent to which this approach would mitigate shared losses in light of the uncertainty over the length of the PHE (at the time of the comment period, which closed on July 7, 2020, the PHE was known to extend through July 25, 2020) and the potential for ''early termination'' of the PHE. Several commenters suggested that CMS extend the extreme and uncontrollable circumstances policy for mitigating shared losses for the duration of PY 2020. Several commenters suggested that CMS extend the policy to any performance year that starts during the PHE. One commenter questioned how CMS would adjust the methodology to account for variability in impact if the Secretary were to amend the PHE from a nationwide declaration to a regional one. More generally, one commenter explained the Shared Savings Program extreme and uncontrollable circumstances policy had previously been used to address natural phenomena (such as hurricanes or wildfires), which may be short-lived, and noted the COVID–19 global pandemic is different due to the uncertainty over when it may end.

One commenter, in expressing support for the approach to mitigating shared losses under the extreme and uncontrollable circumstances policy described in the May 8th COVID–19 IFC, also expressed their support for the continued ability of ACOs to share in savings generated from their diligent investments in the health and safety of their patient populations during the COVID–19 crisis. This echoed some other commenters' suggestions, underscoring the importance of shared savings payments in helping to address the financial strains placed on ACOs by COVID–19.

Response: We appreciate the commenters' support for the clarification regarding the duration of the PHE for COVID–19 and the applicability of the extreme and uncontrollable circumstances policy to mitigate shared losses for PY 2020.

In December 2017, we issued an interim final rule with comment period entitled ''Medicare Program: Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017'' (hereinafter referred to as the ''December 2017 IFC''), which appeared in the December 26, 2017 **Federal Register** (82 FR 60912 through 60919). In the December 2017 IFC (82 FR 60914), we aligned the extreme and uncontrollable circumstances policies under the Shared Savings Program with the policy established under the Quality Payment Program. Specifically, the Shared Savings Program extreme and uncontrollable circumstances policies apply when we determine that an event qualifies as an automatic triggering event under the Quality Payment Program. We use the determination of an extreme and uncontrollable circumstance under the Quality Payment Program, including the identification of affected geographic areas and applicable time periods, for purposes of determining the applicability of the extreme and uncontrollable circumstances policies with respect to both financial performance and quality reporting under the Shared Savings Program. We extended the extreme and uncontrollable circumstances policies finalized for PY 2017, including the alignment with the Quality Payment Program, to PY 2018 and subsequent years in the CY 2019 PFS final rule (83 FR 59969 through 59973). The Medicare Shared Savings Program and Quality Payment Program interact closely. All of the tracks of the Shared Savings Program are considered MIPS APMs, and Track 2, the ENHANCED track, and Level E of the BASIC track are also designated Advanced APMs. The two programs have several overlapping goals, including achieving better health for individuals, better population health, and lowering growth in expenditures. Because of these interactions and overlaps, we continue to believe that it is appropriate to use the same time periods and geographic areas as the Quality Payment Program when implementing the Shared Savings Program extreme and uncontrollable circumstances policies. We further clarify that if the PHE for COVID–19 transitions from a national PHE to a regional PHE, the Shared Savings Program will continue to apply the extreme and uncontrollable circumstances policy in the impacted geographic areas. At the time of this final rule, the PHE for COVID–19 has been renewed for another 90 days, with an effective date of October 23, 2020. Unless the PHE for COVID–19 is terminated early, all shared losses for performance year 2020 would be mitigated.

d. Adjustments to Shared Savings Program Calculations To Address the COVID–19 Pandemic

(1) Background

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established and updated under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for Medicare FFS beneficiaries assigned to the ACO. Such benchmark shall be adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate, and updated by the projected absolute amount of growth in national per capita expenditures for Parts A and B services. Section 1899(d)(1)(B)(i) of the Act specifies that, in each year of the agreement period, an ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures under the ACO for Medicare FFS beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, is at least the percent specified by the Secretary below the applicable benchmark under section 1899(d)(1)(B)(ii) of the Act.

Section 1899(i)(3) of the Act grants the Secretary the authority to use other payment models if the Secretary determines that doing so would improve the quality and efficiency of items and services furnished under Title XVIII and the alternative methodology would result in program expenditures equal to or lower than those that would result under the statutory payment model. The authority under section 1899(i)(3) of the Act to use other payment models includes authority to adopt alternatives to the benchmarking methodology set forth in section 1899(d)(1)(B)(ii) of the Act, and alternatives to the methodology for determining expenditures for each performance year as set forth in section 1899(d)(1)(B)(i) of the Act. As discussed in earlier rulemaking, we have used our authority under section 1899(i)(3) of the Act to adopt alternative policies to the provisions of section 1899(d)(1)(B) of the Act for updating the historical benchmark,[72] and calculating performance year expenditures.[73] We have also used our authority under section 1899(i)(3) of the Act to establish the Shared Savings Program's two-sided payment models,[74] and to mitigate shared losses owed by ACOs affected by extreme and uncontrollable circumstances during PY 2017 and subsequent performance years.[75]

Under the Shared Savings Program, providers and suppliers continue to bill for services furnished to Medicare beneficiaries and receive FFS payments under traditional Medicare. CMS uses payment amounts for Parts A and B FFS claims for a variety of Shared Savings Program operations, which include: Calculations under the benchmarking methodology; determining an ACO's eligibility for shared savings and liability for shared losses for each performance year under the program's financial models as specified in the regulations in subpart G; determining an ACO's eligibility for certain participation options as set forth in § 425.600(d); and calculating the amount of the repayment mechanism required for ACOs participating in a two-sided model according to § 425.204(f)(4). These operations typically require the determination of expenditures for Parts A and B services under the original Medicare FFS program for a specified population of Medicare FFS beneficiaries or the Medicare Parts A and B FFS revenue of ACO participants. We note that the Medicare FFS beneficiary population for which expenditures are determined may

[72] Such as using only assignable beneficiaries instead of all Medicare FFS beneficiaries in calculating the benchmark update based on national FFS expenditures (81 FR 37986 through 37989), calculating the benchmark update using factors based on regional FFS expenditures (81 FR 37977 through 37981), and calculating the benchmark update using a blend of national and regional expenditure growth rates (83 FR 68027 through 68030).

[73] Such as excluding indirect medical education and disproportionate share hospital payments from ACO performance year expenditures (76 FR 67921 through 67922), and determining shared savings and shared losses for the 6-month performance years (or performance period) in 2019 using expenditures for the entire CY 2019 and then pro-rating these amounts to reflect the shorter performance year or performance period (83 FR 59949 through 59951, 83 FR 67950 through 67956).

[74] See earlier rulemaking establishing two-sided models: Track 2 (76 FR 67904 through 67909), Track 3 (subsequently renamed the ENHANCED track) (80 FR 32771 through 32772), and the BASIC track (83 FR 67834 through 67841).

[75] See earlier rulemaking establishing policies for mitigating shared losses owed by ACOs affected by extreme and uncontrollable circumstances (82 FR 60916 through 60917, 83 FR 59974 through 59977).

differ depending on the specific program operation being performed and may reflect expenditures for the ACO's assigned beneficiaries, assignable beneficiaries as defined in § 425.20, or all Medicare FFS beneficiaries. The applicable Medicare FFS beneficiary population is specified in the regulations governing each program operation.

(2) Removing Payment Amounts for Episodes of Care for Treatment of COVID–19 From Shared Savings Program Expenditure and Revenue Calculations

Section 3710 of the CARES Act amended section 1886(d)(4)(C) of the Act to specify that for discharges occurring during the emergency period described in section 1135(g)(1)(B) of the Act, in the case of a discharge of an individual diagnosed with COVID–19, the Secretary shall increase the weighting factor that would otherwise apply to the diagnosis-related group (DRG) to which the discharge is assigned by 20 percent. Further, the Secretary shall identify a discharge of such an individual through the use of diagnosis codes, condition codes, or other such means as may be necessary. In this section of this final rule, we refer to this increase in the weighting factor for DRGs as the ''DRG adjustment.''

In the May 8th COVID–19 IFC (85 FR 27578), we explained our expectation that the localized nature of infections (for example, rapid outbreaks in individual nursing facilities (NFs)) and the unanticipated increase in expenditures, along with the increased flexibilities that have been implemented to allow healthcare providers to identify and treat COVID–19 patients would affect the level of Medicare Parts A and B expenditures during 2020, both for the Medicare FFS beneficiaries assigned to ACOs and for the other populations of Medicare FFS beneficiaries whose expenditures are considered in performing calculations under the Shared Savings Program. The localized nature of outbreaks and the increased utilization of acute care occurring in PY 2020 and the associated higher costs are not reflected in ACOs' historical benchmarks, which are determined under § 425.601(b), § 425.602(b), or § 425.603(d), as applicable, based on Parts A and B expenditures for the beneficiaries who would have been assigned to that ACO during the three benchmark years. For some ACOs, the higher costs associated with COVID–19 may not be fully accounted for (or in other cases may be over-represented) by the retrospective application of the update factor to the benchmark at the time of financial reconciliation. In addition, the prospective CMS–HCC risk scores, which are used to adjust the historical benchmark each performance year for changes in severity and case mix (refer to §§ 425.601(a)(10), 425.602(a)(9), and 425.603(c)(10); and §§ 425.604(a)(1), 425.605(a)(1), 425.606(a)(1), and 425.610(a)(1), (2)), would not be expected to meaningfully adjust for such variability because they are prospective, and therefore, use diagnoses from 2019 to predict costs in 2020.

Furthermore, including the increased expenditures related to treatment of COVID–19 in calculations of ACO benchmarks for which CY 2020 is a benchmark year could lead to higher than anticipated future historical benchmarks unnecessarily advantaging some ACOs once the prevalence of COVID–19 in the population begins to decrease, and the corresponding reduction in expenditures is reflected in performance year expenditures. In contrast, we explained our belief that the methodology used to update benchmarks would appropriately reflect any reduction in expenditures due to a cumulative yearlong decline in elective services and the deferral of other services as a result of regionally-uniform responses by beneficiaries and providers/suppliers to directives issued at federal, state, and local levels. Therefore, the retrospective application of the historical benchmark update (which for PY 2020 is either an update factor based on national growth rates, regional growth rates, or a blend of national and regional growth rates, depending on the start date of the ACO's agreement period) would be expected to reasonably account for lower utilization of services by non-COVID–19 patients and prevent windfall shared savings payments to ACOs for PY 2020.

In the May 8th COVID–19 IFC (85 FR 27579), we explained that including payment amounts for treatment of acute care for COVID–19 in calculations for which calendar year 2020 is used as a reference year could also distort repayment mechanism estimates and the identification of high and low revenue ACOs and influence ACO participation options. For example, ACOs could potentially be misclassified as either high revenue or low revenue, due to changes in expenditures arising from the COVID–19 pandemic, and either moved more quickly to higher levels of risk and reward if they are identified as high revenue ACOs or allowed additional time under a one-sided model (if eligible) or in relatively lower levels of performance-based risk if they are identified as low revenue ACOs.

We explained our belief, at the time of the May 8th COVID–19 IFC, that ACOs currently participating in a performance-based risk track urgently needed to understand how we would address any distortions in expenditures resulting from the COVID–19 pandemic. Under the Shared Savings Program's regulations at § 425.221(b)(2)(ii)(A), an ACO under a two-sided model that voluntarily terminates its participation agreement with an effective date of termination after June 30th of the applicable performance year is liable for a pro-rated share of any shared losses determined for that performance year. Under § 425.220(a) of the regulations, ACOs are required to provide CMS at least 30 days' advance notice of their decision to voluntarily terminate from the program. As a result, ACOs participating under a two-sided model would need to provide notice to CMS no later than June 1, 2020, to avoid liability for a pro-rated share of any shared losses that may be determined for PY 2020. We explained that ACOs and other program stakeholders had expressed concern that ACOs would need to make participation decisions in advance of this June 1, 2020 deadline, and might choose to terminate their participation in the Shared Savings Program on or before June 30th, rather than risk owing pro-rated shared losses for PY 2020. We noted that the Shared Savings Program's extreme and uncontrollable circumstances policy would mitigate shared losses for these ACOs. However, given the uncertainty surrounding the duration of the PHE for COVID–19, at the time of the May 8th COVID–19 IFC, specifically, whether the PHE would cover the entire CY 2020, and absent information regarding the steps that CMS intended to take to address the high costs associated with COVID–19 patients, we acknowledged that many risk-based ACOs might elect to leave the program by June 30, 2020, to avoid the risk of owing shared losses.

We explained our belief that it was necessary to revise the policies governing Shared Savings Program financial calculations, as well as certain other program operations, to mitigate the impact of unanticipated increases in expenditures related to the treatment of COVID–19. Given that ACOs in two-sided models had very limited time (less than 2 months at the time of development of the May 8th COVID–19 IFC) to decide whether to continue their participation in the program or voluntarily terminate without being liable for shared losses, we identified an urgent need to establish policies to

address the impact of COVID–19 on Shared Savings Program financial calculations. More generally, we explained that ACOs engage in care coordination and population-based activities for Medicare FFS beneficiaries, as they work towards achieving the Shared Savings Program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries. We noted the urgency in taking steps to avoid adversely impacting ACOs, many of which rapidly adapted to the circumstances of the PHE for COVID–19 in order to continue to coordinate care and deliver value-based care to Medicare FFS beneficiaries and meet program goals. We expressed our concern that, in the absence of policies that adjust certain program calculations to remove payment amounts for episodes of care for treatment of COVID–19, ACOs might elect to leave the Shared Savings Program, setting back progress made in transitioning the healthcare system from volume-based to value-based payment. Therefore, as described in the May 8th COVID–19 IFC, we found good cause to waive prior notice and comment rulemaking to establish policies to mitigate the impact of the COVID–19 pandemic on Shared Savings Program financial calculations.

We revised our policies under the Shared Savings Program to exclude from Shared Savings Program calculations all Parts A and B FFS payment amounts for an episode of care for treatment of COVID–19, triggered by an inpatient service during the PHE for COVID–19, and as specified on Parts A and B claims with dates of service during the episode. We relied on our authority under section 1899(d)(1)(B)(ii) of the Act to adjust benchmark expenditures for other factors in order to remove COVID–19-related expenditures from the determination of benchmark expenditures. We also exercised our authority under section 1899(i)(3) of the Act to apply this adjustment to certain other program calculations, including the determination of performance year expenditures.

We explained that an approach that makes the triggering event for this adjustment the beneficiary's receipt of inpatient care for COVID–19, would identify the most acutely ill patients and, as a result, those patients with the highest-costs associated with acute care treatment. In contrast, we explained our belief that treatment for COVID–19 that does not result in an inpatient admission does not raise the same level of concern in terms of generating unexpected performance year expenditures that are not appropriately reflected in the benchmark calculations. As William Bleser and colleagues described,[76] citing a recent actuarial estimate of COVID–19 costs,[77] outpatient care was approximately 10 percent of the cost of hospital care, indicating that hospital costs are the dominant source of overall costs for treatment of COVID–19. We believed these findings supported an approach that bases the exclusion of expenditures on the triggering event of an inpatient admission for treatment of COVID–19. Furthermore, we explained that some outpatient care would occur close-in-time to an eventual inpatient admission and following discharge. Under the approach we established, where an episode of care includes the month of admission and the month following discharge, outpatient care occurring within the timeframe for an episode of care would also be excluded from financial calculations.

Accordingly, under the approach we adopted in the May 8th COVID–19 IFC, we indicated we would identify an episode of care triggered by an inpatient service for treatment of COVID–19, based on either: (1) Discharges for inpatient services eligible for the 20 percent DRG adjustment under section 1886(d)(4)(C) of the Act; or (2) discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the IPPS, such as CAHs, when the date of admission occurs within the PHE for COVID–19 as defined in § 400.200.

For example, we indicated that we would identify discharges of an individual diagnosed with COVID–19 using the following ICD–10–CM codes:

- B97.29 (Other coronavirus as the cause of diseases classified elsewhere) for discharges occurring on or after January 27, 2020, and on or before March 31, 2020.
- U07.1 (COVID–19) for discharges occurring on or after April 1, 2020, through the duration of the PHE for COVID–19, as defined in § 400.200.[78]

We explained that episodes of care for treatment of COVID–19 may be triggered by an inpatient admission for acute care either at an acute care hospital or other healthcare facility, which may include temporary expansion sites, Medicare-enrolled ASCs providing hospital services to help address the urgent need to increase hospital capacity to treat COVID–19 patients, CAHs, and potentially other types of providers.[79]

We defined the episode of care as starting in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date. We explained that this approach to measuring the length of the episode of care in units of months aligns with the Shared Savings Program's methodology for calculating benchmark year and performance year expenditures by performing separate calculations for each of four Medicare enrollment types (ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid). As described in the final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations'', which appeared in the June 10, 2016 **Federal Register** (81 FR 37950), we account for circumstances where a beneficiary is enrolled in a Medicare enrollment type for only a fraction of a year (see 81 FR 37981). Specifically, we determine the number of months that an assigned beneficiary is enrolled in each specific Medicare enrollment type and divide by 12. Summing these fractions across all assigned beneficiaries in each Medicare enrollment type results in total person years for the beneficiaries assigned to the ACO. Benchmark and performance year expenditures for each enrollment type are calculated on a per capita basis. The numerator of the per capita expenditure calculation for a particular enrollment type reflects the total Parts A and B expenditures incurred by all assigned beneficiaries in that enrollment type during the year, with adjustments made to exclude indirect medical education and disproportionate share hospital payments, to include individually beneficiary identifiable

[76] Bleser WK, et al. Maintaining Progress Toward Accountable Care And Payment Reform During A Pandemic, Part 1: Utilization And Financial Impact. *Health Affairs.* April 14, 2020. Available at *https://www.healthaffairs.org/do/10.1377/hblog20200410.281882/full/.*

[77] COVERED California. The Potential National Health Cost Impacts to Consumers, Employers and Insurers Due to the Coronavirus (COVID–19). Policy/Actuarial Brief (March 22, 2020). Available at *https://hbex.coveredca.com/data-research/library/COVID-19-NationalCost-Impacts03-21-20.pdf.*

[78] *See* for example, MLN Matters, ''New Waivers for Inpatient Prospective Payment System (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the CARES Act'' (April 15, 2020), available at *https://www.cms.gov/files/document/se20015.pdf.*

[79] *See* CMS fact sheet, ''Hospitals: CMS Flexibilities to Fight COVID–19'', dated March 30, 2020, available at *https://www.cms.gov/files/document/covid-hospitals.pdf*, describing flexibilities CMS specified for hospitals for the provision of inpatient care to fight COVID–19.

final payments made under a demonstration, pilot or time limited program, and to truncate beneficiary expenditures to minimize variation from catastrophically large claims. The denominator reflects total person years for the enrollment type.

In addition to excluding Parts A and B payment amounts with dates of service in the months associated with an episode of care for treatment of COVID–19, we explained that we would also exclude the affected months from total person years used in per capita expenditure calculations. For example, if a beneficiary had an episode of care for COVID–19 that lasted for 2 months, but was otherwise enrolled as an aged/non-dual eligible beneficiary for the full calendar PY, we would exclude their Parts A and B expenditures for those 2 months and compute their fraction of the year enrolled in the aged/non-dual eligible population as 10/12. Adjusting both expenditures and person years ensures that both the numerator and denominator used to calculate per capita expenditures are based on the same number of months of beneficiary experience and allow ACOs to be treated equitably regardless of the degree to which their assigned beneficiary population is affected by the pandemic.

We expressed our belief that this approach would provide for a more equitable comparison between an ACO's performance year expenditures and its historical benchmark and help to ensure that ACOs are not rewarded or penalized for having higher/lower COVID–19 spread in their assigned beneficiary populations which, in turn, would help to protect CMS against paying out windfall shared savings and ACOs in two-sided models from owing excessive shared losses. Further, we described our belief that the retrospective application of the historical benchmark update, which is calculated based on factors that reflect actual expenditure and utilization changes nationally and regionally, other than expenditures for episodes of care for treatment of COVID–19, would also help to mitigate the potential for windfall savings due to potentially lower utilization of services not related to treatment for COVID–19.

In the May 8th COVID–19 IFC, we established an adjustment to the following Shared Savings Program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19:

- Calculation of Medicare Parts A and B FFS expenditures for an ACO's assigned beneficiaries for all purposes, including the following: Establishing, adjusting, updating, and resetting the ACO's historical benchmark and determining performance year expenditures.
- Calculation of FFS expenditures for assignable beneficiaries as used in determining county-level FFS expenditures and national Medicare FFS expenditures, including the following calculations:

++ Determining average county FFS expenditures based on expenditures for the assignable population of beneficiaries in each county in the ACO's regional service area according to §§ 425.601(c) and 425.603(e) for purposes of calculating the ACO's regional FFS expenditures. For example, for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, we will use county FFS expenditures from which we exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19 in determining the regional component of the blended national and regional growth rates used to (1) Trend forward benchmark year 1 and benchmark year 2 expenditures to benchmark year 3 according to § 425.601(a)(5)(iii), and (2) to update the benchmark according to § 425.601(b)(3). Further, we will use county expenditures from which we exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19 to update the ACO's rebased historical benchmark, according to § 425.603(d) for ACOs in a second agreement period beginning on or before January 1, 2019, based on regional growth rates in Medicare FFS expenditures.

++ Determining the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries for purposes of the following: (1) Truncating assigned beneficiary expenditures used in calculating benchmark expenditures (§§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4)), and performance year expenditures (§§ 425.604(a)(4), 425.605(a)(3), 425.606(a)(4), 425.610(a)(4)); and (2) truncating expenditures for assignable beneficiaries in each county for purposes of determining county FFS expenditures according to §§ 425.601(c)(3) and 425.603(e)(3).

++ Determining 5 percent of national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries for purposes of capping the regional adjustment to the ACO's historical benchmark according to § 425.601(a)(8)(ii)(C).

++ Determining the flat dollar equivalent of the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program for assignable beneficiaries, for purposes of updating the ACO's historical benchmark according to § 425.602(b)(2).

++ Determining national growth rates that are used as part of the blended growth rates used to trend forward benchmark year 1 and benchmark year 2 expenditures to benchmark year 3 according to § 425.601(a)(5)(ii) and as part of the blended growth rates used to update the benchmark according to § 425.601(b)(2).

- Calculation of Medicare Parts A and B FFS revenue of ACO participants for purposes of calculating the ACO's loss recoupment limit under the BASIC track as specified in § 425.605(d).
- Calculation of total Medicare Parts A and B FFS revenue of ACO participants and total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries for purposes of identifying whether an ACO is a high revenue ACO or low revenue ACO, as defined under § 425.20, and determining an ACO's eligibility for participation options according to § 425.600(d).
- Calculation or recalculation of the amount of the ACO's repayment mechanism arrangement according to § 425.204(f)(4).

We noted that there are certain payments related to the PHE for COVID–19 that fall outside of Medicare FFS Parts A and B claims, and by virtue of this fact, these payments would not be utilized under the Shared Savings Program methodology for determining beneficiary expenditures. For example, we would not account for recoupment of accelerated or advance payments,[80] which occurs outside of the FFS claims processing system. This is because the underlying Parts A and B claims used in Shared Savings Program expenditure calculations would continue to reflect the amount the providers/suppliers are eligible to be paid, although that payment may be subject to offset for repayment of accelerated or advance payments. Further, Shared Savings Program expenditure calculations also would not need to account for lump sum payments made to hospitals and other healthcare providers through the

[80] *See* CMS, ''Fact Sheet: Expansion of the Accelerated and Advance Payments Program for Providers and Suppliers During COVID–19 Emergency,'' available at *https://www.cms.gov/files/document/accelerated-and-advanced-payments-fact-sheet.pdf.*

CARES Act Provider Relief Fund,[81] that occur outside of Parts A and B claims. We explained that we would continue to capture Medicare FFS Parts A and B payments to providers/suppliers, including hospitals and other healthcare providers receiving these funds, in Shared Savings Program calculations.

We explained that it was necessary to use our authority under section 1899(i)(3) of the Act to remove payment amounts for episodes of care for treatment of COVID–19 from the following calculations: (1) Performance year expenditures; (2) updates to the historical benchmark; and (3) ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track. To use our authority under section 1899(i)(3) of the Act to adopt an alternative payment methodology to remove payment amounts for episodes of care for treatment of COVID–19 from these calculations, we had to determine that the alternative payment methodology would improve the quality and efficiency of items and services furnished to Medicare beneficiaries, without resulting in additional program expenditures. We explained our belief that these adjustments, which remove payment amounts for episodes of care for treatment of COVID–19 from the specified Shared Savings Program calculations, would capture and remove from program calculations expenditures that are outside of an ACO's control, but that could significantly affect the ACO's performance under the program. In particular, we believed that failing to remove this spending would likely create highly variable savings and loss results for individual ACOs that happen to have over-representation or under-representation of COVID–19 hospitalizations in their assigned beneficiary populations.

Based on our assessment of the impacts of this policy for purposes of the May 8th COVID–19 IFC (85 FR 27615 and 27616), we did not believe excluding payment amounts for episodes of care for treatment of COVID–19 from the specified calculations would result in an increase in spending beyond the expenditures that would otherwise occur under the statutory payment methodology in section 1899(d) of the Act. Further, we believed these adjustments to our payment calculations to remove expenditures associated with treatment of COVID–19, in combination with the optional 1-year extension for ACOs whose current agreement periods expire on December 31, 2020 (as discussed in section II.L.1. of the May 8th COVID–19 IFC, 85 FR 27574 and 27575), and the option for ACOs in the BASIC track's glide path to elect to maintain their current level of risk and reward for PY 2021 (as discussed in section II.L.2. of the May 8 CthOVID–19 IFC, 85 FR 27575 and 27576) would provide greater certainty for currently participating ACOs. As a result, we expected that these policies would support ACOs' continued participation in the Shared Savings Program in the face of significant uncertainty arising from the disruptions due to the COVID–19 pandemic and the resulting PHE. We believed that, in turn, these organizations would continue working towards meeting the Shared Savings Program's goals of lowering growth in Medicare FFS expenditures and improving the quality of care furnished to Medicare beneficiaries.

Based on these considerations, and our assessment of the impacts of these adjustments in the May 8th COVID–19 IFC (85 FR 27615 and 27616), we believed adjusting certain Shared Savings Program calculations to remove payment amounts for episodes of care for treatment of COVID–19 from the calculation of performance year expenditures, updates to the historical benchmark, and ACO participants' Medicare FFS revenue used to determine the loss sharing limit in the two-sided models of the BASIC track, would meet the requirements for use of our authority under section 1899(i)(3) of the Act.

In the May 8th COVID–19 IFC, we also acknowledged that some trends and longer lasting effects of the COVID–19 pandemic were challenging to anticipate at the time of development of the IFC, and we would continue to evaluate the ongoing impact of the COVID–19 pandemic to determine whether additional rulemaking would be necessary to further adjust Shared Savings Program policies. For example, we noted that it was unclear whether the COVID–19 pandemic may have longer-term effects into 2021, such as through rebounding elective procedure costs in 2021 following potentially sustained reductions in 2020 or to what extent the reduction in these procedures may persist. Further, we anticipated learning more about the potential longer-term implications of the COVID–19 pandemic on Medicare beneficiaries' health and the healthcare system.

We added a new provision at § 425.611 to describe the adjustments CMS makes to Shared Savings Program calculations to address the impact of the COVID–19 pandemic.

We received comments on the approach to adjusting program calculations to mitigate the financial impact of the COVID–19 pandemic on ACOs that we established in the May 8th COVID–19 IFC. The following is a summary of the comments we received and our responses.

Comment: Many commenters that commented on the adjustments to Shared Savings Program calculations generally supported removal of Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment COVID–19 from those calculations. Some commenters specified their support in particular for application of this adjustment to the determination of benchmark expenditures, truncation factors, and performance year expenditures. Some commenters specified their support for adjustments to remove Parts A and B FFS payment amounts associated with episodes of care for treatment of COVID–19 from revenue calculations used for purposes of determining loss recoupment limits, as well as identifying whether an ACO is a high revenue ACO or low revenue ACO, and determining the ACO's eligibility for certain participation options. One commenter also stated its support for adjustment of repayment mechanism amount calculations, or recalculations of these amounts, to remove episodes of care for treatment of COVID–19.

A few commenters agreed that these adjustments would lead to more equitable comparisons between ACOs' performance year expenditures and their benchmarks, and assist in ensuring ACOs are not rewarded or penalized for being more or less impacted by COVID–19. One commenter stated that these adjustments would address potential distortions in the determination of shared savings and shared losses for the months impacted by COVID–19. One commenter, addressing the adjustment to remove payment amounts for episodes of care from benchmark expenditures, indicated that the approach adopted in the May 8th COVID–19 IFC addressed uncertainty related to COVID–19. One commenter explained that this adjustment will help to protect ACOs from circumstances out of their control at a time of immense financial risk and will provide them with important protections that will allow them to continue participating in the Shared Savings Program.

Response: We appreciate the support of commenters for the approach we established in the May 8th COVID–19 IFC to adjust certain Shared Savings

[81] *See* HHS website, CARES Act Provider Relief Fund, at *https://www.hhs.gov/provider-relief/index.html.*

Program calculations to exclude all Parts A and B FFS payment amounts for a beneficiary's episode of care for treatment of COVID–19, as described previously in this section of this final rule and specified in § 425.611.

Comment: A few commenters stated that the existing benchmarking methodology, and in particular the retrospective application of the benchmark update that reflects Medicare cost trends in the ACO's regional service area, was resilient to the impacts of COVID–19, suggesting that CMS' concern over windfall shared savings may be overstated. Some commenters indicated that the effects of the adjustment of benchmark and performance year expenditures for episodes of care are uncertain and could be either beneficial or disadvantageous to ACOs when they are compared to the national or regional expenditure trends that factor into their benchmarks.

One commenter explained that for ACOs in markets hard hit by COVID–19, the benchmark update will reflect those additional costs, and ACOs will be judged by whether they reduced costs relative to other healthcare providers that are subject to the same market conditions. Another commenter, describing concerns about the Shared Savings Program's blended national and regional growth rates used to trend and update the benchmark, explained that relying too heavily on a national trend (for ACOs whose assigned beneficiaries represent a large share of the assignable beneficiaries in their regional service area) is especially problematic during a pandemic with regional variation as it ignores important local market dynamics that differ across the country. This commenter explained that ACOs in COVID–19 hot spots will likely have higher costs than the overall nation. Therefore, according to this commenter, using the national trend as part of the benchmarking methodology would be detrimental and unfair to these ACOs as it is not reflective of the pandemic's effect on costs in their region.

Several commenters indicated that if COVID–19 causes Medicare costs to drop in a market, the benchmark update will reflect those lower costs, and ACOs in those markets would have to lower costs even more to generate shared savings. One commenter expressed concern over whether the retrospective application of the benchmark update would reasonably account for lower utilization of services by non-COVID–19 patients. Some commenters viewed this dynamic as potentially unfair for ACOs engaged in efforts to reduce inappropriate utilization or over utilization compared to existing high spending ACOs.

A few commenters urged CMS to undertake further analysis of the impact of COVID–19 on ACO benchmarks. For example, commenters urged CMS to evaluate whether the factors based on regional FFS expenditures in program calculations sufficiently account for irregular distribution of COVID–19 impacts across different regions and even within regions, wide variation in expenses, divergent practice patterns, and the unprecedented change in beneficiary behavior.

Response: We continue to believe the adjustments to Shared Savings Program calculations for episodes of care for treatment of COVID–19 are an important and necessary safeguard to help to protect ACOs from owing excessive shared losses, and the Medicare Trust Funds from paying out windfall shared savings.

We believe one significant function of the adjustment for episodes of care for treatment of COVID–19 is to protect ACOs from higher-cost COVID–19 expenditures that may be variable and therefore hard to predict. At the time of this final rule, based on initial analysis of data through Q2 of 2020 used in developing Shared Savings Program reports, most ACOs appear to have experienced a relatively small impact from the adjustments that remove episodes of care for treatment of COVID–19 from performance year expenditures. We observed a 1 percent or less median difference between adjusted and non-adjusted Q2 2020 expenditure values for ACOs relative to non-adjusted Q1 2020 expenditure values. We also observed, for example, that ACOs with higher impacts as a result of removing episodes of care for treatment of COVID–19 also tended to have higher proportions of older beneficiaries and beneficiaries who are dually eligible for Medicare and Medicaid, which is consistent with observations about COVID–19 trends in the Medicare population.[82]

Currently, ACOs participating in the Shared Savings Program are subject to several different benchmarking methodologies that vary in the degree to which trends in national or regional FFS expenditures are used in calculating the annual update to the ACO's historical benchmark, which is applied retrospectively following the conclusion of the performance year. Depending on the ACO's agreement period start date, an ACO's benchmark will be updated for performance year 2020 according to one of the following approaches (as applicable): Blended national and regional expenditure growth rates (§ 425.601(b)); growth rates in risk-adjusted FFS expenditures among assignable beneficiaries in the ACO's regional service area (§ 425.603(d)); or the absolute amount of projected growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program, for assignable beneficiaries (§ 425.602(b)).

As we have described in earlier rulemaking (see for example, 76 FR 67925 through 67927, 81 FR 38004, and 83 FR 68026), benchmark updates could have mixed effects on ACOs, depending on changes in utilization and expenditure patterns within the assignable beneficiary population used to calculate these factors in the performance year compared to benchmark year 3. We agree with commenters that significant changes in expenditures and utilization within the Medicare FFS population during a performance year, including as a result of COVID–19, have the potential to result in variances in the benchmark update.

Early analysis indicates that the adjustment to remove episodes of care for treatment of COVID–19 may mitigate commenters' concerns that ACOs may be disadvantaged by the benchmark update methodology under the circumstances of the pandemic. When modeling the impact of removing episodes of care for treatment of COVID–19 from trend factors for ACOs with the highest rates of COVID–19 diagnoses, these ACOs' regional trends appear lower than national trends, suggesting that ACOs in ''hot spots'' appear to benefit from the blend. Additionally, after removing episodes of care for treatment of COVID–19, the distribution of ACO expenditure trends and regional expenditure trends between Q1 and Q2 2020 are fairly similar. This suggests ACOs and their regions are likely experiencing the same localized effects as a result of the pandemic and that use of regional factors in updating ACOs' benchmarks should help to protect against windfall

[82] These observations appear consistent with other recent observations about COVID–19 trends in the Medicare population. See for example, CMS Press Release, ''Trump Administration Issues Call to Action Based on New Data Detailing COVID–19 Impacts on Medicare Beneficiaries'' (June 22, 2020), available at *https://www.cms.gov/newsroom/press-releases/trump-administration-issues-call-action-based-new-data-detailing-covid-19-impacts-medicare* (Describing a snapshot of data on the Medicare population, for the period between January 1 and May 16, 2020. Observations included the following: Older Americans and those with chronic health conditions are at the highest risk for COVID–19; and dual eligible beneficiaries had the second highest rates of hospitalization among the Medicare population).

savings without unduly disadvantaging ACOs.

However, at the time of this final rule, we believe it is still too soon to identify the full extent of the impact of COVID–19 on regional and national FFS expenditures. We anticipate better understanding these impacts as we analyze data for the remaining quarters of 2020 and the performance year 2020 results (determined after the conclusion of the performance year). We agree with the comments indicating the importance of ongoing evaluation of factors used in program calculations. We anticipate continuing to monitor the program's calculations, and in particular, the factors used to trend and update the benchmark, to understand the impact of any anomalies in Medicare FFS expenditures resulting from the costs of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic.

More generally, as described in the recently released results for performance years (or the performance period) in 2019, we are still gaining experience with the benchmarking methodology established in the Shared Savings Program December 2018 final rule (83 FR 68005 through 68030) and specified in § 425.601, which includes the use of blended national and regional trend and update factors. However, we believe the 2019 Shared Savings Program results are a promising indicator that this benchmarking methodology provides appropriate incentives for Shared Savings Program ACOs.[83]

Comment: One commenter sought clarification of the retrospective application of the historical benchmark update discussed in the May 8th COVID–19 IFC.

Response: The Shared Savings Program's benchmarking methodology is specified in regulations in part 425, subpart G (titled Shared Savings and Losses), and in particular within §§ 425.601, 425.602, 425.603, and 425.611. For detailed information on how CMS calculates the financial benchmark that is used to assess annual financial performance, we also refer readers to the Shared Savings and Losses and Assignment Methodology Specifications, available on the Shared Savings Program ''Program Guidance & Specifications'' web page, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-guidance-and-specifications.*

At the time of financial reconciliation for each performance year, which follows the conclusion of the performance year, CMS calculates and applies an update to the ACO's historical benchmark to reflect the rate of growth in expenditures since benchmark year 3. The methodology for calculating the update to the benchmark is determined based on the ACO's agreement period start date as specified in the regulations at §§ 425.601(b), 425.603(d), and 425.602(b), as applicable.

The update to the benchmark is calculated and applied retrospectively after the conclusion of the performance year. CMS provides each ACO with the calculated updated benchmark amount in the financial reconciliation report for the performance year. ACOs reconciled for participation in performance year 2020 will receive a financial reconciliation report in the summer of 2021, which will include the ACO's updated historical benchmark, for which the update will have been determined after removing expenditures for episodes of care for treatment of COVID–19 as specified in § 425.611.

Comment: One commenter expressed its belief that removing spending for COVID–19 is unlikely to produce a reasonable estimate of what spending would have been without COVID–19. The commenter stated that this approach may, for example, underestimate the services patients with certain chronic conditions (who are disproportionately affected by COVID–19) would have used had they not been admitted for inpatient hospital services for COVID–19. The commenter indicated that the approach for adjusting expenditures for episodes of care for treatment of COVID–19 might increase the possibility that CMS will be rewarding ACOs for random variation rather than reductions in spending resulting from ACOs' care management. The commenter indicated there is uncertainty about how the adjustment to performance year expenditures to remove episodes of care for treatment of COVID–19 would affect the ACO when those expenditures are compared against the updated benchmark that reflects a regional and/or national trend.

Response: As discussed in the May 8th COVID–19 IFC, we adjust beneficiary person years to exclude months associated with episodes of care. The ACO's performance year expenditures, adjusted for episodes of care for treatment of COVID–19, will be weighted by person years calculated by Medicare enrollment type (ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid) that are also adjusted to exclude months associated with an episode of care for treatment of COVID–19. To the extent that beneficiaries being hospitalized for treatment of COVID–19 tend to have chronic conditions, the removal of these beneficiaries' months of experience from expenditure calculations could shift more weight to expenditures among healthier beneficiaries. However, as described elsewhere in this section of this final rule, we will also exclude from program calculations beneficiaries' CMS–HCC risk scores from months associated with episodes of care for treatment of COVID–19, which would also cause weighted average risk scores to be similarly weighted towards healthier beneficiaries. We believe that this balanced approach to expenditures and risk scores may mitigate to some degree the commenter's concern about the potential for underrepresentation of beneficiaries' acuity in relation to adjusted expenditures within program calculations leading to windfall savings for ACOs.

Comment: A few commenters pointed to the program's existing policies to limit shared savings, specifically the shared savings rates (under which ACOs may share in a percentage of savings based on quality performance) and the cap on the amount of shared savings that will be paid to an ACO under each track (or payment level within a track), as built in protection against ACOs' receiving windfall shared savings.

Response: We agree with commenters that the sharing rates based on quality performance and the performance payment limits provide some built in protections against windfall shared savings. However, we believe that absent the adjustment for episodes of care for treatment of COVID–19, the Shared Savings Program financial calculations would not fully address the unique expenditure experience resulting from the PHE for COVID–19 and leave ACOs and CMS vulnerable to these variations in Medicare FFS expenditures.

Comment: A few commenters expressed concerns about the mid-year change to the methodology for determining the updated benchmark for performance year 2020 to remove Parts A and B FFS payment amounts for episodes of care for treatment of COVID–19, when the ACO agreed to participate based on the policy that existed prior to the May 8th COVID–19 IFC.

[83] Verma S. 2019 Medicare Shared Savings Program ACO Performance: Lower Costs And Promising Results Under 'Pathways To Success.' *Health Affairs.* September 14, 2020. Available at *https://www.healthaffairs.org/do/10.1377/hblog20200914.598838/full/.*

Response: Under § 425.212, an ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless otherwise required by statute: (1) Eligibility requirements concerning the structure and governance of ACOs; and (2) calculation of sharing rate. Typically, we would undertake notice and comment rulemaking to propose modifications to provisions of the program's financial methodology, including to the benchmarking methodology, and subsequently issue a final rule, reflecting any policies that we finalize taking into consideration public comments received on the proposals, prior to the start of any performance year during which such policies would apply. In establishing the adjustment for episodes of care for treatment of COVID–19 in the May 8th COVID–19 IFC, we explained the urgent need for Shared Savings Program ACOs to understand how we would address any distortions in expenditures resulting from the COVID–19 pandemic (85 FR 27579). We found good cause to waive notice and comment procedures for the regulatory changes made to the Shared Savings Program in the May 8th COVID–19 IFC (85 FR 27607 and 27608). In addition, section 1871(e)(1)(A)(ii) of the Act permits the Secretary to issue a rule for the Medicare program with retroactive effect if the failure to do so would be contrary to the public interest. In the May 8th COVID–19 IFC (85 FR 27609), we explained that we believed it would be contrary to the public interest not to implement certain Medicare provisions in the IFC as soon as we were authorized to do so under the authority of section 1871(e)(1)(A)(ii) of the Act, that is retroactively to either the start of the national emergency or the PHE for the COVID–19 pandemic, as applicable. In the case of the adjustment to remove expenditures associated with episodes of care for the treatment of COVID–19, we determined that it would be contrary to the public interest not to implement this adjustment retroactively to the start of the PHE for COVID–19 in January 2020 to ensure that all costs associated with episodes of care for treatment of COVID–19 could be removed from financial calculations for performance year 2020.

Comment: Some commenters expressed uncertainty around whether the full extent of the impact of COVID–19 on ACOs' benchmark and performance year expenditures, and revenue, will be accounted for in the adjustment to program calculations for episodes of care for treatment of COVID–19 triggered by an inpatient service for a patient that has a COVID–19 diagnosis.

Commenters' uncertainty over the adequacy of the adjustment for episodes of care for treatment of COVID–19 often stemmed from the many unknown factors surrounding COVID–19 and the COVID–19 pandemic. For instance, the length and severity of the COVID–19 pandemic and its geographic distribution; the end date of the PHE for COVID–19; long term effects of the virus on patients' health; whether patients may experience worse health outcomes because of postponed or foregone care resulting from widespread delay or cancellation of elective or non-urgent procedures and/or preventive well visits or patients' avoidance of care, and in particular the potential for these circumstances to exacerbate chronic conditions; and the unknown impact of the COVID–19 pandemic on utilization and expenses, including the reduction in elective surgeries that impact revenue, and the potential for increased costs that result from ''catch up'' utilization and expenses for elective services and procedures, as well as the potential for unaccounted for variations in utilization in program calculations.

Some commenters suggested that alternative modifications were necessary in light of their concerns that CMS' approach for adjusting program calculations to remove episodes of care for treatment of COVID–19 triggered by an inpatient service may not be sufficient to address the impact of COVID–19 or the COVID–19 pandemic on ACOs. Commenters offered a variety of alternative approaches, including the following suggestions.

One commenter suggested that CMS disregard ACO financial and quality performance in 2020 to the extent possible, and instead implement an alternative incentive system for ACOs for COVID–19 specific activities, such as by compensating ACOs to focus on COVID–19 surveillance, data collection, and care management activities (particularly for beneficiaries with high risk chronic diseases). This commenter suggested that by disregarding 2020 performance, ACOs and their ACO participants would be allowed to respond to COVID–19 without considering the traditional cost and savings incentives of the Shared Savings Program.

Some commenters suggested modifications to how CMS determines benchmark or performance year expenditures. For example, one commenter suggested the benchmark may need to be increased to offset increased utilization. Another commenter suggested that CMS cap actual performance year 2020 expenditures at an estimate of expected expenditures based on the Shared Savings Program and other benchmark-based population models, similar to the approach used by the Comprehensive Care for Joint Replacement (CJR) model in response to the PHE for COVID–19.

Some commenters suggested that CMS modify the program's payment models for purposes of determining shared savings and shared losses for performance year 2020, such as to: Increase the minimum loss rate corridor to further protect ACOs under two-sided models from shared losses; eliminate shared losses altogether but maintain shared savings; eliminate both shared losses and shared savings; reduce shared losses and reduce shared savings; or eliminate shared losses and reduce shared savings. For example, one commenter suggested that CMS avoid imposition of downside risk for 2020, and cap shared savings at 2 percent of benchmark for ACOs that are eligible to share in savings, and provide bonus payments to ACOs that are not eligible to share in savings but that are still participating in the Shared Savings Program in performance year 2021, such as bonus payment of 0.5 percent of benchmark. These suggestions reflected commenters' differing perspectives. While some commenters believed it was an appropriate trade-off to reduce or eliminate shared savings in combination with reducing or eliminating downside risk, some commenters strongly supported an approach that continued ACOs' ability to fully share in savings generated under the program's existing payment models while protecting ACOs from losses.

Some commenters more generally encouraged CMS to continue to work with ACOs and other program stakeholders, commit to ongoing monitoring or evaluation of the Shared Savings Program, and make adjustments as needed, such as to the participation options, financial methodology, including the benchmarking methodology, beneficiary assignment methodology, and quality measurement methodology.

Response: For the reasons discussed in the May 8th COVID–19 IFC and in this final rule, we believe the adjustment to Shared Savings Program calculations for episodes of care for treatment of COVID–19, which we are finalizing in this final rule, address the impact of COVID–19. We plan to continue to monitor for and consider the impact of the COVID–19 pandemic on ACOs and their ACO participants, and

we would address any additional modifications to Shared Savings Program policies in future notice and comment rulemaking. Therefore, we decline at this time to adopt commenters' suggestions for alternative payment models, alternative approaches to determining benchmark and performance year expenditures, and other modifications to the program's financial calculations. We note that elsewhere in this final rule, we address comments received in response to the May 8th COVID–19 IFC related to changes to the beneficiary assignment methodology (refer to section III.G.5.e of this final rule), and the quality performance requirements for performance year 2020 (refer to section III.I. of this final rule).

Comment: One commenter suggested that CMS consider applying the adjustment for episodes of care for treatment of COVID–19 on a case-by-case basis, for ACOs in areas with higher COVID–19 prevalence, rather than program-wide.

Response: We decline to revise the approach adopted in the May 8th COVID–19 IFC to apply the adjustment for episodes of care for treatment of COVID–19 on a case-by-case basis. Given that ACOs' assigned beneficiary populations are often dispersed across different regions, we believe it would be difficult to fairly and accurately apply the policies on an individual ACO basis when (as commenters point out) the impacts of COVID–19 are variable from region to region. We also believe that a program-wide approach is more reflective of the PHE for COVID–19, which is nationwide. Further, a program-wide approach allows for greater certainty, transparency, and less complexity, than an approach applied on a case-by-case basis when there are more than 500 ACOs actively participating in the program as of January 1, 2020.[84]

Comment: A few commenters expressed their support for an approach that identifies episodes of care triggered by inpatient care for treatment of COVID–19. One commenter stated their belief that CMS struck the right balance of capturing the most variable COVID–19 costs in a well-defined episode.

One commenter explained that the effects of COVID–19 on patients vary greatly, providing as an example that patients who were previously healthy can require lengthy hospitalizations, intubation and mechanical ventilation, and a host of other costly interventions. Consequently, according to this commenter, ACOs and their providers cannot be reasonably expected to manage costs for these patients during an inpatient episode of care. This commenter welcomed the decision by CMS to exclude from Shared Savings Program financial calculations all Parts A and B FFS payment amounts for an episode of care for treatment of COVID–19, triggered by an inpatient service.

Response: We appreciate commenters' support for the approach we adopted in the May 8th COVID–19 IFC, under which an episode of care for treatment of COVID–19 is triggered by an inpatient service.

Comment: A few commenters suggested that there was a lack of clarity around when an episode of care will be triggered by acute care inpatient services for treatment of COVID–19 from facilities not paid under the IPPS, including SNFs. Several commenters asked that CMS clarify that such services will trigger an episode of care when the date of admission occurs within the PHE for COVID–19.

Response: In the May 8th COVID–19 IFC, we adopted an approach to identifying inpatient services for the treatment of COVID–19 provided by non-IPPS providers at § 425.611(b)(1)(ii), which applies when the date of admission occurs within the PHE as defined in § 400.200. Since the issuance of the May 8th COVID–19 IFC, we have determined that this approach to identifying inpatient services for the treatment of COVID–19 provided by non-IPPS providers creates an unintended inconsistency with the approach in § 425.611(b)(1)(i) to identifying inpatient services for the treatment of COVID–19 furnished by IPPS providers eligible for the 20 percent DRG adjustment under section 1886(d)(4)(C) of the Act, which is based on discharges within the PHE for COVID–19. If the approaches are not synchronized, we may (for example) identify fewer inpatient services provided by non-IPPS providers occurring near the start of the PHE for COVID–19, since the admission date for these services would have needed to occur within the PHE, as opposed to the discharge date occurring with the PHE. Further, we may capture more inpatient services furnished by non-IPPS providers at the end of the PHE for COVID–19 because the admission occurs during the PHE, but the discharge does not. This discrepancy could cause a distortion in the effects of the adjustment within program calculations, depending on the type of facility that provides the inpatient service that is the trigger for the episode of care for treatment of COVID–19.

To ensure greater consistency in the description of the policies used to identify inpatient services provided by IPPS and non-IPPS providers that trigger an episode of care for treatment of COVID–19, we are making a revision to the regulation at § 425.611(b)(1)(ii) that establishes the criteria for identifying an episode of care triggered by inpatient services furnished by a non-IPPS provider. We are revising the provision to specify that CMS identifies episodes of care for treatment of COVID–19 based on discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of discharge occurs within the Public Health Emergency as defined in § 400.200. Furthermore, because the purpose of this revision is to avoid distorting the effects of the adjustment for episodes of care for the treatment of COVID–19 within program calculations, we believe it is in the public interest to use our authority under section 1871(e)(1)(A)(ii) of the Act to apply this change retroactively to the start of the PHE for COVID–19 on January 27, 2020. We note that this is consistent with the applicability date for the original provision, which was also retroactive to the start of the PHE in January 2020, and will help to ensure that adjustments under § 425.611 are made consistently regardless of the type of provider that furnished the inpatient services for COVID–19.

Further, we anticipate identifying inpatient claims that trigger an episode of care for treatment of COVID–19 using all of the following criteria, regardless of whether the claim is submitted by an IPPS or non-IPPS provider. Claims that do not meet these criteria will not trigger an episode of care for treatment of COVID–19.

- Inpatient claims identified by claim type 60.
- Facility type as identified by the character in the third position of the CMS Certification Number (CCN) equal to ''T'' (Rehabilitation Unit) or ''R'' (CAH Rehabilitation Unit), or by the last four digits of the CCN in any of the following ranges: 0001–0879, Short-term (General or Specialty) Hospital; 0880–0899, Hospital that participated in an Office of Research and Development demonstration project; 1300–1399, CAH; 2000–2299, Long-term Care Hospital; 3025–3099, Inpatient Rehabilitation Facility; 3300–3399, Children's Hospital.
- Admission date and discharge date both populated.

[84] CMS, ''Shared Savings Program Fast Facts—As of January 1, 2020'', available at *https://www.cms.gov/files/document/2020-shared-savings-program-fast-facts.pdf.*

• Discharge date between January 27, 2020, and March 31, 2020 (inclusive), and diagnosis code equal to B97.29, or discharge date between April 1, 2020, and expiration date of the PHE for COVID–19 specified in § 400.200 (if known, inclusive) and diagnosis code equal to U07.1. (The applicable diagnosis code may be present in any diagnosis code field based on established coding guidelines.)

We note that the aforementioned criteria were used in identifying episodes of care for treatment of COVID–19 in Q2 and Q3 2020 program reports provided to ACOs. Prior to preparing the Q4 2020 program reports we plan to incorporate an additional criterion that will ensure that expenditures related to treatment of COVID–19 are not excluded from program calculations when the IPPS provider is not eligible to receive the 20 percent DRG adjustment, for example because the provider has specified a billing note NTE02 ''No Pos Test'' on the electronic claim 837I, or a remark ''No Pos Test'' on a paper claim. This note or remark on the claim indicates that the beneficiary did not have a positive laboratory test result for COVID–19 documented in the beneficiary's medical record. This is for consistency with CMS' new requirement that there must be a positive laboratory test result for COVID–19 documented in the beneficiary's medical record in order for an IPPS provider to receive the 20 percent DRG adjustment. This requirement was developed to address potential Medicare program integrity risks, and became effective with admissions occurring on or after September 1, 2020.[85]

Comment: One commenter urged CMS to clarify that an inpatient COVID–19 stay (with proper ICD–10–CM codes and within the PHE for COVID–19) in a SNF, which the commenter indicated was an ''other type of provider'' as described in the May 8th COVID–19 IFC, will be considered a triggering inpatient admission for an episode of care for treatment of COVID–19. This commenter explained that many ACO beneficiaries that reside in long-term care facilities have been transferred from a long-term care bed to a dedicated Medicare-covered bed within the same facility when they were diagnosed with COVID–19, due to the waiver of the 3-day hospital stay in connection with the PHE for COVID–19, as well as hospital capacity issues. These beneficiaries received Part A SNF services in the facility while they remained at that level of care. The commenter further explained that while many of these beneficiaries were never admitted to an acute inpatient hospital for their COVID–19 treatment, they still incurred inpatient COVID–19 related Part A and B costs. This commenter explained that exclusion of these beneficiaries' costs for treatment of COVID–19 from Shared Savings Program calculations is needed to ensure ACOs with long-term care Medicare beneficiaries are not unfairly penalized for treating patients at the inpatient SNF level of care during the pandemic.

Response: Under § 425.611(b)(1)(ii), as modified by this final rule, a discharge for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the IPPS, which would include a SNF, will trigger an episode of care when the date of discharge occurs within the PHE as defined in § 400.200. Elsewhere in this section of this final rule, we have detailed the criteria we will use for identifying claims for inpatient services that trigger an episode of care, which include: Claim type 60, facility type identified based on certain CCNs, admission date and discharge date both populated, and discharge date within the PHE for COVID–19 with a diagnosis code equal to either B97.29 or U07.1 (for an inclusive range of dates). A claim for inpatient services provided in a SNF that meets these criteria would be identified as the trigger for an episode of care for treatment of COVID–19.

We discussed the related issue of services furnished by SNFs under arrangements with an acute care hospital in an FAQ.[86] Under flexibilities adopted in response to the COVID–19 pandemic, a SNF (for example) can work with hospitals under arrangement to be able to provide inpatient acute care to Medicare beneficiaries and these admissions would trigger an excluded COVID–19 episode of care.[87] If a SNF is working under arrangement with a hospital to provide inpatient acute care, we would expect these services to be billed by the hospital which would be one of the CCN types we use to identify an inpatient claim that triggers an episode of care, as described elsewhere in this section of this final rule. However, if the beneficiary's SNF admission is for post-acute services, this alone would not trigger an episode of care for treatment of COVID–19. It is important to note that if post-acute care, such as SNF care, follows a beneficiary's discharge from a facility or unit where they were receiving inpatient services for treatment of COVID–19, payment amounts for post-acute care in the month of and the month following the discharge date (along with all other Parts A and B services) will also be excluded. As specified in § 425.611(b)(2), CMS defines an episode of care for the treatment of COVID–19 as starting in the month in which the inpatient stay begins, as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date.

Comment: When the comment period for the May 8th COVID–19 IFC closed on July 7, 2020, the PHE for COVID–19 extended until July 25, 2020.[88] Some commenters suggested CMS use inpatient services provided after the end of the PHE for COVID–19 to identify episodes of care for treatment of COVID–19. Some commenters suggested that CMS extend the identification of episodes of care for treatment of COVID–19 through the remainder of 2020. One commenter believed this extension was necessary to provide more certainty to ACOs in the event that the PHE is not extended beyond July 25, 2020, expressing concern that there could be a ''second wave'' of infections and a non-continuous PHE scenario. Some commenters suggested that CMS reevaluate whether additional revisions may be necessary to allow the policy to extend into 2021. These commenters explained that these approaches were needed to further protect two-sided model ACOs against financial losses, or more generally to ensure the future success of Shared Savings Program ACOs.

A few commenters suggested CMS remove any end-point to the adjustment. One commenter explained that limiting

[85] For more information, see CMS, MLN Matters, ''New Waivers for Inpatient Prospective Payment Systems (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the Cares Act'' (revised September 11, 2020), available at *https://www.cms.gov/files/document/se20015.pdf.*

[86] CMS, ''COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-For-Service (FFS) Billing'', available at *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf.* Refer to section U ''Medicare Shared Savings Program—Accountable Care Organizations (ACO)'' question 29.

[87] Refer to CMS, ''Medicare 1135 Waivers & Two Interim Final Rules Enabling Health System Expansion'', available at *https://www.cms.gov/files/document/covid-19-regulations-waivers-enable-health-system-expansion.pdf.*

[88] Renewal of determination that a public health emergency existed, with an effective date of April 26, 2020, for the duration of the emergency or 90 days, unless extended by the Secretary. Refer to U.S. Department of Health & Human Services, Public Health Emergency web page, ''April 21, 2020: Renewal of the Determination that a Public Health Emergency Exists as the Result of the Continued Consequences of Coronavirus Disease 2019 (COVID–19) (formerly called 2019 Novel Coronavirus (2019–nCoV))'', available at *https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-21apr2020.aspx.*

the adjustment to discharges within the PHE established an artificial cutoff point, which the commenter believed was unnecessary because the adjustment was already limited to a select group of ICD–10–CM diagnosis codes that were inherently tied to the treatment of COVID–19. Another commenter pointed to unknowns about the recovery time of infected individuals, suggesting it may take years to recover. This commenter further indicated that lifting the time limitation on the applicability of the adjustment would help ensure that ACOs are not penalized for having higher COVID–19 spread in their assigned beneficiary populations.

Response: At the time of this final rule, the PHE for COVID–19 has been renewed with an effective date of October 23, 2020, and, unless terminated early, will remain in effect for 90 days after the effective date. Under this extension, we would continue to identify episodes of care for treatment of COVID–19 until at least late-January 2021. Some commenters' suggestions, such as to extend the approach to identifying episodes of care to inpatient services for treatment of COVID–19 for the duration of the performance year 2020, or into 2021, are therefore addressed by the latest renewal of the PHE for COVID–19.

At this time, we decline to adopt the commenters' suggestions to use inpatient services with a discharge date after the end of the PHE for COVID–19 (as defined under § 400.200) to identify an episode of care for treatment of COVID–19 for purposes of adjusting Shared Savings Program calculations. Under the statutory requirements established in section 3710 of the CARES Act, with the conclusion of the PHE, IPPS providers will no longer receive the 20 percent DRG adjustment, which is one factor that the existing adjustment was designed to address.

We recognize that COVID–19 may continue to exist in communities even after the conclusion of the PHE for COVID–19 and that, as a result, some Medicare FFS beneficiaries will likely continue to require higher-cost care, including inpatient care, for the treatment of COVID–19. We believe a number of existing aspects of the Shared Savings Program payment methodology will help to mitigate the impact of these higher costs on ACOs, in the absence of the adjustment for episodes of care for treatment of COVID–19 following the conclusion of the PHE for COVID–19. For instance, as discussed elsewhere in this section of this final rule, the program's existing methodology for updating historical benchmarks, reflecting regional and/or national FFS expenditure trends, will help to ensure that an ACO's benchmark remains comparable with the performance year expenditures, which may include higher costs of care for patients with COVID–19. Further, the program's methodology for truncating assigned beneficiary expenditures, used in calculating benchmark expenditures (§§ 425.601(a)(4), 425.602(a)(4), 425.603(c)(4)) and performance year expenditures (§§ 425.604(a)(4), 425.605(a)(3), 425.606(a)(4), 425.610(a)(4)), at the 99th percentile of national Medicare FFS expenditures for assignable beneficiaries, will continue to help minimize variation from catastrophically large claims.

We also note that the adjustments for episodes of care for the treatment of COVID–19, as applied for the duration of the PHE for COVID–19, will continue to be reflected in program calculations for the affected time period. In particular, 2020 serves as a performance year for currently participating ACOs, and will be a benchmark year for future program entrants with 2022 and 2023 start dates. In light of the shift to 5-year agreement periods, adjustments made to expenditures during benchmark year 2020 will continue to be reflected in benchmark calculations until the end of performance year 2027 (the final performance year for 2023 starters), under the program's existing policies.

However, we anticipate monitoring the program's calculations for the impact of any anomalies in Medicare FFS expenditures resulting from the costs of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic. We may revisit the need to extend or modify the adjustment to program calculations in future notice and comment rulemaking.

Comment: One commenter suggested that we exclude short term, CAH swing-bed costs from Shared Savings Program financial calculations during the PHE for COVID–19. This commenter explained that swing-beds in CAHs can be safer for patients in hard-hit COVID–19 areas needing post-acute care than SNFs, but they are paid at approximately 3 times the rate.

Response: CAH swing-bed services, for skilled nursing care, have a ''Z'' in third position of the CCN. Elsewhere in this section of this final rule, we detail the criteria we use for identifying claims for inpatient services that trigger an episode of care for treatment of COVID–19, which include: Claim type 60, facility type identified based on certain CCNs, admission date and discharge date both populated, and discharge date within the PHE for COVID–19 with a diagnosis code equal to either B97.29 or U07.1 (for an inclusive range of dates). According to these criteria, we would not identify a CAH swing-bed service billed by a CCN with ''Z'' in the third position of the CCN, as a trigger for an episode of care for treatment of COVID–19.

However, a claim for inpatient services provided by a CAH may meet the criteria to be identified as the trigger for an episode of care for treatment of COVID–19. For example, if an inpatient service is provided by a CAH, and billed under a CCN identified by ''R'' (CAH Rehabilitation Unit) in the third position of the CCN or with the last four digits of the CCN in the range of 1300–1399 (CAH), this inpatient service would be the basis for an episode of care, if the other previously described criteria are also met. Further, CAH swing-bed services that fall within an episode of care for treatment of COVID–19, triggered by an inpatient admission identified according to the criteria in § 425.611, would also be excluded.

We decline to more broadly exclude all CAH swing-bed costs from the determination of ACO expenditures, which goes beyond the scope of the adjustment for episodes of care for treatment of COVID–19 that we adopted in the May 8th COVID–19 IFC. We believe the existing higher payments for care furnished in swing-beds in CAHs are presently reflected in ACOs' benchmark expenditures. Further adjustments to performance year expenditures to remove all such swing-bed costs would likely exclude expenditures associated with swing bed services that would have been rendered even in the absence of the PHE for COVID–19, creating asymmetry between benchmark and performance year calculations.

Comment: Some commenters suggested that CMS exclude as part of the adjustment for episodes of care for treatment of COVID–19, costs for outpatient services associated with a COVID–19 diagnosis regardless of whether the patient has an inpatient hospital admission. A few commenters explained that the long-term effects of COVID–19 are unknown, and patients may need ongoing care as they recover, and this care may not be provided in the inpatient setting. A few commenters explained that there is an increased cost of care for COVID–19 patients treated solely on an outpatient basis, including increased utilization of high-tech imaging and follow-up care. Pointing to the description in the May 8th COVID–19 IFC in which CMS explained that outpatient care was approximately 10

percent of the cost of hospital care for COVID–19, one commenter noted the costs of outpatient care for beneficiaries who do not have an inpatient admission for treatment of COVID–19 represents potentially sizeable COVID–19-related costs that would not be captured by episodes of care triggered by the receipt of inpatient services for the treatment of COVID–19, particularly for non-hospital-based ACOs.

One commenter, concerned about the impact of increased outpatient care costs of COVID–19 on ACO expenditures, suggested that CMS exclude all COVID–19 related payment amounts from performance year expenditures when these expenses are not reflected in the ACO's benchmark.

Further, a few commenters suggested that CMS monitor the long-term costs of outpatient care for recovered COVID–19 patients, to fully assess the total cost of care implications of the disease. One commenter suggested CMS do so before including these costs in Shared Savings Program benchmark calculations. Another commenter noted it would not expect COVID–19 related outpatient costs to vary significantly within a region, but encouraged CMS to monitor COVID–19 costs outside an episode of care for treatment of COVID–19 as defined in the May 8th COVID–19 IFC.

Response: As one commenter asserted, we would not expect COVID–19 related outpatient costs to vary significantly within a region. Data from quarterly reports appears to support this; as noted elsewhere within this section of this final rule, the distribution of ACO expenditure trends and regional expenditure trends between Q1 and Q2 2020 after removing episodes of care for treatment of COVID–19 are fairly similar. As a result, we believe the program's existing methodology for updating historical benchmarks, which incorporates regional and/or national FFS expenditures trends, should adequately adjust an ACO's benchmark to be more comparable with performance year expenditures by reflecting the changes in outpatient utilization as a result of COVID–19 and the COVID–19 pandemic. For related reasons, we do not believe that changes in outpatient utilization will unfairly impact physician-led ACOs as these changes should also be reflected in the adjusted expenditure trends used to update these ACOs' benchmarks.

We also expect outpatient care for COVID–19 to taper off as a beneficiary's symptoms resolve. As a result, if we were to remove expenditures arising during months of outpatient care for individuals with a diagnosis for COVID–19 that are not already captured by the definition of episode of care for treatment of COVID–19 in § 425.611(b), we could risk removing too many months of care for assigned beneficiaries from program calculations, which in turn could cause benchmarks to become less accurate and disrupt ACOs' shared savings potential.

We decline at this time to modify our approach to exclude all costs for outpatient care for treatment of COVID–19 or, more generally, all costs for treatment of COVID–19. As we have explained elsewhere in this section of this final rule, we believe it is too soon to identify the full extent of the impact of COVID–19 on FFS expenditures. We anticipate monitoring the program's calculations for the impact of any anomalies in Medicare FFS expenditures resulting from the costs of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic. We may revisit these considerations in future notice and comment rulemaking for the Shared Savings Program.

Comment: A few commenters urged CMS to clarify that an episode of care can be triggered when a COVID–19 diagnosis code is present on a claim and does not need to be the primary diagnosis code to trigger the episode of care. These commenters explained that this will be critical as there has been a large amount of variability in the manner in which COVID–19 diagnoses are listed on claims, due to the often ''multi-system'' nature of COVID–19 related illnesses.

More generally, several commenters cited concerns that inaccuracies in coding of COVID–19 diagnoses, or variations in coding, will affect the accuracy of CMS' adjustment for episodes of care for treatment of COVID–19.

One commenter encouraged CMS to evaluate the accuracy of the episode-based exclusion in capturing true COVID–19 impacts, such as by comparing the episode of care results to regional COVID–19 prevalence.

Response: As we explained in an FAQ,[89] we will identify claims for treatment of COVID–19, for use in identifying episodes of care, when the diagnosis code B97.29 or U07.1 is present in any diagnosis code field. Further, we believe some of the comments reflect a concern that our approach could under-identify episodes of care for the treatment of COVID–19 in the event of inaccuracies in coding. We note that it is incumbent upon providers to accurately code diagnoses and to ensure the accuracy of information submitted on claims based on established coding guidelines. For additional information, refer to guidelines for providers for coding encounters related to COVID–19,[90] and CMS claims processing instructions.[91]

As previously described in this section of this final rule, following the issuance of the May 8th COVID–19 IFC, CMS announced additional requirements for a positive COVID–19 laboratory test documented in the patient's medical record, in order for inpatient services furnished by an IPPS hospital to qualify for the 20 percent DRG adjustment.[92] For purposes of the adjustments to expenditures for episodes of care for the treatment of COVID–19 under the Shared Savings Program, this requirement could further ensure the accuracy of the adjustment for episodes of care for inpatient services identified based on discharges for inpatient services eligible for the 20 percent adjustment, according to § 425.611(b)(1)(i). This requirement would potentially rule out certain episodes of care that would otherwise trigger the adjustment under § 425.611 of the Shared Savings Program regulations.

We appreciate the commenter's suggestion that CMS evaluate the accuracy of the episode-based exclusion in capturing true COVID–19 impacts, and we anticipate continuing to monitor and evaluate the impact of COVID–19 on program calculations, to help inform potential future policy modifications to the Shared Savings Program.

Comment: One commenter expressed concern about how CMS defines an episode of care as ending with the month following the end of the inpatient stay as identified by the discharge date. The commenter explained that an increasing body of evidence suggests that COVID–19 infection may cause a host of lingering

[89] CMS, ''COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-For-Service (FFS) Billing'', available at *https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*. Refer to section U ''Medicare Shared Savings Program—Accountable Care Organizations (ACO)'' question 31.

[90] See for example, CDC, ''ICD–10–CM Official Coding and Reporting Guidelines: April 1, 2020 through September 30, 2020'', available at *https://www.cdc.gov/nchs/data/icd/COVID-19-guidelines-final.pdf*.

[91] See for example, CMS, MLN Matters, ''July 2020 Quarterly Update to the Inpatient Prospective Payment System (IPPS) Fiscal Year (FY) 2020 Pricer'', available at *https://www.cms.gov/files/document/mm11764.pdf*.

[92] Refer to CMS, MLN Matters, ''New Waivers for Inpatient Prospective Payment Systems (IPPS) Hospitals, Long-Term Care Hospitals (LTCHs), and Inpatient Rehabilitation Facilities (IRFs) due to Provisions of the Cares Act'' (revised September 11, 2020), available at *https://www.cms.gov/files/document/se20015.pdf*.

health effects including serious circulatory, respiratory, and neurologic conditions. The commenter also believes additional health issues associated with COVID–19 will likely be identified as more research is done on COVID–19 positive patients. Given the unknowns of this novel virus, the commenter asserts that neither it nor CMS can know that the one-month post discharge end date for a COVID–19 episode will fully address the increased resource demands required to treat these patients. The commenter requested that CMS evaluate and publicly report data on the impacts of COVID–19 on all service utilization for patients with and without an inpatient admission.

Response: We agree with the commenter, regarding the importance of ongoing monitoring of Shared Savings Program calculations for the impact of healthcare utilization resulting from COVID–19 as research helps us better understand the effects of the virus on the Medicare FFS beneficiary population. At this time, we believe that defining an episode of care for the treatment of COVID–19 as set forth in § 425.611(b)(2), as the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date, is sufficient to remove the higher costs of care surrounding an inpatient service for the treatment of COVID–19 with a discharge date within the PHE for COVID–19. Further, to the extent that a beneficiary is subsequently admitted for inpatient care for complications related to COVID–19, following their initial discharge for inpatient services, a claim associated with the new hospitalization would trigger a new episode of care for treatment of COVID–19 if it meets the criteria we described elsewhere in this section of this final rule for identifying inpatient services that trigger an episode of care for treatment of COVID–19, including a discharge date within the PHE for COVID–19.

Comment: One commenter stated its support for the exclusion of affected months associated with an episode of care from total person years used in per capita expenditure calculations.

Response: We appreciate the support for the approach we described in the May 8th COVID–19 IFC (85 FR 27580) of excluding affected months associated with an episode of care from total person years used in per capita expenditure calculations. For consistency within program calculations, we will exclude months associated with episodes of care for the treatment of COVID–19 from program calculations that incorporate monthly data, including the following:

- Calculation of ACO, county, or national level weighted mean CMS-Hierarchical Condition Categories (HCC) prospective risk scores or demographic risk scores used in program risk adjustment calculations described in §§ 425.601, 425.602, 425.603, 425.604, 425.605, 425.606, and 425.610. CMS will exclude monthly prospective beneficiary CMS–HCC risk scores (based on diagnoses from the prior calendar year) from months associated with episodes of care for treatment of COVID–19. CMS will also exclude these months when computing person year values that are used to calculate weighted means of CMS–HCC and/or demographic risk scores across beneficiaries. Note, however, that CMS will continue to use diagnoses that meet risk adjustment criteria from claims submitted by FFS providers for items and services furnished during the months associated with episodes of care for treatment of COVID–19, when calculating final CMS–HCC risk scores for future years. For example, final CMS–HCC risk scores for 2021 will include risk adjustment eligible diagnoses from all eligible claims in 2020, including claims from months associated with episodes of care for treatment of COVID–19. CMS calculates risk scores for all Medicare beneficiaries and these risk scores are used in a variety of calculations across the Medicare Program; CMS does not calculate separate CMS–HCC risk scores for use in Shared Savings Program calculations.

- Calculation of assigned beneficiary person years used in determining the proportion of the ACO's assigned beneficiaries in each county by Medicare enrollment type (ESRD, disabled, aged/dual eligible, aged/non-dual eligible) used to weight risk-adjusted county FFS expenditures as described in §§ 425.601(d) and 425.603(f).

- Calculation of the weights applied to national and regional components of the blended growth rates used to trend forward benchmark year (BY) 1 and BY2 expenditures to BY3 according to § 425.601(a)(5) and to update the benchmark according to § 425.601(b).

- Calculation of assigned beneficiary enrollment proportions used to calculate the weighted average across the four Medicare enrollment types in order to obtain a single per capita updated benchmark and a single performance year per capita expenditure value.[93]

- Calculation of total person years used to calculate total benchmark expenditures and total performance year expenditures used in financial reconciliation calculations.[94]

Comment: One commenter asked for clarification of how adjustments to program calculations would be reflected in Shared Savings Program reports provided to ACOs. Specifically, the commenter asked if CMS would provide amended aggregate expenditure/utilization reports for Quarter 1 2020, if payment amounts and beneficiary months associated with episodes of care for treatment of COVID–19 are removed from program calculations going back to January 2020.

Response: In response to the Shared Savings Program policy changes established in the May 8th COVID–19 IFC, CMS added several new report tables to the 2020 quarterly reports, and these modified reports were used to provide Q2 and Q3 2020 data to Shared Savings Program ACOs. Specifically these report changes reflect the adjustment for episodes of care for treatment of COVID–19, and changes to the definition of primary care services used in determining beneficiary assignment as specified in § 425.400(c)(2) and described in section III.G.5.e of this final rule. We anticipate specifying the effects of these policies in quarterly and annual aggregate reports to which they apply. Although we are not reproducing quarterly reports for Q1 2020 to include these updated report variables, we note that the report periods of the Q2, Q3, and Q4 2020 reports include the months of January through March 2020.

Comment: One commenter expressed support for the clarification CMS provided that lump sum payments made to hospitals and other healthcare providers through the CARES Act Provider Relief Fund, that occur outside of Parts A and B claims, will not adversely impact ACO expenditures.

Response: We appreciate the commenter's support for this clarification.

Comment: One commenter suggested that CMS should use the financial

[93] For example, refer to the description of the calculation in Sections 4.1.4 and 4.3.1 of the Shared Savings and Losses and Assignment Methodology Specifications, Version 8, available at *https://www.cms.gov/files/document/shared-savings-losses-assignment-spec-v8.pdf-0.*

[94] For example, refer to the description of the calculation in Section 4.3.1 of the Shared Savings and Losses and Assignment Methodology Specifications, Version 8, available at *https://www.cms.gov/files/document/shared-savings-losses-assignment-spec-v8.pdf-0.*

performance and quality data from 2020 to help stakeholders understand the impact of the global pandemic on ACOs' collective ability to deliver care under the modified coverage and payment policy rules implemented, as well as the impact of the stay-at-home and social distancing recommendations in place throughout the country. The commenter indicated that such data would greatly contribute to future work, including developing higher quality, more cost-efficient models of care after the current pandemic has been contained.

Response: We appreciate the commenter's recommendation that CMS make public data that can assist stakeholders in understanding the impact of COVID–19 and the COVID–19 pandemic on ACOs. CMS makes public certain Shared Savings Program data, such as ACO financial performance data included in annual Shared Savings Program ACO public-use files (PUFs). We anticipate releasing a Shared Savings Program ACO PUF, with ACO-level performance year 2020 financial and quality performance data, in the fall of 2021, following financial reconciliation for performance year 2020. Additional information on program data, including a description of and link to the Shared Savings Program ACO PUF, is available through the Shared Savings Program's ''Program Data'' web page, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-data.* More generally, CMS' ''Medicare COVID–19 Data Snapshot'' resources provide data on COVID–19 cases, and hospitalizations for Medicare beneficiaries diagnosed with COVID–19.[95]

Further, ACOs actively participating in the Shared Savings Program periodically receive data from CMS, which we believe supports their ability to detect and respond to developing trends. Under § 425.702, we provide ACOs with aggregate quarterly reports that identify prospectively and preliminarily prospectively assigned beneficiaries, provide aggregated metrics on the ACO's assigned beneficiary population, and utilization and expenditure data, including expenditure data for the national and regional assignable FFS populations. Under § 425.704, we provide ACOs with monthly claim and claim line feed files with beneficiary-identifiable data, which include Parts A, B, and D data for prospectively and preliminarily prospectively assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant that submits claims for primary care services used in beneficiary assignment. We believe these program reports and data feeds will help ACOs in understanding the impact of COVID–19 on their assigned beneficiaries and the impact of the adjustment for episodes of care for treatment of COVID–19.

Comment: Many commenters commenting on the Shared Savings Program policies adopted in the May 8th COVID–19 IFC suggested it is critical that CMS extend the June 30 deadline for ACOs to voluntarily terminate to avoid financial losses to no earlier than October 31, 2020, with no more than 30-days advance notice of termination, as is currently required under § 425.220(a). The commenters asserted that ACOs need more time and data to make informed decisions about their participation. Commenters explained that absent this protection, ACOs in two-sided models may choose to leave the program given the uncertainty around the end date for the PHE for COVID–19, although the commenters were often unclear in indicating whether their concerns centered around the duration of the adjustment for episodes of care for treatment of COVID–19 or loss mitigation under the program's extreme and uncontrollable circumstances policy (as discussed in section III.G.5.c of this final rule), or both. In further explaining the need for ACOs to have additional time to determine whether to remain in the program, some commenters underscored the uncertainty around a resurgence of the virus in the fall of 2020. In addition, some commenters indicated this flexibility would provide ACOs with more time to focus on the pandemic, which would enable them to remain in the program.

Some commenters suggested that CMS provide two-sided model ACOs the opportunity to voluntarily terminate and avoid financial losses until 90 days following the effective date of the May 8th COVID–19 IFC (which would be approximately August 6, 2020, given the May 8, 2020 effective date of the IFC) to allow these ACOs time to consider the policies established with the IFC. One commenter requested that ACOs in two-sided models be given an opportunity to exit the Shared Savings Program without penalty once the rule is finalized. This commenter (an ACO) explained that the ACO faces a very difficult decision about its continued participation, without enough information, and does not wish to act impulsively.

Response: At this time, we decline to make additional modifications to the Shared Savings Program's policy on payment consequences of early termination. At the time of this final rule, the PHE for COVID–19 has been renewed for a further 90 days, with an effective date of October 23, 2020. Unless the PHE for COVID–19 is terminated early, CMS anticipates mitigating shared losses for the duration of 2020 under the Shared Savings Program's extreme and uncontrollable circumstances policy. We believe this mitigation of shared losses addresses the concerns of ACOs and other program stakeholders regarding the payment consequences of early termination for the remainder of performance year 2020.

Further, we believe we struck an appropriate balance with the combination of policies we established in the May 8th COVID–19 IFC, which provide greater certainty to ACOs and thereby encourage their continued participation in the Shared Savings Program, in particular: Allowing eligible ACOs in the BASIC track's glide path to maintain their current level of participation for performance year 2021 (described in section III.G.5.b of this final rule); adjustments to program calculations for episodes of care for treatment of COVID–19 (described in this section of this final rule); and changes to the Shared Savings Program's assignment methodology (described in section III.G.5.e of this final rule). We believe the stabilizing effect of these policies, along with the application of the program's extreme and uncontrollable circumstances policy for mitigating shared losses beginning in January 2020 and for duration of the PHE for COVID–19 (described in section III.G.5.c of this final rule), is evidenced by the fact that only 4 ACOs (including only 2 ACOs under two-sided models) terminated with an effective termination date on or before June 30, 2020, and therefore, will not be reconciled for performance year 2020. Approximately 35 ACOs, including 12 two-sided model ACOs, have voluntarily terminated their participation, and have requested an end-of-year termination date, and therefore will be reconciled for their performance in the program in performance year 2020.

Comment: Commenters suggested modifications to the Shared Savings Program's benchmarking methodologies, which went beyond the modifications to the program's regulations established in the May 8th COVID–19 IFC.

[95] *CMS.gov,* Preliminary Medicare COVID–19 Data Snapshot, available at *https://www.cms.gov/research-statistics-data-systems/preliminary-medicare-covid-19-data-snapshot.*

Commenters' suggestions included the following:

Some commenters, concerned with anomalies in expenditures and revenue for 2020, suggested alternative approaches to how CMS could treat 2020 data when 2020 is used as a benchmark year in future benchmark calculations.

Some commenters suggested that CMS exclude all 2020 data from future benchmarking calculations, such as excluding 2020 as a benchmark year or excluding 2020 data from the calculation of adjustments to the benchmark. Some commenters suggested alternative approaches to identifying benchmark years, which would avoid reliance on 2020 data. For example, for ACOs entering agreement periods beginning on January 1, 2022, one commenter suggested CMS either use 2017, 2018, and 2019 as the benchmark years (instead of 2019, 2020 and 2021), or combine 2019 and 2021 data.

One commenter suggested that CMS consider changing benchmark year weighting, to limit the impact of 2020 data.

Instead of looking at performance over a single year, one commenter suggested that CMS collaborate with program stakeholders to develop a benchmarking and financial reconciliation methodology for ACOs that spans multiple years.

Some commenters suggested CMS revise the methodology for incorporating factors based on regional FFS expenditures into ACO benchmarks through future rulemaking. Some commenters noted their concern that the blended national and regional expenditure growth rates used to trend and update an ACO's historical benchmark (for agreement periods beginning on July 1, 2019, and in subsequent years) overemphasize the national trend component for ACOs that comprise a large market share in their ACO regional service area, and disadvantage these ACOs. Some commenters expressed concern that including an ACO's assigned beneficiaries in the population used to determine regional FFS expenditures will mean the ACO is compared to itself twice: Once using historical ACO spending and another time by including ACO spending in regional spending. Commenters suggested that CMS revise the program's benchmarking methodology to exclude the ACO's assigned beneficiaries from the population of assignable beneficiaries used to determine regional FFS expenditures, typically in combination with a suggestion that CMS replace the blended national and regional expenditure growth rates with a fully regional trend.

Some commenters were concerned about the risk adjustment approach that applies to ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, and suggested that CMS revise this methodology in future rulemaking. Under the current approach, CMS uses full CMS–HCC risk adjustment for all assigned beneficiaries between the benchmark period (benchmark year 3) and the performance year, subject to a cap of positive 3 percent for the agreement period, and CMS does not apply a cap on negative risk score changes. A few commenters stated that controlling for outliers in risk score increases and decreases is important, explaining this is necessary in the context of the COVID–19 pandemic because of the utilization disruptions and health implications that will affect risk scores. Commenters described the 3 percent cap on risk score increases as ''unreasonably low'' when applied across the agreement period, particularly in light of the higher acuity of beneficiaries resulting from COVID–19 and the other effects of the COVID–19 pandemic such as beneficiaries avoiding preventive services and screenings as well as routine primary care. Commenters explained that the absence of a floor on risk score decreases does not account for artificially low risk scores resulting from circumstances surrounding the COVID–19 pandemic. For example, commenters noted that the two new ICD–10–CM diagnosis codes for COVID–19, ''U07.1 COVID–19, virus identified'' and ''U07.2, COVID–19, virus not identified,'' are not mapped to a Hierarchical Condition Code (HCC), and could therefore cause risk scores to look artificially low. Some commenters suggested that CMS revise the Shared Savings Program's risk adjustment methodology in future rulemaking, such as by increasing the 3 percent cap on risk score growth, such as to 4 percent or 5 percent or eliminating the cap altogether and implementing a floor for risk score decreases, such as between zero (which would prevent any risk score decreases from impacting the benchmark) and negative 5 percent.

Some commenters pointed to concerns that the 3 percent cap on risk score increases under in the risk adjustment methodology for ACOs in agreement periods beginning on July 1, 2019, and in subsequent years, is especially problematic for ACOs whose ACO regional service area includes a population of beneficiaries whose risk scores rise more than the cap. One commenter encouraged CMS to adopt a policy of applying a cap on risk score growth after accounting for regional increase in risk scores.

Response: Although the commenters' suggested modifications to the Shared Savings Program's benchmarking methodologies went beyond the scope of the modifications to the program's regulations established in the May 8th COVID–19 IFC, we thank the commenters for their input. We believe it would be premature to specify additional modifications to the program's benchmarking methodology at this time. As we have described elsewhere in this section of this final rule, we believe it is important to continue to monitor the program's calculations and, in particular, the factors used to establish, trend and update the benchmark, to understand the impact of any anomalies in Medicare FFS expenditures resulting from the costs of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic. As we have also indicated elsewhere in this section of this final rule, it is important to gain additional experience with the benchmarking methodology, established in the Shared Savings Program December 2018 final rule (83 FR 68005 through 68030) and specified in § 425.601, which we believe provides for appropriate incentives for Shared Savings Program ACOs, before making further revisions to the benchmarking methodology. However, we will continue to monitor the impact of the benchmarking methodology and other program policies as part of our efforts to continue to improve and strengthen the program.

Following consideration of the comments received in response to the May 8th COVID–19 IFC on the adjustments to Shared Savings Program calculations to address the COVID–19 pandemic, we are finalizing the regulation at § 425.611, with a modification. As described previously in this section of this final rule, we are revising the regulation at § 425.611(b)(1)(ii) to specify that CMS identifies episodes of care for treatment of COVID–19 based on discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of discharge occurs within the Public Health Emergency as defined in § 400.200. For the reasons discussed in this section, we are using our authority under section 1871(e)(1)(a)(ii) of the Act to apply this change retroactively to the start of the

PHE for COVID–19. Further, we anticipate monitoring program calculations for the impact of any anomalies in Medicare FFS expenditures resulting from the cost of treating COVID–19, as well as changes in healthcare utilization by Medicare FFS beneficiaries resulting from the COVID–19 pandemic. We may revisit, in future notice and comment rulemaking, the need to make other modifications to the program's financial methodology to address the impact of COVID–19 and the COVID–19 pandemic on ACOs.

e. Expansion of Codes Used in Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016) and the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018), provides that for performance years beginning on or after January 1, 2019, the Secretary shall assign beneficiaries to an ACO based on their utilization of primary care services provided by physicians participating in the ACO and all services furnished by RHCs and Federally Qualified Health Centers (FQHCs) that are ACO participants. However, the statute does not specify which kinds of services may be considered primary care services for purposes of beneficiary assignment.

For performance years beginning on January 1, 2019, and subsequent performance years, we defined primary care services in § 425.400(c)(1)(iv) for purposes of assigning beneficiaries to ACOs under § 425.402 as the set of services identified by the following HCPCS/CPT codes:

CPT codes:

- 99201 through 99215 (*codes for office or other outpatient visit for the evaluation and management of a patient*).
- 99304 through 99318 (*codes for professional services furnished in a NF; services identified by these codes furnished in a SNF are excluded*).
- 99319 through 99340 (*codes for patient domiciliary, rest home, or custodial care visit*).
- 99341 through 99350 (*codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12*).
- 99487, 99489 and 99490 (*codes for chronic care management*).
- 99495 and 99496 (*codes for transitional care management services*).
- 99497 and 99498 (*codes for advance care planning*).
- 96160 and 96161 (*codes for administration of health risk assessment*).
- 99354 and 99355 (*add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code*).
- 99484, 99492, 99493 and 99494 (*codes for behavioral health integration services*).

HCPCS codes:

- G0402 (*code for the Welcome to Medicare visit*).
- G0438 and G0439 (*codes for the annual wellness visits*).
- G0463 *(code for services furnished in ETA hospitals).*
- G0506 (*code for chronic care management*).
- G0444 (*code for annual depression screening service*).
- G0442 (*code for alcohol misuse screening service*).
- G0443 (*code for alcohol misuse counseling service*).

On March 17, 2020, we announced the expansion of payment for telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 such that Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence, starting March 6, 2020. In the context of the PHE for COVID–19, we recognize that physicians and other healthcare professionals are faced with new challenges regarding potential exposure risks, including for Medicare beneficiaries, for healthcare providers, and for members of the community at large. For example, the CDC has urged healthcare professionals to make every effort to interview persons under investigation for COVID–19 infection by telephone, text messaging system, or video conference instead of in-person. In the March 31st COVID–19 IFC, to facilitate the use of telecommunications technology as a safe substitute for in-person services, we added, on an interim basis, many services to the list of eligible Medicare telehealth services, eliminated frequency limitations and other requirements associated with particular services furnished via telehealth, and clarified several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks (85 FR 19232).

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, many of these specified Medicare telehealth services are still reported using codes that describe ''face-to-face'' services but are furnished using audio/video, real-time communication technology instead of in-person. As such, the majority of the codes for primary care services included in the additional telehealth services added in the March 31st COVID–19 IFC on an interim basis for the duration of the PHE for COVID–19 are already included in the definition of primary care services for purposes of the Shared Savings Program assignment methodology in § 425.400(c)(1)(iv).

The March 31st COVID–19 IFC also established flexibilities for certain services that are furnished virtually using technologies but that are not considered Medicare telehealth services such as virtual check-ins and e-visits as well as telephone E/M services, for which payment has been authorized during the PHE for COVID–19. Prior to the PHE, the codes for these virtual services were not included in the definition of primary care services for purposes of the Shared Savings Program assignment methodology. We explained in the May 8th COVID–19 IFC (85 FR 27582) that we believe it is critical to include these additional codes in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment, so that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for COVID–19 and allowing vulnerable beneficiaries and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. By including services provided virtually, either through telehealth, virtual check-ins, e-visits or telephone, in the definition of primary care services, we ensure that physicians and other practitioners can offer options to beneficiaries whom they treat, while also allowing this care to be included in our consideration of where beneficiaries receive the plurality of their primary care for purposes of assigning

beneficiaries to ACOs. As a result, revising the definition of primary care services used in assignment to include these services further allows for continuity and coordination of care. We also reiterated our policy defined at § 425.404(b) that, for performance years starting on January 1, 2019, and subsequent performance years, under the assignment methodology in § 425.402, CMS treats a service reported on an FQHC/RHC claim as a primary care service performed by a primary care physician.

(2) Use of Codes for Virtual Check-Ins, Remote Evaluation E-Visits, Telephone Evaluation and Management Services, and Telehealth in Beneficiary Assignment

As we described in the May 8th COVID–19 IFC (85 FR 27583 through 27586), based on feedback from ACOs and the expansion of payment, on an interim basis, for the virtual services discussed above, we revised the definition of primary care services used in the Shared Savings Program assignment methodology for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19, as defined in § 400.200, to include the following additions: (1) HCPCS code G2010 (*remote evaluation of patient video/images*) and HCPCS code G2012 (*virtual check-in*); (2) CPT codes 99421, 99422 and 99423 (*online digital evaluation and management service (e-visit)*); and (3) CPT codes 99441, 99442, and 99443 (*telephone evaluation and management services*).

We explained that because the services are similar to and may replace an E/M service for a beneficiary, we believed it would be appropriate to include these CPT and HCPCS codes in the definition of primary care services used for assignment because the services represented by these codes are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. We explained our belief that it is important to include these services in our assignment methodology because we determine assignment to ACOs based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting assigned beneficiary population. Including these codes in the definition of primary care services used in assignment for performance years during the PHE for COVID–19 results in a more accurate identification of where beneficiaries have received the plurality of their primary care services.

In the May 8th COVID–19 IFC (85 FR 27583), we also clarified that CPT codes 99304, 99305 and 99306, 99315 and 99316, 99327 and 99328, 99334 through 99337, 99341 through 99345, and 99347 through 99350 will be included in the assignment methodology when these services are furnished using telehealth, consistent with additions to the Medicare telehealth list for the duration of the PHE for COVID–19 as discussed in the March 31st COVID–19 IFC (85 FR 19235 through 19237). We use the assignment methodology described in §§ 425.402 and 425.404 for purposes of assigning beneficiaries to ACOs for a performance year or benchmark year based on preliminary prospective assignment with retrospective reconciliation (including quarterly updates) or prospective assignment.

We explained that with the emergence of the virus that causes COVID–19, there is an urgency to expand the use of technology to allow people who need routine care, vulnerable beneficiaries, and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. Limiting community spread of the virus, as well as limiting beneficiaries' exposure to other patients and healthcare staff members, will slow viral spread. We explained that we anticipated that the patterns and types of care provided during the PHE for COVID–19 would be different, and that it was important to capture these changes in the methodology used to assign beneficiaries to ACOs as soon as possible. We explained this was particularly important for ACOs under preliminary prospective assignment with retrospective reconciliation for PY 2020, so that they can understand the beneficiary population for which they will be responsible during PY 2020.

As discussed in the March 31st COVID–19 IFC (85 FR 19244), in the CY 2019 PFS final rule, we finalized separate payment for a number of services that could be furnished via telecommunications technology, but that are not Medicare telehealth services. Specifically, beginning with CY 2019, we finalized separate payment for remote evaluation of video and/or images, HCPCS code G2010 *(Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment),* and virtual check-in, HCPCS code G2012 *(Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report E/M services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion).*

These codes were finalized as part of the set of codes that is only reportable by the physicians and practitioners who can furnish E/M services. Per the March 31st COVID–19 IFC, on an interim basis for the PHE for COVID–19, we allow these codes to be used for new patients. In the March 31st COVID–19 IFC (85 FR 19244), we explained that, in the context of the PHE for COVID–19, when brief communications with practitioners and other non-face-to-face services might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we believe that these services should be available to as large a population of Medicare beneficiaries as possible. In some cases, use of telecommunication technology could mitigate the exposure risk, and in such cases, the clinical benefit of using technology to furnish the service is self-apparent. This would be especially true should a significant increase in the number of people or healthcare professionals needing treatment or isolation occur in a way that would limit access to brief communications with established providers. Therefore, on an interim basis, during the PHE for COVID–19, we finalized that these services, which may only be reported if they do not result in a visit, including a telehealth visit, can be furnished to both new and established patients

As discussed in the March 31st COVID–19 IFC (85 FR 19254), in the CY 2019 PFS final rule (83 FR 59452), we finalized payment for new online digital assessment services, also referred to as ''E-Visits,'' beginning with CY 2020 for practitioners billing under the PFS. These are non-face-to-face, patient-initiated communications using online patient portals. These digital assessment services are for established patients who require a clinical decision that otherwise typically would have been provided in the office. Per the March 31st COVID–19 IFC (85 FR 19244), while the code descriptors for these e-visit codes refer to an ''established patient'', during the PHE for COVID–19, we are exercising enforcement

discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Practitioners who may independently bill Medicare for E/M visits (for instance, physicians and NPs) can bill the following codes:

- 99421 *(Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5–10 minutes.)*
- 99422 *(Online digital evaluation and management service, for an established patient, for up to 7 days cumulative time during the 7 days; 11–20 minutes.)*
- 99423 *(Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes.)*

In the May 8th COVID–19 IFC (85 FR 27584), we explained that we also considered adding additional e-visit HCPCS codes that are used by clinicians who may not independently bill for E/M visits and who are not included in the definition of ACO professional in § 425.20 (for example, PTs, OTs, SLPs, CPs). However, because these services are not furnished by ACO professionals, we determined it was not necessary to include the following codes in our definition of primary care services for use in assignment:

- G2061 *(Qualified non-physician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes.)*
- G2062 *(Qualified non-physician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes.)*
- G2063 *(Qualified non-physician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes.)*

As discussed in the March 31st COVID–19 IFC (85 FR 19264 through 19265) and in the May 8th COVID–19 IFC, CMS finalized, on an interim basis for the duration of the PHE for COVID–19, separate payment for CPT codes 99441 through 99443 and 98966 through 98968, which describe E/M and assessment and management services furnished via telephone. While the code descriptors for these services refer to an ''established patient'', CMS has indicated in the COVID–19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing (*https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf*) that during the PHE for COVID–19 we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Practitioners who may independently bill Medicare for E/M visits (for instance, physicians and NPs) can bill the following codes:

- 99441 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion.)*
- 99442 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion.)*
- 99443 *(Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion.)*

In the May 8th COVID–19 IFC (85 FR 27584), we explained that we also considered adding the additional telephone assessment and management CPT codes that are used by clinicians who may not independently bill for E/M visits and who are not included in the definition of ACO professional in § 425.20 (for example, PTs, OTs, SLPs, CPs). However, because these services are not furnished by ACO professionals, we determined it was not necessary to include these codes in our definition of primary care services for use in assignment:

- 98966 *(Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5–10 minutes of medical discussion.)*
- 98967 *(Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 11–20 minutes of medical discussion.)*
- 98968 *(Telephone assessment and management service provided by a qualified non-physician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 21–30 minutes of medical discussion.)*

We also explained that several codes, detailed below, that are included on the ''Covered Telehealth Services for PHE for the COVID–19 pandemic, effective March 1, 2020'' list available at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes*, are already included in the definition of primary care services used in the Shared Savings Program assignment methodology:

- 99304 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)*
- 99305 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or*

family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.)

• 99306 *(Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 45 minutes are spent at the bedside and on the patient's facility floor or unit.)*

• 99315 *(Nursing facility discharge day management; 30 minutes or less.)*

• 99316 *(Nursing facility discharge day management; more than 30 minutes.)*

• 99327 *(Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.)*

• 99328 *(Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/or family or caregiver.)*

• 99334 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent with the patient and/or family or caregiver.)*

• 99335 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent with the patient and/or family or caregiver.)*

• 99336 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.)*

• 99337 *(Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.)*

• 99341 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.)*

• 99342 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.)*

• 99343 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.)*

• 99344 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.)*

• 99345 *(Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high*

complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.)

- 99347 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 15 minutes are spent face-to-face with the patient and/or family.)*
- 99348 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.)*
- 99349 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.)*
- 99350 *(Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.)*

We clarified that because these CPT codes are already included in the definition of primary care services used in the Shared Savings Program assignment methodology, these CPT codes would continue to be included in the definition of primary care services used for assignment, including when they are furnished via telehealth during the PHE for COVID–19, beginning March 1, 2020. We explained our belief that it is important to include these services in our assignment methodology, regardless of whether they are furnished in-person or via telehealth, because we determine assignment based upon where beneficiaries receive the plurality of their primary care services or whether they have designated an ACO professional as their primary clinician, responsible for their overall care, and hold ACOs accountable for the resulting assigned beneficiary population. We explained that including these codes in the definition of primary care services used in assignment during the PHE for COVID–19, even when services are furnished via telehealth, would result in a more accurate identification of where beneficiaries receive the plurality of their primary care services.

Accordingly, we added paragraph (c)(2) to our regulation at § 425.400, in which we specified additional primary care service codes that would be considered for purposes of beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19, as defined in § 400.200. Under this provision the existing CPT codes and HCPCS codes included in the definition of primary care services at § 425.400(c)(1) continue to apply for purposes of determining beneficiary assignment under § 425.402.

We received public comments on the revisions to the definition of primary care services for purposes of assignment that we adopted in the May 8th COVID–19 IFC, including the alternative considered with regard to adding codes used by non-ACO professionals. The following is a summary of the comments we received and our responses.

Comment: Commenters generally supported the addition of the telemedicine, e-visits, and virtual services to the list of primary care services used for purposes of beneficiary assignment during the PHE for COVID–19. Commenters noted that the expansion of the definition of primary care services will allow ACOs to continue managing their patient populations but also advised CMS to monitor closely for unintended consequences. Commenters also noted that the expanded definition will allow CMS to accurately identify where beneficiaries receive the plurality of their primary care services during the PHE, which is critical for the stability of ACOs and primary care physicians transitioning into value-based payment arrangements. The revised definition also protects ACOs from undue declines in their assigned beneficiary populations due to the transition to telehealth services. Other commenters supported the expanded definition of primary care services used for assignment, as telehealth has proven to be critical for many independent physicians and practices during the pandemic. More patients than ever are using telehealth as a routine part of their care, and more clinicians and hospitals are offering it. Incorporating these services into the assignment methodology ensures that ACOs are rewarded for their efforts to transform their practices from in-person to virtual to support social distancing, as necessary during the PHE for COVID–19. Another commenter supported this change and appreciated the Agency's recognition of the increased delivery of care through telehealth due to the pandemic and the clarification that services included in the existing definition of primary care services would be considered in assignment when furnished in accordance with the telehealth rules.

However, commenters cautioned against unintended consequences. One such unintended consequence could be assignment to ACOs of beneficiaries residing in states from which the ACO had not previously received assigned beneficiaries. One commenter encouraged CMS to develop clear guardrails for patient attribution that balance the expanded role of telehealth post-COVID–19 with the potential for healthcare providers to reach patients far outside their normal geographic region. Another commenter believed this expansion may result in a patient

being attributed to the ACO through a telehealth visit with an ACO professional, and that ACO subsequently becoming responsible for the cost and quality of care of that patient, who may not continue to see ACO professionals participating in that ACO once the pandemic ends. A few commenters expressed their belief that the expansion of virtual services provided during the PHE for COVID–19 will result in telemedicine continuing to be a significant mode of providing clinical services as the COVID–19 pandemic continues, and in the post-COVID–19 era.

Response: We appreciate the comment that the expansion of the definition of primary care services for the duration of the PHE for COVID–19 will allow ACOs to effectively manage their patient populations. We believe that the revised definition will allow ACOs and their ACO participants to make determinations regarding the appropriate and effective use of telehealth and in-person services based on the needs of the beneficiary balanced with safety considerations during the PHE for COVID–19. By expanding the definition, ACOs will not be penalized if they elect to furnish more services through telehealth and telemedicine during the PHE for COVID–19.

We have continued to monitor assignment data for anomalies. In the first quarter of 2020, we observed a significant drop in the utilization of HCPCS and CPT codes used in assignment; however, as of the third quarter of 2020, utilization of these codes, including the new codes added in the May 8th COVID–19 IFC, has rebounded to near typical utilization.

Further, as of the third quarter of 2020, we are seeing minimal decreases in assigned and assignable beneficiaries for ACOs participating under preliminary prospective assignment, similar to percentage decreases seen when comparing assignable and assigned beneficiaries in Q1 to assignable and assigned beneficiaries in Q3 of 2019. For 2019, the Q1 to Q3 average decrease in assigned beneficiaries was less than 1 percent. For 2020, the Q1 to Q3 average decrease in assigned beneficiaries is 3 percent. The average decrease in assignable beneficiaries from Q1 to Q3 of 2019 was less than one percent while the average decrease in assignable beneficiaries from Q1 to Q3 of 2020 is less than 5 percent. These minor average differences indicate that the PHE for COVID–19 is not having a large impact on beneficiary assignment for ACOs under preliminary prospective assignment.

We also continue to monitor rates of beneficiary churn, that is, the rate at which beneficiaries are assigned to an ACO and subsequently not assigned to that ACO; through the third quarter of 2020, rates of beneficiary churn remain consistent with rates seen prior to the PHE for COVID–19. The consistent rates of beneficiary churn indicate that the majority of beneficiaries continue to receive the plurality of their services from healthcare providers who participate in the ACO to which they were assigned at the start of the performance year. Our analyses also indicate that, on average, ACOs are losing fewer beneficiaries to competition with other ACOs and non-ACO affiliated healthcare providers during 2020 than were lost during 2019. Based on these findings, we believe that the PHE for COVID–19 is not having a significant impact on beneficiary retention.

With regard to comments that ACOs may have beneficiaries assigned to them based on telehealth visits, including beneficiaries that reside outside the ACO's normal geographic region, and those beneficiaries may not receive in-person services from ACO professionals after the PHE for COVID–19 ends, we do not believe that this is a concern for the Shared Savings Program because we continue to determine assignment based upon where beneficiaries receive the plurality of their primary care services and whether beneficiaries have designated an ACO professional as their primary clinician. Our analysis through the third quarter of 2020 indicates that the utilization of telehealth and telemedicine services is beginning to decrease, and in-person visits are beginning to rebound. To the extent that beneficiaries who had been receiving telehealth and telemedicine services from an ACO professional return to receiving in-person services from other healthcare providers (outside the ACO), assignment based on the plurality of primary care services will result in beneficiaries being assigned appropriately.

Finally, we agree with commenters that telemedicine will likely continue to be a significant mode of providing clinical services and we will continue to refine the definition of primary care services, as appropriate, in future rulemaking.

Comment: Several commenters requested that CMS clarify that the agency's existing policy has been to consider all codes listed in § 425.400(c)(1)(iv) when performing beneficiary assignment even when those services that are eligible for telehealth are delivered via telehealth. They suggested that such a clarification would mitigate confusion and emphasize the importance of these services in assignment.

Response: We appreciate this request for clarification. CMS maintains a list of services that are payable under the Medicare Physician Fee Schedule when furnished via telehealth (*https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes*). Several of the codes included on the List of Telehealth Services are also included in the Shared Savings Program definition of primary care services for purposes of assigning beneficiaries. Specifically, we clarify that those HCPCS and CPT codes included in the List of Telehealth Services that are also included in the Shared Savings Program definition of primary care services for purposes of assignment are used for assignment regardless of whether they are furnished in person or via telehealth, provided they are billable and payable under Medicare FFS payment policies and a specific place of service exclusion is not included for the codes in our assignment methodology.

Comment: One commenter expressed concern about the special assignment rules for services furnished in Electing Teaching Amendment (ETA) hospitals. Specifically, the commenter was concerned that only institutional claims (Part A claims) for services furnished in these hospitals are used in assignment calculations. The commenter expressed concern that beneficiaries who would have been assigned to an ACO in which an ETA hospital is participating based on in-person office visits at the ETA hospital will not be assigned to the ACO on the basis of telemedicine services, even if these services were provided by one of the physicians within its network, by which we assume the commenter means physicians that practice in the ETA hospital and bill through the ETA hospital's TIN that is included on the ACO's ACO participant list. This commenter urged CMS to examine the impact of this issue and to update the beneficiary assignment methodology immediately. This commenter also urged CMS to continue attributing Medicare beneficiaries to ACOs with Electing Teaching Hospitals (ETAs) as ACO participants through Institutional/Part A claims, but to include telehealth encounters billed under Institutional/Part A claims (that is, claims under HCPCS code Q3014).

Response: We appreciate the commenter's concern regarding the special assignment rules for ETA hospitals that rely on institutional claims. However, because we did not

include institutional claims billed under HCPCS code Q3014 as part of the revisions to the definition of ''primary care services'' in the May 8th COVID–19 IFC, or otherwise propose to add this code to the definition of primary care services used for assignment, we cannot finalize its inclusion as part of this final rule. We also note section 1899(c) of the Act, which governs the assignment process under the Shared Savings Program, and the implementing regulations at part 425 subpart E, make clear that assignment is based upon primary care services furnished by certain practitioners, and services reported on claims from FQHCs and RHCs, which are treated as primary care services performed by a primary care physician. Because HCPCS code Q3014 describes a telehealth originating facility site fee that is billable by the site hosting the patient rather than the distant site physician or practitioner who is furnishing the service and does not identify the actual service that was furnished during the telehealth visit, it does not represent a primary care service that may be considered in the assignment methodology under the Shared Savings Program.

Comment: Some commenters expressed concerns about anomalous CY 2020 utilization patterns impacting beneficiary assignment. For example, as one commenter detailed, the COVID–19 pandemic could cause an overall decrease in assigned beneficiaries, and change the demographics of the assigned population (including beneficiaries' CMS–HCC risk profiles). Some commenters were especially concerned about the impact on ACOs under prospective assignment. For example, one commenter explained that these ACOs may experience a disproportionate increase in their average risk score, due to the loss of relatively healthy beneficiaries who were assigned to an ACO based on only 1–2 visits as beneficiaries' care-seeking behaviors have changed as a result of the pandemic (for example, receiving care through telehealth outside the ACO, sheltering in a different geographic location and receiving services from healthcare providers there, and deferring or foregoing routine care). Some commenters suggested that CMS address the impact of atypical patterns of care on beneficiary assignment by adjusting the data used in determining assignment. For instance, a few commenters suggested that CMS disregard 2020 data when determining assignment for benchmark or performance years, but did not provide detailed suggestions for an alternative approach. Some commenters suggested that CMS use an extended assignment window for determining PY 2021 prospective assignment, such as a 24-month or 18-month assignment window instead of a 12-month assignment window, which would include months during 2020. One commenter suggested that CMS carefully review the methodology to ensure that beneficiary assignment is fair and equitable.

Response: We continue to monitor assignment trends. To date, we have seen minimal decreases in the overall number of beneficiaries assigned to ACOs participating in the Shared Savings Program, with a slight decrease (−3.0 percent) in the median number of beneficiaries assigned to individual ACOs between Q1 and Q3 2020. We interpret the comments suggesting that we disregard 2020 data in benchmark and performance year assignment to mean that CMS should not use fee-for-service claims with dates of service in 2020 to assign beneficiaries, and instead determine alternate assignment windows that do not include 2020. At this time, we are not adopting commenters' suggestions to disregard 2020 data in benchmark year and performance year assignment, or to redefine the assignment window for PY 2021 prospective assignment to include additional months, as our analyses of assignment and utilization trends indicate such policy updates are not necessary. We will continue to monitor the impact of the PHE for COVID–19 on assignment and may consider proposing changes in future notice and comment rulemaking if warranted.

(3) Applicability of Expanded Definition of Primary Care Services

After further consideration of our existing beneficiary assignment methodology in part 425, subpart E, which includes the use of an assignment window to conduct beneficiary assignment for both benchmark and performance years, we have determined that it is necessary to modify § 425.400(c)(2) to better reflect the way in which we conduct assignment for the Shared Savings Program.

In the June 2015 final rule (80 FR 32699) we finalized the definition of ''assignment window'' under § 425.20 to mean the 12-month period used to assign beneficiaries to an ACO. As described in the December 2018 final rule, the assignment window for ACOs under prospective assignment is a 12-month period off-set from the calendar year, while for ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window is the 12-month period based on the calendar year (83 FR 67861). Operationally, in determining beneficiary assignment for each performance year and benchmark year, we identify allowed charges for services billed under the HCPCS and CPT codes included in the applicable definition of primary care services under § 425.400(c), and according to the methodology specified in subpart E of the Shared Savings Program's regulations, during all months of the 12-month period of the assignment window.

The new provision at § 425.400(c)(2) states that we will apply the expanded definition of primary care services, which includes codes for virtual check-ins, remote evaluation e-visits, telephone E/M services, and telehealth, to determine beneficiary assignment for the performance year starting on January 1, 2020, and for any subsequent performance year that starts during the PHE for COVID–19 as defined in § 400.200. We have determined it is necessary to modify the provision to make clear that the expanded definition of primary care services will apply not only to assignment for performance years during the PHE for COVID–19, but also to assignment for any benchmark years during the PHE.

To further clarify the applicability of the expanded definition of primary care services, we believe it is necessary to specify when a performance year's or benchmark year's assignment is affected by the PHE for COVID–19, because the assignment window for such years may span a period which includes months during or outside the PHE for COVID–19. For consistency with our operational approach, we believe it is necessary to apply the definition of primary care services consistently to all months of the assignment window. Further, because the HCPCS and CPT codes included in the expanded definition of primary care services in § 425.400(c)(2) capture the unique utilization patterns during the PHE for COVID–19, we believe that applying this expanded definition to all months of the assignment window will help ensure we are appropriately identifying the ACO's assigned population that will be used in determining ACOs' financial performance.

As discussed in section III.G.2.a of this final rule, we are finalizing the inclusion of online digital E/M services CPT codes (99421, 99422, and 99423) and HCPCS codes G2010 (code for the remote evaluation of patient video/images) and G2012 (code for virtual check-in) in the definition of primary care services under § 425.400(c)(1)(v), applicable for the performance year

starting on January 1, 2021, and subsequent performance years. The telephone E/M services CPT codes (99441, 99442, and 99443), included in the expanded definition of assignment under § 425.400(c)(2) but not under § 425.400(c)(1), are not payable under the Medicare Physician Fee Schedule payment rules outside of the PHE for COVID–19. We anticipate that applying the telephone E/M services CPT codes to months of the assignment window that occur outside of the PHE for COVID–19 will have a limited impact on assignment.

Therefore, we are revising § 425.400(c)(2) to make clear that we will use the expanded definition of primary care services to identify allowed charges used in beneficiary assignment when the assignment window for a benchmark or performance year includes any month(s) during the PHE for COVID–19, as defined in § 400.200. Furthermore, in determining beneficiary assignment, we will consider services billed under the additional primary care service codes specified in § 425.400(c)(2) during all months of the assignment window, including months that occur outside of the PHE for COVID–19.

The following example illustrates the applicability of the approach we are finalizing. For ACOs under prospective assignment, beneficiary assignment for PY 2021 will be based on the October 1, 2019, through September 30, 2020 assignment window, which includes months before the start of and during the PHE for COVID–19. Accordingly, we will consider any services billed under the additional primary care service codes specified in § 425.400(c)(2) during this assignment window when conducting beneficiary assignment for PY 2021. Further, we will use this same approach in determining prospective assignment for 2021 when it serves as a benchmark year.

We also wish to clarify that the expanded definition of primary care services specified in § 425.400(c)(2) does not apply for purposes of determining prospective assignment for PY 2020, or under prospective assignment for 2020 when it serves as a benchmark year, because the months in the assignment window were not during the PHE for COVID–19. Prospective assignment is completed before the start of the performance year, according to § 425.400(a)(3). Although we may make certain adjustments to remove beneficiaries from an ACO's prospective assignment list if they are no longer eligible for assignment according to § 425.401(b), we do not add beneficiaries to an ACO's prospective assignment list after the start of the performance year, as described in earlier rulemaking (see for example, 80 FR 32774 and 32775). Prospective assignment for PY 2020 was completed prior to the start of the PHE for COVID–19, based on services furnished during the assignment window from October 1, 2018, through September 30, 2019. As a result, we do not believe it is either necessary to address the change in care patterns during the PHE for COVID–19 or consistent with the prospective assignment methodology in § 425.400(a)(3) to update PY 2020 beneficiary assignment for ACOs under prospective assignment to reflect utilization of the primary care services specified in § 425.400(c)(2) during the assignment window for the performance year.

Accordingly, for clarity and greater consistency with the beneficiary assignment methodology in part 425, subpart E, we are revising the text of the regulation at § 425.400(c)(2) to specify that the additional primary care service codes will be used in conducting beneficiary assignment when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the PHE for COVID–19 defined in § 400.200. We are also adding a new provision at § 425.400(c)(2)(ii) to specify that we will apply the additional primary care service codes, specified in § 425.400(c)(2)(i) (as renumbered), to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) of the PHE for COVID–19 as defined in § 400.200. We are also making conforming revisions to renumber the existing provisions of the regulation at § 425.400(c)(2) to reflect this addition.

In the May 8th COVID–19 IFC (85 FR 27583), we determined that there was good cause to waive prior notice and comment rulemaking in order to implement the expanded definition of primary care services in § 425.400(c) immediately for purposes of determining beneficiary assignment for PY 2020. In addition, we also explained that we believed it would be contrary to the public interest not to implement certain Medicare provisions in the IFC as soon as we were authorized to do so under the authority of section 1871(e)(1)(A)(ii) of the Act, that is, retroactively to either the start of the national emergency or the PHE for the COVID–19 pandemic, as applicable (85 FR 27609). Because the revisions we are making to § 425.400(c)(2) in this final rule are intended to clarify the applicability of the expanded definition of primary care services to the determination of beneficiary assignment, we believe it is in the public interest to use our authority under section 1871(e)(1)(A)(ii) of the Act to apply this change retroactively to ensure that it applies to the determination of beneficiary assignment under § 425.400(a)(2) for the performance year starting on January 1, 2020, for ACOs under preliminary prospective assignment with retrospective reconciliation. We note that this is consistent with the applicability date for the provision as originally adopted in the May 8th COVID–19 IFC (see 85 FR 27551, 27609).

We will apply this expanded definition of primary care services, as revised, to determine beneficiary assignment for ACOs under prospective assignment according to § 425.400(a)(3), and for ACOs under preliminary prospective assignment with retrospective reconciliation according to § 425.400(a)(2). The revised definition is also applicable for purposes of determining beneficiary assignment for Track 1+ Model ACOs in the same way in which it applies to Shared Savings Program ACOs under prospective assignment according to § 425.400(a)(3).[96] We also note that we will apply this revised definition consistently when performing beneficiary assignment in program operations, which includes (for example), determining the ACO's performance year assigned population, determining the assigned population for purposes of producing quarterly assignment list reports and quarterly aggregate reports for ACOs, and determining assignment for benchmark years.

In summary, following consideration of the comments received in response to the May 8th COVID–19 IFC, we are finalizing the regulation at § 425.400(c)(2) with modifications. We are finalizing the use of the following additional primary care codes in determining beneficiary assignment when the assignment window (as defined at § 425.20) for a benchmark or performance year includes any months during the PHE for COVID–19 defined in § 400.200: (1) HCPCS code G2010 (*remote evaluation of patient video/images*) and HCPCS code G2012 (*virtual check-in*); (2) CPT codes 99421, 99422 and 99423 (*online digital evaluation and management service (e-visit)*); and

[96] Refer to the terms of the Track 1+ Model Participation Agreement, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

(3) CPT codes 99441, 99442, and 99443 (*telephone evaluation and management services*). Additionally, in this final rule we are revising the regulation to add a new provision at § 425.400(c)(2)(ii) to specify that we will apply the additional primary care service codes, specified in § 425.400(c)(2)(i) (as renumbered), to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) during the PHE for COVID–19 defined in § 400.200.

f. Applicability of Policies to Track 1+ Model ACOs

In the May 8th COVID–19 IFC (85 FR 27586 and 27587), we provided a comprehensive discussion of the applicability of policies, either clarified or modified by the IFC, to Track 1+ Model ACOs. We explained which changes to Shared Savings Program regulations would apply to Track 1+ Model ACOs, and which changes in policies would become applicable to Track 1+ Model ACOs through an amendment to the ACO's Track 1+ Model Participation Agreement.[97]

Generally, comments regarding the application of policies discussed in the May 8th COVID–19 IFC, to Track 1+ Model ACOs have been addressed as part of the discussion of those policies elsewhere in section III.G.5 of this final rule. Accordingly, rather than repeating comments related to the applicability of these policies to ACOs participating in the Track 1+ Model, we refer readers to the relevant discussion in section III.G.5. of this final rule.

H. Notification of Infusion Therapy Options Available Prior To Furnishing Home Infusion Therapy Services

Section 5012 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255; enacted December 13, 2016) created a separate Medicare Part B benefit under section 1861(s)(2)(GG) and section 1861(iii) of the Act to cover home infusion therapy-associated professional services for certain drugs and biologicals administered intravenously or subcutaneously through a pump that is an item of durable medical equipment, effective for January 1, 2021. Section 5012 of the Cures Act also added section 1834(u) to the Act, which establishes the payment and related requirements for home infusion therapy under this benefit. Section 1834(u)(6) of the Act requires that, prior to the furnishing of home infusion therapy to an individual, the physician who establishes the plan of care described in section 1861(iii)(1) of the Act shall provide notification (in a form, manner, and frequency determined appropriate by the Secretary) of the options available (such as home, physician's office, HOPD) for the furnishing of infusion therapy under this part.

As discussed in the 2021 PFS proposed rule, (85 FR 50074), we recognize there are several possible forms, manners, and frequencies that physicians may use to notify patients of their infusion therapy treatment options. We solicited comments in the CY 2020 PFS proposed rule (84 FR 40716) and the CY 2020 HH PPS proposed rule (84 FR 34694), regarding the appropriate form, manner, and frequency that any physician must use to provide notification of the treatment options available to their patient for the furnishing of infusion therapy (home or otherwise) under Medicare Part B. We also invited comments on any additional interpretations of this notification requirement. We summarized the comments received in the CY 2020 PFS final rule (84 FR 62568) and the CY 2020 HH PPS final rule (84 FR 60478), and we stated we would take these comments into consideration as we continue developing future policy through notice-and-comment rulemaking.

Many commenters stated that physicians already routinely discuss the infusion therapy options with their patients and annotate these discussions in their patients' medical records. For home infusion therapy services effective beginning CY 2021, physicians are to continue with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. We did not propose to create a mandatory form nor did we propose to require a specific manner or frequency of notification of options available for infusion therapy under Part B prior to establishing a home infusion therapy plan of care, as we believe that current practice provides appropriate notification. However, we noted that if current practice is later found to be insufficient in providing appropriate notification to patients of the available infusion options under Part B, we may consider additional requirements regarding this notification in future rulemaking. We referred stakeholders to the CY 2020 HH PPS final rule (84 FR 60478) for further information regarding the policies on home infusion therapy services beginning CY 2021 and for subsequent years.

In response to the 2021 PFS proposed rule, (85 FR 50252), we received 14 public comments, all in support of physicians continuing with the current practice of discussing options available for furnishing infusion therapy under Part B and annotating these discussions in their patients' medical records prior to establishing a home infusion therapy plan of care. Two of these commenters mentioned other issues that were discussed in the CY 2020 HH PPS final rule (84 FR 60478) regarding the general home infusion therapy services policy. After consideration of these comments, and since we did not propose any specific requirements, we are not adopting specific notification requirements in this final rule. Rather, as noted previously, if current practice is later found to be insufficient, we may consider additional requirements regarding this notification in future rulemaking. Stakeholders may refer to the CY 2020 HH PPS final rule (84 FR 60478) for further information regarding the policies on home infusion therapy services beginning CY 2021.

I. Modifications to Quality Reporting Requirements and Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

Following the hurricanes and wildfires during 2017, we issued an IFC, entitled ''Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017,'' which appeared in the December 26, 2017 **Federal Register** (82 FR 60912) (hereinafter referred to as the ''December 2017 IFC''). The December 2017 IFC established a policy for determining quality performance scores for ACOs, when the ACO was impacted by extreme and uncontrollable circumstances such as hurricanes, wildfires, or other triggering events, in performance year 2017, including the applicable quality reporting period for the performance year if the quality reporting period was not extended. In the CY 2019 PFS final rule, we extended the policies finalized in 2017 to performance year 2018 and subsequent performance years. In the March 31st COVID–19 IFC (85 FR 19267 and 19268), we updated the extreme and uncontrollable circumstances policy to eliminate the restriction that the policy applies only if the quality reporting period is not extended.

We determine whether an ACO has been impacted by an extreme and

[97] See for example, the Medicare ACO Track 1+ Model Participation Agreement, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/track-1plus-model-par-agreement.pdf.*

uncontrollable circumstance using the following criteria:

- 20 percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance (§ 425.502(f)(1)(i)).
- The ACO's legal entity is physically located in an area identified as being affected by an extreme and uncontrollable circumstance under the Quality Payment Program (§ 425.502(f)(1)(ii)).

Under the current regulation at § 425.502(f)(2), ACOs that meet one or both of the above criteria will have their quality performance score set to equal the mean quality performance score for all Shared Savings Program ACOs for the relevant performance year. However, if an ACO that meets one or both of the criteria above completely and accurately reports all quality measures, we use the higher of the ACO's quality performance score or the mean quality performance score for all Shared Savings Program ACOs to calculate the ACO's quality performance score.

The PHE for COVID–19 applies to all counties in the United States, and therefore, for performance year 2020 all ACOs are considered to be affected by an extreme and uncontrollable circumstance.

1. Changes to the CAHPS for ACOs Reporting Requirements for Performance Year 2020

In the CY 2021 PFS proposed rule, we explained that as part of the March 31st COVID–19 IFC, we made updates to the Part C and Part D Star Rating Systems for 2021 and 2022 based on concerns that the PHE for COVID–19 would pose significant challenges and safety concerns in successfully completing the CAHPS survey. In the March 31st COVID–19 IFC, we noted that many of the survey administration protocols could not be completed remotely, requiring staff to work in mail facilities and call centers where telephone interviewers assemble in close quarters to perform the telephone administration of the survey. Accordingly, to be in compliance with social distancing, travel bans, quarantine, and promoting health and safety of all involved in CAHPS data collection, we amended regulations in parts 417, 422, and 423 to eliminate requirements for collection of CAHPS data for performance year 2020 (85 FR 19271 and 19272).

In order to maintain consistency with the public safety determinations made in the March 31st COVID–19 IFC with respect to the CAHPS survey that is used in the Part C and Part D Star Ratings Systems, as noted above, and to address concerns about the negative impacts of COVID–19 on sample size and performance scores, we proposed to modify our regulations to remove the requirement that ACOs field a CAHPS for ACOs survey for performance year 2020. Instead, we proposed that ACOs would automatically receive full credit for each of the CAHPS survey measures within the patient/caregiver experience domain for performance year 2020. We acknowledged that the proposal would be retroactive for performance year 2020. However, section 1871(e)(1)(A) of the Act allows for retroactive application of a substantive change when the failure to apply the change retroactively would be contrary to the public interest. Based on the concerns described in the proposed rule, we concluded it would be in the public interest not to require ACOs to field the CAHPS for ACOs survey. Accordingly, we proposed to amend § 425.500(d) to add language stating that for performance year 2020 we would waive the CAHPS for ACOs reporting requirement and would automatically give all ACOs full credit for the CAHPS for ACOs survey measures (85 FR 50252 through 50254).

We sought comment on the proposal to waive the CAHPS for ACOs reporting requirement and to give ACOs full credit for the CAHPS for ACOs survey measures for performance year 2020. The following is a summary of the comments we received and our response.

Comment: A majority of commenters supported our proposal to waive the CAHPS for ACOs reporting requirement for performance year 2020 and to provide ACOs automatically with full credit for each of the CAHPS survey measures. Commenters pointed to inadequate sample size, an inability to generalize results of the survey due to safety measures implemented during the PHE for COVID–19, reduction of burden on Medicare ACO beneficiaries, and concerns that paper surveys were not a sanitary choice for gathering feedback, as reasons why they supported our proposal. Only one commenter urged CMS to require ACOs to participate in the CAHPS for ACOs survey in a pay-for-reporting capacity for PY 2020 or to at least encourage interested ACOs to voluntarily participate in the survey. The commenter explained that without the CAHPS for ACOs survey, ACOs will be unable to capture the experience of patients during the PHE for COVID–19, as well as continue internal performance improvement efforts.

Response: We appreciate the support for our proposal to remove the CAHPS for ACOs survey reporting requirement for performance year 2020 and to give ACOs automatic full credit for each of the CAHPS survey measures. We acknowledge the commenter's concern with regard to ACOs' inability to capture the experience of patients during the PHE for COVID–19; however, we note that outside of the Shared Savings Program requirements, each ACO is at liberty to determine if it wants to continue with the administration of the CAHPS for ACOs survey. Therefore, we are finalizing our proposal to waive the CAHPS for ACOs reporting requirement for performance year 2020 and to assign all ACOs automatic credit for each of the CAHPS survey measures within the patient/caregiver experience domain. We are adopting the proposed amendments to § 425.500(d) without modification.

2. Comment Solicitation on Modifications to the Extreme and Uncontrollable Circumstances Policy for Performance Year 2020

In the March 31st COVID–19 IFC (85 FR 19267–68), we noted that we would consider whether the current extreme and uncontrollable circumstances policy under which we assign an ACO the higher of the mean quality score across all ACOs and the ACO's own quality score, in the event the ACO is determined to be impacted by an extreme and uncontrollable circumstance would continue to be appropriate for PY 2020 and beyond. We explained that any change to that current policy would be made through future notice and comment rulemaking. While we did not propose any specific changes to the extreme and uncontrollable circumstances policy for PY 2020 in the March 31st COVID–19 IFC, we did receive public comments in response to both the March 31st COVID–19 IFC and the May 8th COVID–19 IFC regarding the impact of the PHE for COVID–19 on quality reporting and quality performance for PY 2020. The following is a summary of the comments we received in response to both the March 31st COVID–19 IFC and the May 8th COVID–19 IFC and our response.

Comment: Many commenters urged CMS to make all ACO quality measures pay-for-reporting for PY 2020. Several of the commenters who suggested this approach stated that the current extreme and uncontrollable circumstances policy was better suited for focal disasters, such as hurricanes or floods. The commenters explained that as a result of the PHE for COVID–19, ACO participants have faced, and will continue to face, numerous challenges during 2020, such as prioritizing care

for COVID–19 patients, canceling in-person preventative and chronic condition management visits to prevent the spread of the virus, and supplying personal protective equipment for the safety of healthcare providers and patients. Commenters stated that a move towards pay-for-reporting for 2020 would provide ACOs and their participating providers and suppliers the flexibility to respond to the PHE for COVID–19 while continuing to monitor and report these metrics. One commenter noted that the quality of care and patients' experience of care is as important as ever during these unprecedented times and encouraged CMS to continue to collect quality measure data as feasible and appropriate in 2020. The commenter explained that making quality measures pay-for-reporting in PY 2020 would ensure that an ACO's quality score does not adversely impact its financial performance due to factors outside of the ACO's control, such as COVID–19 related shifts in care delivery sites and staffing, deferred routine care, and increased telehealth utilization. The commenter stated that reverting quality scores to pay-for-reporting would also help to offset the anticipated deflationary impact of deferred care on the PY 2020 benchmark, which would lower the total amount of savings available to Shared Savings Program ACOs. Another commenter explained that pay-for-reporting for PY 2020 is warranted because, for the remainder of 2020, hospitals, group practices, and individual healthcare providers will be focused almost exclusively on urgent or emergent patients, as well as protecting themselves, their staff, and other patients from the coronavirus. One commenter stated that some measures would be difficult to satisfy if patients are not engaging with their healthcare providers in office or via telehealth and that, the restriction on elective procedures could make it difficult for patients to get their breast cancer, colon cancer, and various other screenings. The commenter noted that this problem could get worse if there is a resurgence of COVID–19 in the fall.

For various reasons, many commenters asserted that the current extreme and uncontrollable circumstances policy, which assigns an ACO the higher of the mean quality score across all ACOs and the ACO's own quality score, is insufficient for PY 2020 and beyond. One commenter explained that given the massive shifts in care delivery sites and staffing, increased telehealth utilization, data collection challenges and other COVID–19 related impacts in 2020, the application of either an average quality score or an individual ACO's own quality score based on data from the 2020 performance year is neither feasible nor appropriate. Other commenters expressed concern that the current extreme and uncontrollable circumstances policy is insufficient to mitigate the vast impacts of the PHE for COVID–19 on ACO quality performance because many ACOs are deploying their quality improvement staff to provide clinical care and assist in triaging patients, detracting them from their more typical quality improvement and care coordination work. These commenters explained that while there is value in ACOs' reporting what data they can during this challenging time, ACOs should not be held accountable to typical quality performance standards during this highly irregular PHE for COVID–19.

Several commenters expressed concerns about whether ACOs could meet the quality reporting requirements for PY 2020 because of the shift to providing services via telemedicine. One commenter stated that while CMS has expanded telehealth coverage for Medicare beneficiaries, several quality measures cannot be properly met in a remote setting such as immunizations and mammography screening, which are services that can only be performed in person. Another commenter requested that CMS allow patient-reported information provided during telehealth visits to satisfy quality measures where applicable. The commenter explained that per the quality measure specification for HTN–2 (NQF 0018)(ACO–28): Controlling High Blood Pressure, only blood pressure readings performed by a clinician or a remote monitoring device are acceptable for numerator compliance with this measure and that CMS does not permit information reported or taken by the member. The commenter noted that Medicare beneficiaries may be reluctant to have an in-person office visit and may not have access to a remote monitoring device, as described in the measure specification, and their information may not be available for use in determining the ACO's performance on the measure.

Other commenters suggested that CMS should allow ACOs to continue quality reporting efforts when possible, but that CMS should hold the ACOs harmless for any performance changes. Several commenters explained that it would not be appropriate to compare performance during 2020 to quality benchmarks established based on performance in previous years because the avoidance of care by patients and the postponement of certain critical services to preserve PPE will have lasting effects on quality. These commenters stated that they believe that ACOs will struggle to manage patients with chronic conditions and to provide proper preventive care during this time because patients are avoiding primary care, well visits, chronic care maintenance, and other health services. For these reasons, these commenters encouraged CMS to exclude 2020 quality performance data from future quality benchmarking. One commenter suggested that CMS mirror past Shared Savings Program performance rates and essentially grade on a curve for 2020. The commenter explained that the quality benchmarks should be adjusted so that the average Shared Savings Program quality score mirrors the average Shared Savings Program quality score in 2018. The commenter stated that this approach would keep the focus on quality and allow CMS to use quality performance to differentiate among ACOs in 2020, but would not unfairly transfer savings from ACOs to CMS due to difficulties in maintaining high rates of performance on quality measures (particularly routine preventative measures) during the PHE for COVID–19.

For PY 2021 and beyond, several commenters urged CMS to continue to study the impact of the PHE for COVID–19 on ACO quality performance in the months and years to come, as it is likely that additional policy changes will be necessary in the future. Other commenters encouraged CMS to consider how to mitigate the long-term impact of the PHE for COVID–19 on quality performance and stated that it might be necessary to modify quality measures that have narrow timelines for performance and to reset the measure targets in future years. One commenter suggested that CMS should commit to ongoing reevaluations of the Shared Savings Program and the other APMs it operates to adjust for any changes in patient risk and resource use in future financial and quality measurement methodologies. Another commenter requested that CMS collaborate closely with ACOs and health systems across the country to monitor and address the impacts of the PHE for COVID–19 on clinical quality and quality measure benchmarks in future performance years.

Response: We appreciate the feedback from commenters and we understand that there are myriad concerns related to quality reporting and quality performance for performance year 2020. However, we believe that ACOs should

be in a position to report CMS Web Interface measures for performance year 2020 beginning in January 2021. All ACOs were determined to be impacted by the PHE for COVID–19, which was declared during the quality reporting period for performance years starting in 2019. Yet, 98.7 percent of ACOs completely reported CMS Web Interface measures for 2019, including all 65 ACOs that were also impacted by a natural disaster during 2019 or the quality reporting period. We want to encourage reporting for performance year 2020 while still being cognizant of the impacts that the PHE for COVID–19 could have on quality reporting and quality performance. Accordingly, we do not believe that it is necessary to make performance year 2020 a pay-for-reporting year. Rather, we believe that maintaining our current extreme and uncontrollable circumstances policy, coupled with giving ACOs automatic full credit for the CAHPS for ACOs survey measures, offers appropriate relief to ACOs for performance year 2020, while still incentivizing ACOs to fully and completely report the remaining measures. All 10 CAHPS for ACOs survey measures are in one of the four domains used to calculate an ACO's quality performance score. This means 25 percent of an ACO's quality performance score for performance year 2020 would come from receiving full credit on the CAHPS for ACOs survey measures. In addition, each of the other three domains has at least one or more measures that is pay-for-reporting in performance year 2020, resulting in over 50 percent of the measures (14 out of 23) being assigned full points if the ACO completely and accurately reports quality data. Furthermore, because there is at least one measure in each domain for which ACOs would receive full points provided they completely report quality data, ACOs in their second or subsequent performance year would achieve the minimum attainment level on at least one measure in each domain as required under § 425.502(d)(2)(iii) to be eligible to share in any savings. We believe this may address some of the concerns expressed by stakeholders about the impact of the PHE for COVID–19 on 2020 quality performance. We also believe it is in the public interest to encourage ACOs to report quality data because ACOs could otherwise share in any savings earned without being held accountable for the quality of care that they provide to the more than 11 million beneficiaries who receive care through Shared Savings Program ACOs. In addition to incentivizing the reporting of quality of care measures, we believe it is critical to incorporate ACO performance on those measures into quality performance scoring for performance year 2020 in a meaningful way that also considers the impact of the current PHE for COVID–19.

Although we did not propose any specific modifications to the extreme and uncontrollable circumstances policy for performance year 2020 in the CY 2021 PFS proposed rule, we did solicit comment on a potential alternative approach to scoring ACOs for performance year 2020. The potential alternative modification we considered would be similar to the current policy for scoring quality performance under the extreme and uncontrollable circumstances policy, but would use the higher of an ACO's 2020 quality performance score or its 2019 quality performance score for ACOs that completely report web interface data for 2020. For new ACOs that completely report, we would continue to score them as pay-for-reporting and assign a quality score of 100 percent. ACOs that do not complete quality reporting would receive the 2020 ACO mean quality score as provided in § 425.502(f)(2).

Specifically, we solicited comments on the following potential modifications to the extreme and uncontrollable circumstances policy for performance year 2020:

(1) If an ACO in a second or subsequent performance year completely and accurately reports the CMS Web Interface measures for performance year 2020, the ACO will receive the higher of its performance year 2020 ACO quality performance score that would include automatic full credit for the CAHPS for ACOs survey measures, or the score used in 2019 for purposes of financial reconciliation. For re-entering ACOs that terminated in their second or subsequent agreement period, the ACO would receive the higher of its most recent prior ACO quality performance score or its 2020 quality performance score.

(2) If an ACO in a second or subsequent performance year or a re-entering ACO that terminated in its second or subsequent agreement period does not completely and accurately report the CMS Web Interface measures for performance year 2020, the ACO will receive the 2020 ACO mean quality performance score.

(3) If an ACO in its first performance year in the program or a re-entering ACO that terminated in its first agreement period and is now in its first performance year of a new agreement period completely and accurately reports the CMS Web Interface measures, it will receive a quality performance score of 100 percent that reflects automatic full credit for the CAHPS for ACO survey measures.

(4) If an ACO in its first performance year or a re-entering ACO that terminated in its first agreement period and is now in its first performance year of a new agreement period, does not completely and accurately report the CMS Web Interface measures for performance year 2020, it will receive the 2020 mean ACO quality performance score.

We received public comments on this potential alternative approach to scoring ACOs under the extreme and uncontrollable circumstances policy for performance year 2020. The following is a summary of the comments we received and our response.

Comment: While many commenters supported the alternative approach of assigning the higher of the ACO's 2019 or 2020 quality scores for ACOs that report quality, they explained that they considered this a ''fallback option'' and that they would prefer CMS to convert all measures to pay-for-reporting for performance year 2020 due to the impact of the PHE for COVID–19.

Response: The intent of the Shared Savings Program extreme and uncontrollable circumstances policy is to mitigate any negative impact of an extreme and uncontrollable circumstance on an ACO's quality performance or ability to report quality data to CMS and the resultant effect on financial reconciliation due to emergency circumstances outside of the ACO's control. As discussed above, given the high percentage of ACOs that completely reported CMS Web interface measures for 2019, we believe that ACOs should be in a similar position to report CMS Web Interface measures for performance year 2020 beginning in January 2021. While we understand commenters' concerns about the potential adverse impacts of the PHE for COVID–19 on quality reporting and quality performance scores, more than half of the measures in the Shared Savings Program quality measure set are pay-for-reporting for all ACOs for performance year 2020, which is higher than in previous years. We appreciate commenters' feedback on the potential alternative approach to scoring ACOs under the extreme and uncontrollable circumstances policy for performance year 2020. After careful consideration, however, we believe that our current extreme and uncontrollable circumstances policy, in addition to giving ACOs automatic full credit for the CAHPS for ACOs survey measures, will mitigate the negative effects of the

PHE for COVID–19 on quality performance for performance year 2020. Accordingly, pursuant to the current regulation at § 425.502(f)(2), ACOs will have their quality performance score set to equal the mean quality performance score for all Shared Savings Program ACOs for performance year 2020. However, if an ACO completely and accurately reports all CMS Web Interface measures during the quality reporting period, we will use the higher of the ACO's quality performance score for performance year 2020 or the mean quality performance score for performance year 2020 for all Shared Savings Program ACOs to calculate the ACO's quality performance score.

3. Change to Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy Provision Adopted in the March 31st COVID–19 IFC

As noted previously in this section, in the March 31st COVID–19 IFC, we modified the Shared Savings Program extreme and uncontrollable circumstances policy as it applies to disasters that occur during the reporting period to eliminate the restriction that the extreme and uncontrollable circumstances policy applies only if the reporting period is not extended (85 FR 19267 through 19268). The PHE for COVID–19 was declared during the quality reporting period for performance years starting in 2019 and it applied to all counties in the United States. As we explained in the March 31st COVID–19 IFC, we believed that it was appropriate to offer relief under the Shared Savings Program extreme and uncontrollable circumstances policy to all Shared Savings Program ACOs that were unable to completely and accurately report quality for 2019 by the extended deadline due to the PHE for COVID–19. We explained that this policy needed to be effective starting with the quality reporting period for performance years starting in 2019 to provide relief for Shared Savings ACOs who needed to focus resources on patient care during the PHE for COVID–19. Further, we acknowledged that, as illustrated by the current PHE for COVID–19, there could be unanticipated situations in the future, during which extension of a quality reporting window alone would not provide sufficient relief from reporting burden at a time when ACOs and their ACO providers and suppliers need to focus on patient care. Accordingly, in the March 31st COVID–19 IFC, we amended the regulation at § 425.502(f) to remove the phrase ''if the quality reporting period is not extended,'' effective for quality reporting for performances years starting in 2019.

We received public comments on modifying the extreme and uncontrollable circumstances policy as it applies to disasters that occur during the reporting period for performance years starting in 2019 to eliminate the restriction that the extreme and uncontrollable circumstances policy applies only if the reporting period is not extended. The following is a summary of the comments we received and our response.

Comment: Commenters were supportive of providing relief to all ACOs during the reporting period for performance years starting in 2019 by eliminating the restriction that the extreme and uncontrollable circumstances policy applies only if the reporting period is not extended. Commenters stated that this was a thoughtful approach to addressing the quality submission challenges resulting from the PHE for COVID–19 and welcomed this change. One commenter stated that they appreciated the acknowledgment by CMS that the previously issued 30-day extension of the PY 2019 quality reporting period alone was insufficient relief from the reporting burden for ACOs and their ACO providers/suppliers during this public health emergency. Another commenter noted appreciation for this approach, explaining that a number of physicians may be unable to submit quality data in a timely manner due to the demands on their practices associated with the PHE for COVID–19.

Response: We thank commenters for their positive feedback. We are finalizing, without modification, the revisions that were made to the regulation at § 425.502(f) in the March 31st COVID–19 IFC to remove the restriction which prevented the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended.

J. Removal of Selected National Coverage Determinations

In the CY 2021 PFS proposed rule (85 FR at 50255), we proposed to use the notice and comment rulemaking to identify and remove older NCDs that we believed no longer contained clinically pertinent and current information or no longer reflected current medical practice. We explained that eliminating an NCD changes a substantive legal standard related to Medicare coverage and payment under section 1871(a)(2) of the Act because items that were covered nationally under Title XVIII would no longer be automatically covered by Medicare (42 CFR 405.1060). Instead, in the absence of an NCD, the coverage determinations for those items and services would be made by Medicare Administrative Contractors (MACs). We also noted that if the previous NCD barred coverage for an item or service under title XVIII (that is, national noncoverage NCD), a MAC would now be able to cover the item or service if the MAC determined that such action was appropriate under the statute. Removing a national non-coverage NCD may permit access to technologies that may be beneficial for some uses. We explained that as the scientific community continues to conduct research producing new evidence, the evidence base we previously reviewed may have evolved to support other policy conclusions. In the proposed rule, we also described the circumstances that we had used in determining whether an older NCD should be removed.

We sought public comments that may identify other reasons for proposing to remove NCDs. We also noted that we were interested in whether the time-based threshold of ''older''—which had been designated as 10 years—continued to be appropriate or whether stakeholders believe a shorter period of time or some other threshold criterion unrelated to time would be more appropriate.

We also described two previous times that we used an expedited public process for removing NCDs. The proposals and final decisions related to these removals are located in the Medicare Coverage Database, available at *https://www.cms.gov/medicare-coverage-database/indexes/medicare-coverage-documents-index.aspx?MCDIndexType=7&mcdtypename=Expedited+Process+to+Remove+National+Coverage+Determinations&bc=AgAAAAAAAAAAAA%3d%3d&*.

As discussed in the proposed rule, we continue to recognize the need to periodically review our policies and processes to ensure that we remain effective and efficient as well as open and transparent. We noted that we are aware that clinical science and technology evolve and that items and services that were once considered state-of-the-art or cutting edge may be replaced by more beneficial technologies or clinical paradigms. Additionally, proactively removing obsolete broad non-coverage NCDs removes barriers to innovation and reduces burden for stakeholders and CMS. In light of the Supreme Court's decision in *Azar* v. *Allina Health*

Services, 587 U.S. ___, 139 S. Ct. 1804 (2019)), we have determined it would be appropriate to use the notice and comment rulemaking procedures described in section 1871(a)(2) of the Act to remove outdated or unnecessary NCDs.

In Table 37 of the proposed rule, we listed the NCDs that we proposed to remove and described the mechanisms by which we identified NCDs for consideration. We solicited comment on the nine NCDs discussed in Table 41, as well as comments recommending other NCDs for CMS to consider for future removal. In the CY 2021 PFS proposed rule, we summarized each of the nine NCDs and provided a rationale for removal for each one. NCDs are listed in the Medicare National Coverage Determinations Manual located at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/internet-Only-Manuals-IOMs-Items/CMS014961*.

TABLE 41: Proposed NCDs for Removal

NCD Manual Citation	Name of NCD
20.5	Extracorporeal Immunoadsorption (ECI) using Protein A Columns (01/01/2001)
30.4	Electrosleep Therapy
100.9	Implantation of Gastroesophageal Reflux Device (06/22/1987)
110.14	Apheresis (Therapeutic Pheresis) (7/30/1992)
110.19	Abarelix for the Treatment of Prostate Cancer (3/15/2005)
190.1	Histocompatibility Testing
190.3	Cytogenetic Studies (7/16/1998)
220.2.1	Magnetic Resonance Spectroscopy (09/10/2004)
220.6.16	FDG PET for Inflammation and Infection (03/19/2008)

In summary, we solicited comment on the proposals to remove each of the nine NCDs, as well as comments recommending other NCDs for CMS to consider for future removal. Additionally, we solicited public comments that may identify other reasons for proposing to remove NCDs. We solicited comments on whether the time-based threshold of ''older'' which was designated as 10 years in the 2013 notice continues to be appropriate or whether stakeholders believe a shorter period of time or some other threshold criterion unrelated to time is more appropriate. We requested commenters include a rationale to support their comments. We noted that we will use the public comments to help inform our decision to take one of three actions on the nine NCDs proposed for removal:

- Remove the NCD, as proposed, allowing for coverage to be determined by the MACs.
- Retain the current policy as an NCD.
- Reconsider the NCD. We also noted that comments suggesting that the NCD should be revised, rather than eliminated, should include previously unreviewed evidence in order to support a change in national coverage.

We received more than 100 public comments on the proposed removal of selected NCDs, the process for identifying NCDs for removal, as well as the vehicle for removing NCDs. The following is a summary of the comments we received and our responses.

Comment: Many commenters generally supported the proposal to periodically identify and remove NCDs that are no longer clinically relevant or are infrequently used and appreciated CMS seeking input from stakeholders. Commenters agreed with agency efforts to ensure that NCDs are based on current scientific evidence, are relevant to the Medicare population and some acknowledged that the Medicare coverage process is designed to provide greater contractor flexibility. Many also agreed with using rulemaking for removing outdated NCDs as a transparent way to gather input from stakeholders and ensure beneficiary access to services.

Response: We thank commenters for their support for periodically removing outdated NCDs and for their support for using rulemaking.

Comment: Several commenters noted that CMS should have other options for retirement of NCDs that do not include notice and comment rulemaking. One commenter stated that rulemaking does not provide enough flexibility for CMS to retire obsolete NCDs upon receipt of clinical data demonstrating that the NCD is no longer appropriate. Another commenter disagreed with CMS' legal interpretation of Supreme Court's decision in *Azar* v. *Allina Health Services,* 587 U.S. ___, 139 S. Ct. 1804 (2019), and suggested that the statute provides for CMS to remove outdated NCDs through an expedited administrative process such as the process we described in 2013 (78 FR 48164). The commenters also noted that CMS should have a process that is nimble and flexible and requested that CMS finalize a policy that allows retirement of NCDs through a subregulatory process similar to the 2013 expedited subregulatory administrative process.

Response: We do not agree that section 1871(a)(2) of the Act would permit the removal of multiple NCDs at one time through a subregulatory process. While not legally binding on the public, NCDs establish controlling coverage policies for particular items and services for Medicare contractors and adjudicators in the Medicare appeals process, § 405.1060, and establish substantive legal standards related to coverage and payment. Given the importance of NCDs in notifying the public when particular items or services will (or will not) be covered under Title XVIII of the Act, we believe that a public process is necessary to remove those controlling policies. We note that Congress has separately established a public comment process in section 1862(l) of the Act, to be used in making NCDs and that NCDs are expressly exempt from the rulemaking requirements in section 1871(a)(2) of the Act. While the statute does not establish a specific process for removing NCDs, using the process required by section 1871(a)(2) of the Act is appropriate when changing a substantive legal standard governing the scope of benefits or payment for services. This result is consistent with the Supreme Court's

decision in *Azar* v. *Allina Health Services,* 139 S. Ct. 1804 (2019).

Comment: A few commenters questioned whether we will now be using rulemaking for NCD reconsiderations in addition to removals and whether we will create new NCDs through rulemaking. One commenter questioned if an NCD specifies coverage and non-coverage for multiple indications under the NCD, would this process be used to remove non-covered indications under the NCD. The commenter also questioned how would CMS address situations when a specific non-coverage portion of the NCD could be considered for removal.

Response: We thank commenters for their questions and the opportunity to clarify. As noted above, section 1871(a)(2) of the Act contains an exception for NCDs, and we are not required to use rulemaking procedures to establish or change a particular NCD. We will continue to use the NCD procedures established by section 1862(l) of the Act and that include an opportunity for public comment to reconsider or revise particular NCDs, as explained in the August 7, 2013 **Federal Register** notice (78 FR 48164). We proposed to use rulemaking to remove multiple old NCDs at one time, which would be more efficient than reconsidering each NCD separately.

Comment: A few commenters questioned whether CMS will use this process to remove and/or ''wrap up'' Coverage with Evidence Development (CEDs) as well as NCDs, given that CEDs are part of an NCD.

Response: We may consider using the removal process for CED NCDs in the future, but we note that none of the NCDs we proposed for removal at this time are CED NCDs.

Comment: Some commenters stated that CMS should rarely or never remove NCDs, but should retain and update them, optimizing appropriate use of NCDs rather than minimizing their use. Several commenters noted that CMS should only remove NCDs that provide for broad non-coverage, such as for items and services once considered experimental. These commenters noted that NCDs that provide even limited coverage for certain indications act as a floor and should be either retained or updated instead of allowing coverage determinations to be made at the local level.

Response: We believe it is in the best interests of the Medicare program and Medicare beneficiaries to regularly evaluate both coverage and broad-noncoverage NCDs because medical science may change over time. When we identify outdated NCDs or stakeholders bring them to our attention, we use our discretion either to reconsider and update the NCD as appropriate or to propose to remove the NCD if appropriate to allow the coverage determination to be made by the local MACs. Removing outdated NCDs in some cases can remove barriers to innovation and can pave the way for a robust local determination. This flexibility will allow stakeholders to provide new evidence for our consideration to support either reconsideration or the removal of an outdated NCD. We do not agree that it is always in the best interests of beneficiaries to keep old NCDs as a coverage floor; there are instances when NCDs are outdated and the practice of medicine has changed to the extent that some covered indications are obsolete or potentially create coverage barriers if the information is no longer current.

When we evaluate particular NCDs for removal, we take into account information gathered from stakeholders, the claims data for those items and services, and factors such as whether there may be documentation requirements within the NCD that are outdated and create a barrier to coverage. The rulemaking process will provide an opportunity to consider public input before the NCD would be removed. We could decide to retain those NCDs after considering public comments.

Comment: One commenter suggested that CMS should collect quality data collected as a part of an NCD in order to evaluate and maintain quality care, particularly related to new technology, previously unstudied populations.

Response: We thank the commenter for the suggestion about incorporating quality data into NCDs, though it is outside the scope of this proposal. Because there are many different quality programs established by the Medicare Act, it is difficult to evaluate in the abstract whether data collection through NCDs would be consistent with the existing statutory and regulatory requirements.

Comment: Several commenters opposed removing NCDs, either generally, or with regard to specific NCDs in this rule, because they believed that Medicare Advantage (MA) Plans are not required to follow LCDs created by MACs. The commenters noted removing NCDs that provide for coverage or limited coverage will create access barriers for MA plan enrollees because they noted the MA plans will choose not to continue covering those services.

Response: We appreciate the commenters' concerns, but believe there are sufficient beneficiary protections in place. Medicare Advantage plans (MA) are required to cover all Part A and Part B benefits for their enrollees, subject to limited exclusions such as for hospice care and kidney acquisition costs. The MA program regulation at 42 CFR 422.101(b) requires, and has required since the inception of the MA program, MA plans to comply with the written coverage determinations (that is, LCDs) of the local Medicare contracts (that is, the MACs) in the geographic area where the MA plan provides coverage (63 FR 34986, 35077). Section 1852(a)(1)(C) of the Act provides MA plans with the option to comply with the LCD that provides the more beneficial coverage to the plan's enrollees in cases where the MA plan service area includes more than one LCD area. All of this is further explained in the Medicare Managed Care Manual, Chapter 4, section 90, available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf*.

Comment: In response to our solicitation for public comments about other reasons that may support the removal of an NCD, a number of commenters support the continued use of the factors that CMS has used in removing outdated NCDs since 2013. Other commenters identified other factors that might be relevant for CMS to consider. One commenter stated that CMS needs to be more flexible and nimble in responding to changes in the standard of care and that the only criterion for removal should be presentation of sufficient clinical data to CMS to support retirement of an NCD irrespective of how old it is. The requestor recommended that CMS provide examples of what amount and type of information and clinical data would be ''sufficient'' to support removal. The commenter proposed an example of evidence-based professional society guidelines with a grade of evidence of A or B as sufficient to demonstrate whether an NCD should, and therefore could, be retired. Another commenter recommended that CMS assess and propose applying criteria similar to those under other Medicare programs, including for Medicare Part D.

Response: We appreciate the commenters that supported the use of the factors that CMS had previously used in identifying outdated NCDs. We will continue to consider those factors as modified by the additional public suggestions. We also agree with the commenter that suggested we pay attention to the changes in the standard of care, and that some NCDs may need to be removed in those circumstances regardless of age. We will consider

changes in the standard of care in making these determinations. We also agree that changes in evidence-based professional society guidelines with a high grade of evidence could be a good example of information that may support removal of an NCD in some circumstances. In order to be more flexible and nimble, we do not intend to establish an exclusive list of criteria as decisions may depend on the particular changes in medical practice at the time. We are grateful for the helpful public suggestions.

Comment: One commenter questioned whether the 10-year timeframe of ''older NCDs'' is tied to the last effective date or to the NCD's original implementation date. They also questioned how CMS will consider NCDs that are greater than the 10-year timeframe, but have been updated to address clinical changes affecting the services.

Response: To determine the age of NCDs we had used the effective date of the NCD, which, for some NCDs is the same date as the final decision memorandum was released. For determining the age of an NCD that has been reconsidered since the initial NCD was published, the clock restarts whenever a NCD reconsideration is conducted. For example, if we have an NCD for a particular service that was effective February 5, 2009, but was reconsidered in 2016 with an effective date of October 30, 2016, we would consider the NCD to be 4 years old.

Comment: We received many comments and recommendations on the 10-year threshold for identifying older NCDs for further evaluation for potential removal. A number of commenters stated that a specific threshold age, like 10-years, is arbitrary and does not reflect the rapid evolution of medical care in this century, and that age of the NCD should be a rule of thumb and not a categorical restriction. Several commenters stated that in many cases, even if an NCD is less than 10 years old, other evidence will be available that strongly suggests the NCD has most likely become outdated—such as when new and innovative therapies are released that substantially undermine core assumptions of an older NCD. While some commenters generally supported a definition of age at 10-years, we also received a wide variety of recommendations for timeframes ranging from annual review with 10 years as a maximum age, to reviewing NCDs at 3 years, 5 years or 7 years. Several commenters recommended that CMS adopt a shorter threshold and add a clinical evidence exception. These commenters stated that it would be appropriate to allow for the retirement of a NCD that is more than 5 years old, or a more recent NCD if there is new clinical evidence or FDA approval that causes the NCD to be outdated or to restrict beneficiary access to medically necessary items and services. One commenter noted that using 10 years as a look-back period may not be long enough for some items and services that have longer adoption timelines, or that may not be superseded by newer items and services.

Response: We appreciate commenters' thoughtful recommendations. Commenters are correct that the 10-year factor was a general guideline to identify groups of potentially outdated NCDs for further evaluation for possible removal. We also could decide to retain the NCD or reconsider the NCD if the NCD needed to be substantively changed. We acknowledge the rapid pace of medical technology development and changes in standard of care and/or clinical evidence may occur more rapidly than every 10 years, and we will consider those factors as well as we evaluate whether existing NCDs should be removed.

Comment: We received several comments supporting removal of each of the following NCDs: NCD 30.4 Electrosleep Therapy, NCD 100.9 Implantation of Gastrointestinal Reflux Devices, and NCD 220.2.1 Magnetic Resonance Spectroscopy. We also received several comments supporting removal of NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns, some including recommendations for corresponding changes to the claims processing instructions for this service related to removal of the NCD. We also received no comments for NCD 110.19 Abarelix for the Treatment of Prostate Cancer.

Response: We thank commenters for their support and will finalize the removal of each of the 5 NCDs identified above as proposed. We note that we received no comments opposing removal of these specific NCDs. We appreciate the recommendations for corresponding changes to the claims processing instructions and we will consider them as we implement the removal of NCDs. We note that while the change in policy will be effective on the effective date of the final rule, implementing the change for NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns requires changes to national coding systems. The implementing Change Request (CR) will take the time discrepancies between effective and implementation dates into consideration and ensure claims are adjudicated appropriately retroactive back to the effective date of the NCD (in this case, the final rule).

Comment: We received a number of comments supporting removal of NCD 110.14 (Apheresis). Some commenters acknowledged that the NCD was outdated and does not currently reflect advances in apheresis medicine and patient care applications. Several commenters noted their previous support for removing the NCD when we last proposed its removal in 2015. Several expressed their intention to work together with other professional societies to educate the Medicare Administrative Contractors on the intricacies of apheresis care based on the current professional society guidelines.

We also received several comments opposing removal of the apheresis NCD because they believe the NCD—while very outdated— remains relevant and the NCD provides predictability of coverage for indications currently listed in the NCD. The commenters expressed concern that allowing MACs to determine coverage could create inconsistencies in coverage and could reduce access for beneficiaries across Medicare and other payers. Several commenters encouraged CMS to ensure that any changes to NCDs support flexibility, innovation, and patient care.

Response: We thank commenters for their thoughtful and informative feedback, both in support of removing the NCD and for maintaining it. Since commenters shared multiple viewpoints on this issue, we will take more time to consider the specific issues raised by commenters and will not finalize removal of this NCD in this final rule. We will continue to engage with stakeholders on the issue and will consider whether to propose the NCD for removal in next year's PFS proposed rule.

Comment: One commenter supported removing NCD 190.1 (Histocompatibility Testing). The commenter noted their belief that local contractors should have the flexibility to cover not only conventional HLA cross-matching but also other techniques that have been developed and that are emerging. Several commenters did not support removing the NCD and requested that CMS retain or retain and update the NCD to expand the covered indications. While recognizing that it is very outdated, the commenters stated it provides predictability regarding coverage of histocompatibility testing for kidney and other types of transplant care, and other conditions. Several commenters requested that CMS closely monitor local contractor activity to ensure there is no disruption in access

and coverage for current critical applications if CMS decides to remove this NCD.

Response: We appreciate commenter's thoughtful responses. Since commenters shared multiple viewpoints on this issue, we will take more time to consider the specific issues raised by commenters and will not finalize removal of this NCD in this final rule. We will continue to engage with stakeholders on the issue and whether to propose the NCD for removal in the CY 2022 PFS proposed rule.

Comment: One comment supported removing NCD 190.3 (Cytogenetic Studies) stating that ''the NCD is decades old, and laboratories now are able to detect and locate specific DNA sequences on a chromosome using diagnostic techniques that did not exist or were not widely available when the NCD was issued, including next generation sequencing and fluorescence in situ hybridization (FISH).''

Several commenters did not support removing the NCD and requested that CMS retain or retain and update the NCD because while recognizing that it is very outdated, they believe the NCD remains relevant as cytogenetic studies are in widespread use, and provides predictability of coverage, avoiding potentially disparate local coverage policies. Several requested that CMS update the NCD to remove outdated terminology that is now considered offensive. Commenters also stated that cytogenetic studies have not been replaced by Next Generation Sequencing (NGS), but that the tests are used in conjunction. One commenter mentioned that multiple professional guidelines and practice resources exist that support use of cytogenetic studies. Several commenters requested that CMS closely monitor local contractor activity to ensure there is no disruption in access if CMS decides to remove this NCD.

Response: We thank commenters for pointing out that genetic sequencing is commonly used in conjunction with cytogenetic studies. Since commenters shared multiple viewpoints on this issue, we will take more time to consider the specific issues raised by commenters and will not finalize removal of this NCD in this final rule. We will continue to engage with stakeholders on the issue and will consider whether to propose the NCD for removal in next year's PFS proposed rule.

Comment: We received many comments supporting removal of NCD 220.6.16 (FDG PET for Inflammation and Infection) and allowing local contractor discretion to determine coverage for this service. A number of these comments raised a concern about language in NCD 220.6 (Positron Emission Tomography (PET) Scans) that provides for non-coverage, ''. . . that a particular use is noncovered unless this manual provides that such use is covered.'' Commenters requested that CMS also revise NCD 220.6 to ensure that local contractors can make coverage determinations for FDG PET for Inflammation and Infection. Commenters also requested that CMS revise this language to expand coverage and allow for MAC discretion to cover PET for existing and new uses beyond inflammation and infection, to include any non-oncologic condition that falls within an FDA approval and is not currently non-covered by an NCD. A number of commenters offered drafts of revised language for the manual as well as current literature as support.

Response: We will finalize removal of the NCD as proposed, and will modify the NCD manual to ensure that contractors have the authority to make a coverage determination when claims are submitted for PET for Inflammation and Infection. We will ensure MAC discretion is available by making two revisions in the NCD manual. First, we will revise the NCD manual at section 220.6.16 (FDG PET for Inflammation and Infection) to remove the current NCD language and replace it with the following statement of local contractor discretion: ''Effective January 1, 2021, CMS determined that no national coverage determination (NCD) is appropriate at this time for FDG PET for Inflammation and Infection. In the absence of an NCD, coverage determinations for FDG PET for Inflammation and Infection will be made by the Medicare Administrative Contractors (MACs).'' In addition, we will also make a non-substantive conforming change to NCD 220.6 (Positron Emission Tomography (PET) Scans, to add the following sentence to the note section: ''Effective for dates of service on or after January 1, 2021, local Medicare Administrative Contractors (MACs) may determine coverage within their respective jurisdictions for FDG PET for Infection and Inflammation (formerly NCD 220.6.16).'' We are making the conforming change to make it abundantly clear in both sections of the manual that contractors will make the section 1862(a)(1)(A) of the Act determination for this PET indication.

While the change in policy will be effective on the effective date of this final rule (January 1, 2021), implementing this change requires changes to national coding systems and to the NCD manual. The implementing CR will take the time discrepancies between effective and implementation dates into consideration and ensure claims are adjudicated appropriately retroactive back to the effective date of the NCD (in this case, the final rule).

With respect to the request to revise NCD 220.6 to remove the non-coverage language and expand availability of PET for non-oncologic indications at MAC discretion, that revision would require a reconsideration of the NCD that is beyond the scope of this rulemaking. We note the process for submitting a formal reconsideration request is described in the August 7, 2013 **Federal Register** notice (78 FR 48164) and are outlined on the Medicare Coverage page at *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD*. These sources include the factors for considering a request to be complete as well as the electronic and mail methods for submitting a complete, formal request.

Comment: Commenters recommended additional NCDs for future removal including: NCD 10.5 Autologous Epidural Blood Graft, NCD 90.1 Pharmacogenomic Testing for Warfarin Response, NCD 150.10 Lumbar Artificial Disc Replacement (LADR), NCD 160.22 Ambulatory EEG Monitoring, NCD 210.3 Screening Computed Tomography Colonography (CTC) for Colorectal Cancer, and NCD 240.6 Transvenous (Catheter) Pulmonary Embolectomy. We note that NCDs 10.5, 210.3, and 240.6 each were recommended for removal by a number of commenters. In addition, one commenter requested that CMS revise NCD 210.12 Intensive Behavioral Therapy for Obesity to expand the eligible providers that are able to offer IBT to patients with obesity.

Response: We thank commenters for their recommendations of NCDs for us to consider removing in the future. While we do not accept these comments as complete, formal requests, we will take the suggestions under advisement for future review and will continue to communicate with interested stakeholders. As noted above, the process for submitting a request for reconsideration is described in the 2013 **Federal Register** notice and is outlined on the Medicare Coverage page at *https://www.cms.gov/Medicare/Coverage/DeterminationProcess/howtorequestanNCD*.

With respect to the request to reconsider the eligible providers for NCD 210.12, that request is outside the scope of the proposed rule, but we note that interested parties may make a formal request for reconsideration following the process outlined at the website above.

Comment: We received a number of general comments, concerns and suggestions for reforming the NCD and LCD processes used in making coverage determinations.

Response: We thank stakeholders for their comments and suggestions, but those comments are outside the scope of the proposed rule.

After considering the comments, we are not finalizing removal of NCD 110.14 Apheresis, NCD 190.1 Histocompatibility Testing, and NCD 190.3 Cytogenetic Studies. We will take more time to consider the specific issues raised by commenters regarding these NCDs and will consider whether to propose them for removal in next year's PFS proposed rule. We are finalizing removal of six NCDs as proposed, including NCD 20.5 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns, NCD 30.4 Electrosleep Therapy, NCD 100.9 Implantation of Gastrointestinal Reflux Devices, NCD 220.2.1 Magnetic Resonance Spectroscopy, and NCD 220.6.16 FDG PET for Inflammation and Infection. Local Medicare contractors will determine coverage under section 1862(a)(1) of the Act for those specific items or services previously addressed through the NCDs. We will remove all six NCDs on the effective date of the final rule. However, changes in coverage require an implementation process in order to make required changes in manual guidance as well as coding/coverage/payment system edits for the items and services. While it typically takes a number of months to implement a change in coverage, the implementing CR will take the time discrepancies between effective and implementation dates into consideration and ensure claims are adjudicated appropriately retroactive back to the effective date of the final rule.

K. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

1. SUPPORT Act Requirements

Section 2003 of the SUPPORT Act generally mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. Section 2003 of the SUPPORT Act requires that the Secretary use rulemaking to specify circumstances and processes by which the Secretary may waive the EPCS requirement and provides the Secretary with authority to enforce and specify appropriate penalties for non-compliance with EPCS. The SUPPORT Act specifies some circumstances under which the Secretary may waive the electronic prescribing requirement with respect to controlled substances that are covered Part D drugs and also permits HHS to develop other appropriate exceptions. The circumstances that are listed in the statute under which the Secretary may waive the EPCS requirement are at section 1860D–4(e)(7) of the Act, as added by section 2003 of the SUPPORT Act, and include:

- A prescription issued when the practitioner and dispensing pharmacy are the same entity;
- A prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT 2017071 standard;
- A prescription issued by a practitioner who received a waiver or a renewal thereof for a period of time as determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;
- A prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;
- A prescription issued by a practitioner prescribing a drug under a research protocol;
- A prescription issued by a practitioner for a drug for which FDA requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;
- A prescription issued by a practitioner—

++ For an individual who receives hospice care under this title; and

++ That is not covered under the hospice benefit under this title; and

- A prescription issued by a practitioner for an individual who is—

++ A resident of a nursing facility (as defined in section 1919(a)); and

++ Dually eligible for benefits under this title and title XIX.

2. Current Public Health Emergency (PHE)

On January 31, 2020, the Secretary determined that a PHE existed for the United States to aid the nation's health care community in responding to COVID–19 (hereafter referred to as the PHE for COVID–19). On March 13, 2020, President Trump declared the PHE for COVID–19. Effective October 23, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020 and July 25, 2020 that a PHE exists and has existed since January 27, 2020. Because of the PHE for COVID–19, and as the nation reopens, some individuals, such as those who are at high risk, may continue to practice self-isolation and social distancing.

We have implemented many regulatory and policy actions to swiftly aid the nation's healthcare system to effectively address the PHE for COVID–19. These actions include new flexibilities for telehealth and other electronic technologies [98] to ease the burden on providers and assure appropriate care in a range of settings for beneficiaries. Also, the DEA has adopted certain new temporary flexibilities to allow DEA-registered practitioners to prescribe controlled substances without having to interact in person with patients, effective for the duration of the PHE for COVID–19.[99] For example, during the PHE for COVID–19, DEA permits DEA-registered prescribers to issue controlled substance prescriptions to telemedicine patients who they have not seen in person under certain conditions, permits early refills of controlled substances permissible under state law, and allows prescribers to issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance. DEA's COVID–19 information page is available at *https://www.deadiversion.usdoj.gov/coronavirus.html*. The DEA has acknowledged the prevalence of paper prescribing and attempted to address some of the hardships it poses for prescribers and patients during the PHE for COVID–19.

[98] See *https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf.*

[99] See *https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf.*

3. Electronic Prescribing of Controlled Substances (EPCS)

As discussed in the CY 2021 PFS proposed rule (85 FR 50074), we noted that social distancing is likely to be at least in part, responsible for the increase in EPCS during this PHE for COVID–19. In 2020, EPCS has increased to 50 percent of all prescription drug events (PDEs) for controlled substances being prescribed as compared to 38 percent in 2019.[100] With the use of electronic prescribing, once a patient and a provider have an established relationship, a medical visit can be conducted via telehealth and any necessary prescriptions can be electronically transmitted to the pharmacy without having to see each other in-person and risk transmitting COVID–19. Some insurers, including Part D plans, may be permitting medication refills, including for controlled substances, earlier than usual or for a more extended period of time than was previously allowed. Pharmacies that were not previously doing so may deliver medications, or deliver at no charge, and communities and individuals have worked together to design ways for vulnerable persons to continue to receive access to prescribed medications in tandem with these new government and private sector flexibilities.

EPCS provides multiple advantages over the traditional processing of paper prescriptions.[101] [102] [103] [104] [105] [106] In addition to improving workflow efficiencies, electronic prescribing of controlled substances can deter and help detect prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes. It can also provide more timely and accurate data than paper prescriptions by avoiding data entry errors and pharmacy calls to a prescriber to clarify written instructions. By allowing for the direct transmission of electronic prescriptions between providers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. In addition, EPCS (dispensed medication) data is transmitted to Prescription Drug Monitoring Programs (PDMPs), which can help inform providers of patients' medication history and can aid in clinical decision making at the time of prescribing and/or before the medication, is dispensed by a pharmacy. It is also important to continue the assurance of privacy and security in the prescribing process, such as by controlling prescriber access through improved identity controls and authentication protocols. EPCS can also assure prescribers' identity more easily and may permit a single workflow for prescribing both controlled and non-controlled drugs, improving the overall prescribing process.[107]

From the patient standpoint, EPCS may reduce the logistical burden on patients who may otherwise be required to make multiple trips between providers and pharmacies to transport paper prescriptions when filling time-sensitive prescriptions while in pain or otherwise in need of medical treatment with controlled substances. EPCS can lessen the time needed to obtain prescriptions by minimizing trips to the physician to pick up paper prescriptions for refills and minimize transportation costs to and from the provider's office. EPCS identity and security requirements also assure prescribers, patients, and pharmacies that prescriptions are processed as intended. In addition to helping with the reduction in fraud previously described, EPCS minimizes the likelihood that prescriptions have been tampered with, since electronic prescriptions are securely transmitted directly to the pharmacy from health information technology, which minimizes the likelihood of exposure to patients or other third parties. In the Medicare Program: Electronic Prescribing for Controlled Substances; Request for Information issued on August 4, 2020 (85 FR 47151), we requested feedback on the appropriate waivers and whether CMS should impose penalties for noncompliance with the EPCS mandate in its rulemaking, and what should be the penalties. We plan to use the important public feedback we receive from the Request for Information in future standalone rulemaking.

In our proposed rule, we proposed to enact regulations requiring EPCS by January 1, 2022 to strike the balance between not placing too large of a burden on providers and helping ensure that the benefits of EPCS are leveraged expeditiously. Furthermore, we noted that requiring EPCS by January 1, 2022 would allow time to solicit and consider important feedback from the previously discussed Request for Information that is necessary for implementation of the EPCS requirements for waivers from the

[100] Based on Prescription Drug Event data processed through April 30, 2020.

[101] Phillips et. al. ''Market Guide for Identity Proofing and Corroboration.'' April 24, 2018. Gartner, Inc. Retrieved from *https://www.fedscoop.com/gartner-guide-identity-proofing-corroboration-2018/* on April 30, 2020.

[102] Ryan, D. ''FinCEN: Know Your Customer Requirements.'' February 7, 2016. Harvard Law School Forum on Corporate Governance. Retrieved from *https://corpgov.law.harvard.edu/2016/02/07/fincen-know-your-customer-requirements/#2b* on April 30, 2020.

[103] Nix, M. ''Five Questions: Ken Whittemore Talks Past, Present & Future of E-Prescribing Controlled Substances.'' March 31, 2020. SureScripts. Retrieved from *https://surescripts.com/news-center/intelligence-in-action/opioids/five-questions-ken-whittemore-talks-past-present-future-of-e-prescribing-controlled-substances?utm_campaign=IIApercent2FBlogpercent20Subscription&utm_source=hs_email&utm_medium=email&utm_content85955401&_hsencp2ANqtz-8xs36u7xTFZ-ieOxJk3309SApbE7to_fnk1SZvz2jqwz0pA3k7TtW9byiOq2zBlheLInMOeajCMCKeQUTzcEDP79HEaeXI52QiadhAYAWU3Px2eZc&_hsmi=85955401* on April 30, 2020.

[104] Zhang et. al. ''T2FA: Transparent Two-Factor Authentication.'' June 15, 2018. IEEE Access. Retrieved from *https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=8386653* on April 30, 2020.

[105] Konoth R.K., van der Veen V., Bos H. (2017) How Anywhere Computing Just Killed Your Phone-Based Two-Factor Authentication. In: Grossklags J., Preneel B. (eds) Financial Cryptography and Data Security. FC 2016. Lecture Notes in Computer Science, vol 9603. Springer, Berlin, Heidelberg. Retrieved from *https://link.springer.com/chapter/10.1007 percent2F978-3-662-54970-4_24* on April 30, 2020.

[106] Cal and Zhu. ''Fraud detections for online businesses: a perspective from blockchain technology.'' *Financial Innovation* (2016) 2:20. Retrieved from *https://link.springer.com/content/pdf/10.1186/s40854-016-0039-4.pdf* on April 30, 2020.

[107] HHS Office of the National Coordinator, The ONC Doctors' Perspective: Electronic Prescribing of Controlled Substances (EPCS) Is on the Rise, and We Must Work Together to Address Barriers to Use: *https://www.healthit.gov/buzz-blog/health-it/the-onc-doctors-perspective-electronic-prescribing-of-controlled-substances-epcs-is-on-the-rise-and-we-must-work-together-to-address-barriers-to-use.*

requirements and penalties. This included soliciting feedback from prescribers that we do not directly regulate under MA, and/or Part D, and who are not enrolled in Medicare or Medicaid. Section 1860D–4(e)(2)(E) of the Act requires the Secretary to adopt electronic standards for mandatory use by Part D plans. As stated above, the statute provides the Secretary with the authority to develop any exceptions to EPCS that may be warranted, and to enforce and specify appropriate penalties for non-compliance with the requirement. We noted that we do not have an existing process for imposing penalties on non-compliant prescribers for EPCS. In developing an entirely new penalty process, we must make sure that it enforces the new EPCS requirement, allows for exceptions only when needed, but does not reduce beneficiaries' access to needed drugs. Separate from this rule, we noted that we intend to conduct future standalone rulemaking that would address these topics.

Based on these considerations, we proposed to amend 42 CFR 423.160(a) by adding the requirement that all prescribers conduct electronic prescribing of Schedule II, III, IV, and V controlled substances covered under the Medicare prescription drug program using the NCPDP SCRIPT 2017071 standard by January 1, 2022, except in circumstances in which the Secretary waives the requirement. We proposed that prescribers would be required use the NCPDP SCRIPT 2017071 standard because they are already required to use this standard when conducting e-Prescribing for covered Part D drugs for Part D eligible individuals, and we noted that we believe that prescribers should use the same standard for their electronic prescribing of controlled substances.

We also solicited comments regarding the impact of the proposal on overall interoperability and the impact on medical record systems. Finally, we solicited comments on whether the change would be significant enough for a January 1 implementation date, which is required for all significant changes affecting Part D plans.

We received 57 timely public comments in response to this proposed provision. We have summarized these comments and our responses below.

Comment: A majority of commenters supported our proposal requiring that prescribers use the NCPDP SCRIPT 2017071 standard for EPCS prescription transmissions within the Part D program. Commenters echoed their support for many of the reasons set forth in our proposed rule including the increased security of the transmission of the prescription and reduction of the number of callbacks from pharmacists seeking to clarify handwritten prescriptions.

Response: We thank commenters for their support. In light of the overwhelming majority of commenters supporting this proposal, we are finalizing the requirement that prescribers use the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances covered under Medicare Part D.

Comment: A few commenters opposed e-Prescribing of controlled substances because they believed that EPCS would allow prescriptions to be written by a doctor electronically without seeing the patient. One commenter stated that such practices would lead to an increase in the opioid epidemic in our country.

Response: The assumption that electronic prescribing means inappropriate prescribing is an incorrect one. In order for a prescription to be covered under Part D, it must be a valid prescription according to applicable federal and state laws. Under DEA rules,[108] a prescription must be issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient or a covering practitioner in general. Therefore, implementation of EPCS standard should not have an adverse impact on the appropriateness of controlled substances distributed.

Comment: Most commenters addressed our proposal to implement the EPCS requirement by January 1, 2022. A few commenters requested CMS to adhere to the January 1, 2021 date specified in the SUPPORT Act because of the many safety benefits associated with EPCS articulated in the rule. These commenters included Part D sponsors, companies involved in processing e-Prescribing transactions and most, but not all, pharmacies. A few commenters noted that there is an absolute and urgent need to implement section 2003 of the SUPPORT Act by the January 1, 2021 deadline in the statute even if the requirement is not enforced. A commenter stated that they understood that CMS does not believe it will be able to enforce this requirement on prescribers starting in January 2021, so proposed that CMS implement the requirement in mid-2021. Another option presented by the commenters was for CMS to make the rule effective January 1, 2021 but decline to enforce it until some later date. They stated that just having the rule in force would encourage EPCS and cited evidence from state experiences to support this position.

Comments from nearly all prescribers indicate that implementation of EPCS by 2021 would not be feasible. For example, a large system commented that they had planned to implement EPCS by 2021 but were forced to reprioritize human and financial resources to support their colleagues and the patients and families impacted by, the PHE. Several other commenters stated that an EPCS mandate for a 2021 implementation date would undoubtedly cause some prescribers to simply stop prescribing controlled substances as part of their practice and this could inadvertently create patient suffering and harm.

Some prescriber groups supported the proposed January 1, 2022 date, while others requested even more time for implementation. They expressed appreciation for the flexibility that CMS has provided for providers struggling with the challenges of the current PHE and the difficulties they are facing implementing new systems or upgrades. Some commenters noted that there are both cost and implementation efforts required to install EPCS and with the COVID–19 pandemic, physicians face financial and operational hardships which create burden upon those who need to install EPCS functionality. Several commenters expressed views that the delay is prudent and will allow additional time for providers impacted by COVID, rural providers, and small practices to install and become familiar with EPCS. The specific challenges listed by these commenters include upgrading EHR software in a short timeframe, implementing dual authentication measures while social distancing, and paying the cost involved with system upgrades. One commenter noted that their software vendor was not making visits to their practice during the PHE, rendering software upgrades unfeasible.

Response: We appreciate the role that pharmacies, Part D plans and others have played in preparing for and advocating for EPCS. We understand that prescribers would prefer the proposed January 1, 2022 effective date and appreciate concerns raised by commenters about having adequate time to implement EPCS. However, as stated in our proposed rule, approximately 98 percent of pharmacies in the US are ready to accept EPCS, and Part D plans that have been reporting electronically

[108] See Title 21, § 1300.04(3)(f) available at *https://www.deadiversion.usdoj.gov/21cfr/cfr/1300/1300_04.htm.*

to CMS have no concerns about their readiness.

We also believe there are many benefits to EPCS that outweigh commenter concerns regarding readiness. EPCS can help deter and detect prescription fraud and irregularities by requiring an extra layer of identity proofing, two-factor authentication and digital signature processes. It can also help avoid data entry errors and pharmacy calls to a prescriber to clarify written instructions. By allowing for the direct transmission of electronic prescriptions between providers and pharmacies or facilities, EPCS may also reduce the burden on prescribers who need to coordinate and manage paper prescriptions between staff, patients, facilities, other care sites, and pharmacies. In addition, EPCS (dispensed medication) data is transmitted to Prescription Drug Monitoring Programs (PDMPs), which can help inform providers of patients' medication history and can aid in clinical decision making at the time of prescribing and/or before the medication is dispensed by a pharmacy. From the patient standpoint, EPCS may reduce the logistical burden on patients by lessening the time needed to obtain prescriptions, by minimizing trips to the physician to pick up paper prescriptions for refills, and by minimizing transportation costs to and from the provider's office. In addition, EPCS has important safety benefits in that it minimizes the likelihood that prescriptions have been tampered with. Because electronic prescriptions are securely transmitted directly to the pharmacy from health information technology, this minimizes the likelihood of exposure to patients or other third parties. We believe that an earlier effective date would encourage more timely implementation of EPCS in Part D, and therefore, bring these important benefits of EPCS faster to Part D prescribers, patients, and the Part D program.

Regarding the concern that the January 1, 2021 implementation date may cause prescribers to stop prescribing necessary controlled substances, we understand that this may be an issue. In light of this concern, as well as other potential implementation issues, we plan on monitoring the PDE data to look for concerning prescribing patterns, so we can adjust the program accordingly. Due to the PHE, we also seek to mitigate concerns about the impact that the January 1, 2021 deadline would cause by establishing a compliance date in addition to the effective date that would allow prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 to still be considered compliant.

In consideration of the benefits of EPCS and in light of the comments received, we are modifying our proposal by finalizing this provision with an effective date of January 1, 2021 and a compliance date of January 1, 2022. With a January 1, 2022 compliance date, prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 will still be considered compliant with the requirement. We believe that this phased approach strikes a balance of adhering to the timeframe set forth in the SUPPORT Act, supporting more rapid implementation of EPCS, and giving prescribers adequate time to comply with the EPCS implementation requirement.

Comment: Several commenters mentioned the health care provider costs involved in implementing EPCS. One commenter recommended that CMS work with ONC to ensure that the cost of implementing the part D electronic prescribing standard is taken into account when EHR's are evaluated in accordance with one of ONC's EHR certification criteria, and to ensure that EHR developers cannot charge additional fees for building in this prescribing standard capability into their certified products. Accordingly, the commenter requested that HHS take steps to minimize the cost of EPCS requirements to physician practices. Another commenter stated that their practice has delayed implementing EPCS due to the need to upgrade their EHR software, which has proven to be costly. The commenter stated that given the pandemic impact that amount is now unaffordable for their small primary care practice. Another commenter acknowledged that EPCS implementation costs can be high, but that a prudent buyer of software support can find less expensive options.

Response: We share concerns about high health care provider costs associated with implementing EPCS, particularly during the PHE. However, neither ONC nor CMS have the authority to dictate EHR vendor charges for implementing electronic prescribing capabilities that would meet EPCS criteria. We encourage those who provide software solutions to support EPCS to make their products as accessible as possible. As prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 will still be considered compliant with the EPCS implementation requirement, software providers will have more time to review their costs, and providers will have more time to evaluate and choose among available options.

Comment: One commenter noted that even with a delayed compliance date, not all practices or providers are currently using or planning to use this technology due to practice style, size, resources, capability and willingness to adopt new technology. The commenter stated that if modernization is required, alternative options should be available, or assistance should be provided to ease the burden of cost and implementation.

Response: We recognize the difficulties that many providers may have in implementing an EHR or eRx that accommodates EPCS. However, the aforementioned benefits of EPCS, especially in light of current social distancing guidelines, outweigh the burden of implementing an EHR or eRx system for EPCS. Furthermore, based on our conversations with the industry and analysis, CMS believes that once the EHR and eRx systems are implemented, the burden of EPCS will be less than the current manual process.

Comment: Several commenters recommended CMS work with other federal entities that are involved in eRx rules including ONC and the DEA.

Response: We will continue to coordinate with our Federal partners and will continue to coordinate EPCS efforts to the extent possible based on our individual legal mandates.

Comment: One commenter suggested CMS clarify whether the EPCS requirement will apply to inpatient settings as well.

Response: Section 2003 of the SUPPORT Act mandates that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be conducted electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. The proposal that we are finalizing includes all providers who prescribe medications that are Schedule II, III, IV, or V controlled substances that are covered Part D drugs. This generally includes medications dispensed in outpatient pharmacies but may also include medications dispensed to a patient who is being discharged to the home from an inpatient or emergency room setting, a long term care setting, or a Medicare hospice, or who is receiving care in a patient's home.

Comment: One commenter encouraged CMS to provide technical assistance and resources for clinicians in order to streamline this transition.

Response: As EPCS is permitted in every state, and will soon be required in 31 states, many state agency websites and state medical boards provide excellent resources for physicians to use. The DEA, on its website, has also posted frequently inquired about questions related to EPCS that can serve as a helpful resource. As a result, we do not believe that we need to provide any other resources, since they would merely duplicate the information on the websites.

Comment: A few commenters raised concerns about the impact on beneficiaries who have to receive prescriptions electronically rather than via traditional paper prescriptions. One commenter speculated that EPCS would interfere with the patient's pharmacy choice. Others voiced concern that patients may want a paper prescription in hand so they can visit multiple pharmacies and compare prices. The commenter noted that e-Prescribing may harm cancer patients who may benefit from receiving prescriptions from their physicians where the likelihood of adherence and quality improvement increases.

Response: Given that nearly all US pharmacies are ready to accept electronic prescriptions of controlled substances, this means that a prescriber can use EPCS and send the prescription where the patient instructs. We also recognize that the price of a given medication may impact a beneficiary's pharmacy choice. However, EPCS is being implemented in the Part D program at a time when patients and providers will have access to electronic real time benefit tools that can offer price transparency without requiring in person visits or calls to alternate pharmacies for price checking. As required in the May 2019 final rule (84 FR 23851), which updated the Part D e-Prescribing standards, each Part D plan is required to adopt one or more prescriber real time benefit tools that are capable of integrating with at least one prescriber's e-Prescribing system or electronic health record no later than January 1, 2021. We encourage patients and providers to use these tools. We are unaware of any evidence to indicate that the act of a physician handing a prescription to a patient has a positive impact on medication adherence.

Comment: One commenter expressed concern with the health care provider burden associated with reporting EPCS transactions to CMS.

Response: We clarify that there is no added provider burden associated with reporting EPCS transactions to CMS as the NCPDP Telecommunications standard captures the source of a prescription transaction through the prescription origin code. A value of ''3'' in field 419–DJ indicates that a prescription was transmitted electronically; such information is sent to the Part D plan which then conveys that information to CMS through PDE data. No additional action on the part of the prescriber is needed.

Comment: Some commenters questioned about complying with EPCS requirements when it is not reasonable or feasible. These circumstances include instances when NCPDP SCRIPT 2017071 does not support the prescription, systems downtime, lack of internet connectivity or when the patient needs a paper prescription to receive medication in advance of a vacation.

Response: There may be instances when a prescriber is unable to transmit a particular prescription electronically using the named SCRIPT standard. Under those circumstances, paper prescriptions are compliant with CMS requirements. The NCPDP SCRIPT Implementation Recommendations document provides guidance on implementing the standard. We remind commenters that we have issued electronic standards for use in Medicare Part D since the program's inception, and have withheld issuing compliance actions under circumstances such as a sporadic downtime or lack of internet access that the covered entity might experience. Consistent with this previous practice, we do not anticipate issuing compliance actions when a prescriber is unable to transmit a particular prescription electronically using the named SCRIPT standard under such circumstances.

Comment: A commenter suggested establishment of a list of mandated exemption codes and modifying existing NCPDP standards to enable tracking of paper prescriptions exemption codes Prescribers could then handwrite the exemption code(s) on paper prescriptions and/or input the codes in the EHR in notes or in a new custom field. Pharmacies would capture the exemption code(s) through use of the NCPDP telecom standard and convey the information to the payer and on to CMS through PDE data. They noted that this would take years to implement.

Response: We thank the commenter for the suggestion. The proposed solution seems to be one way of leveraging technology to capture information about why EPCS is not being used to transmit a given prescription. However, we would be concerned about the burden that required exemption coding might place on prescribers and pharmacies. Prescribers would have to know the appropriate code to use and enter it onto the paper prescription and pharmacies would have to look for, and enter the code into their dispensing systems in order to convey that information to Part D plans. It is also unclear how the Part D exceptions may/may not overlap with exemptions allowed under state EPCS rules, which could cause confusion. However, as the adoption of EPCS progresses, we would rely on the NCPDP to work with prescriber groups to examine the suggestion in detail. We believe some providers and pharmacies may embrace this mode of communicating why a paper prescription for controlled substances is used, while others may not. We also caution that the absence of such a code would not be a valid reason for a pharmacy not to dispense a medication nor for a Part D plan to deny payment for an otherwise valid written prescription. We look forward to hearing about any discussions about this concept as they progress.

Comment: One commenter requested CMS be specific in defining which NCPDP SCRIPT version 2017071 capabilities are expected to be used before a pharmacy or payer rejects incomplete prescriptions.

Response: Section 2003 of SUPPORT Act makes it clear that the EPCS requirement should not be construed as requiring a sponsor of a prescription drug plan under Part D or a pharmacist to verify that a practitioner, with respect to a prescription for a covered Part D drug, has a waiver from the EPCS requirement under Part D. Consistent with the statute, nothing in our rule should cause the dispensing pharmacy to reject a prescription nor the Part D plan to deny payment for an otherwise valid written, oral, or fax prescriptions that is consistent with laws and regulations. As a result, we do not believe it is our place to define which of the standard's capabilities should be used before the rejection of an incomplete prescription.

Comment: Several commenters expressed concerns that CMS' proposal assumes these functionalities to be successful, when in actuality they still require significant fixes and delayed implementation timelines. Perhaps the biggest challenge clinicians will face, commenters stated, is incorporating EPCS into their EHRs, and most clinician practices are not in a position to cover the costs and acquire the

necessary resources for technical or system upgrades required by EHR vendors—especially rural and small practices. Commenters stated that due to the COVID–19 pandemic, many practices have been forced to delay or cancel implementation altogether of EHRs that support EPCS due to the implementation cost. Commenters voiced the concern that practices that do not currently have the capability to prescribe electronically would be forced to purchase such a software. A commenter supported the intent to facilitate efficiency, convenience, and better security with the implementation of EPCS, but encouraged CMS to avoid unreasonable burden imposed upon clinicians and delay compliance until at least January 1, 2023.

Response: We are aware of the difficulties that clinicians may face when implementing EPCS. However, with potentially broad public health implications, we believe a January 1, 2021 effective date complies with the statutory intent and would enable the safety and other benefits previously discussed to be put in place during the current pandemic. However, in order to help ensure that the burden on prescribers is not unreasonable, we are finalizing a compliance date of January 1, 2022 such that prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 will still be considered compliant with the requirement.

Comment: Many commenters stated their intent to comment on the EPCS request for information. We received a number of comments that requested CMS address the need for exceptions to the EPCS rule and to set forth an overview of the penalties to be used. Some commenters provided comments with regard to waivers, health professionals and practices and their ability to declare a hardship and to be exempt from EPCS requirements; others requested exclusions for those who are unable to electronically prescribe controlled substances by January 1, 2022 for various reasons. A few commenters suggested that CMS explicitly clarify that the current exemptions at § 423.160(a)(3)(iii) will continue to apply for prescriptions of controlled substances where the sender and the beneficiary are part of the same legal entity. Those commenters stated such an exemption would align with CMS' existing policy at § 423.160(a)(1) regarding use of the NCPDP SCRIPT Standard because the prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals is not transmitted using electronic media, and previous clarifications CMS has issued as part of other electronic prescribing requirements. Commenters also stated that CMS should also align such an exception with CMS' existing policy at § 423.160(a)(3)(iii), which allows the use of HL7 messages for transmitting prescriptions and prescription-related information internally by clarifying that exemption's applicability to prescriptions for controlled substances.

Response: We thank the commenters for their feedback and will take all comments included in the Electronic Prescribing for Controlled Substances; Request for Information and comments received on the PFS proposed rule into account as we implement this program. The SUPPORT Act requires that CMS use rulemaking to determine any processes for enforcement, including on any prescriber waivers, penalties and appeals. CMS will continue to consider comments and recommendations received in response to both the proposed rule and the RFI and will propose any such processes in a future rule, to be effective no earlier than January 1, 2022. Based on detailed and thoughtful comments received in response to our proposed rule and the RFI, we understand that any future rulemaking may be better informed through additional inquiry, such as review of state EPCS program characteristics and insight gained from implementing the programs, consideration of the interactions between EPCS and PDMP workflows, and obtaining clarification of the implications of potential updates to the DEA's biometric standards for dual authentication on technical and workflow requirements. CMS will continue to review its own PDE data to better understand EPCS patterns across prescribers and provider groups and what this data can convey about the characteristics of Part D prescribers of controlled substances (such as geographic areas, specialties, and Part D prescribing volume and patient residence locations).

After consideration of the comments received, we are finalizing the provision with an effective date of January 1, 2021 and a compliance date of January 1, 2022 to encourage prescribers to implement EPCS as soon as possible, while helping ensure that our compliance process is conducted thoughtfully.

L. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

1. Background

Medicare Part B covers drugs under a limited drug benefit that includes drugs and biologicals defined in section 1861(t) of the Act. Medicare Part B drugs and biologicals fall into three general categories: Drugs and biologicals furnished incident to a physician's services, drugs and biologicals administered via a covered item of durable medical equipment (DME), and other drugs and biologicals specified by statute. Payment amounts for most separately payable Medicare Part B drugs and biologicals are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on.

Drugs (not including biologicals or biosimilar biological products, as defined in section 1847A of the Act) paid using the methodology in section 1847A of the Act fall into two broad and mutually exclusive categories: Multiple source drugs and single source drugs. These terms are defined in statute and are further discussed in this section and the next section. In most cases the distinction between the multiple source drugs and single source drugs is fairly straightforward and is made as outlined in program instruction published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf*): The payment limit under section 1847A of the Act for that biological product or single source drug is based on the pricing information for products produced or distributed under the applicable FDA approval. However, for a subset of drug products approved through the pathway established under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA), the distinction is less straightforward.

The drug approval pathway established under section 505(b)(2) of the FFDCA has existed since 1984, before the ASP payment methodology was established. The section 505(b)(2) pathway is provided for applications that contain full reports of investigations of safety and effectiveness, where at least some of the information for an approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. An application submitted under section 505(b)(2) (which we refer to as a ''section 505(b)(2) application'') may

rely on FDA's finding of safety and/or effectiveness for a listed drug (an approved drug product) or published literature provided that such reliance is scientifically justified and the section 505(b)(2) applicant complies with the applicable statutory and regulatory requirements, including patent certification if appropriate. Unlike an Abbreviated New Drug Application (ANDA) for a generic drug, a section 505(b)(2) application is not required to have the same labeling as the listed (approved) drug(s) that the application relied upon. However, some drugs approved through the pathway established under section 505(b)(2) of the FFDCA (which we refer to as ''section 505(b)(2) drug products'') share significant portions of their FDA-approved labeling with the listed (approved) drug(s) that the application submitted through section 505(b)(2) relied upon, for example prescribing information on safety, efficacy, and pharmacokinetics. In some cases, the section 505(b)(2) drug product shares significant portions of labeling with generic drugs that are paid as multiple source drugs under section 1847A of the Act. Examples of situations where a section 505(b)(2) drug product shares similar labeling to listed (approved) products include a sterile injectable drug product that had been sold as a lyophilized powder in a vial and was then approved for sale as a concentrated liquid in a vial, as well as a ready-to-use IV bag.

The number of drugs approved through the pathway established under section 505(b)(2) of the FFDCA has been growing, from about 40 per year from 2011 to 2016, to about 60 in 2017, and 70 in 2018. Some of these approvals include drugs paid under Part B. Although we have assigned some section 505(b)(2) drug products to separate single source billing and payment codes, our payment approach for newly marketed section 505(b)(2) drug products, where an existing multiple source code descriptor describes the section 505(b)(2) drug product accurately, and where the active ingredient(s), the drug name, and portions of the prescribing information correspond to existing products that are assigned to and paid under a multiple source drug code, has been to assign the section 505(b)(2) drug products to the existing multiple source code. We believe that this approach, as described in more detail below, is consistent with statutory language in section 1847A of the Act. The definition of multiple source drug at section 1847A(c)(6)(C) of the Act states in part that for a multiple source drug, there are two or more drug products which are rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' also known as the Orange Book). For purposes of Part B drug payment under section 1847A of the Act, we interpret this to mean that if there is an existing HCPCS billing code that includes two or more drug products which are rated therapeutically equivalent and meets the remaining conditions of the definition of a multiple source drug, that billing and payment code is a multiple source drug code, and the section 505(b)(2) drug product meets the definition of a multiple source drug in section 1847A(c)(6)(C) of the Act. The statutory language in section 1847A(b)(3) and (6) of the Act provides discretion for CMS to assign additional drug products to a multiple source drug code. In other words, if a multiple source drug code exists, we are permitted to assign other multiple source drug products to that code for the purpose of payment as a multiple source drug under section 1847A of the Act. We note that if the drug product is described by a multiple source code, it meets the definition of multiple source drug at section 1847A(c)(6)(C) of the Act, and it does not meet the definition of a single source drug at section 1847A(c)(6)(D) of the Act, because the definition of a single source drug expressly excludes a multiple source drug in section 1847A(c)(6)(D)(ii) of the Act.

We assigned section 505(b)(2) drug products to existing multiple source drug codes for Part B payment under section 1847A of the Act in limited situations, that is, where an existing multiple source code descriptor describes the section 505(b)(2) drug product, the active ingredient(s) correspond to one another, the section 505(b)(2) drug product's labeling, particularly the prescribing information, includes information (such as the drug description, dosage and administration, pharmacokinetics, and indications) from other drug products that are paid under the multiple source drug code, and the section 505(b)(2) drug product can be used and prescribed in a manner similar to other products in the multiple source drug code. This information is used to determine whether the section 505(b)(2) drug product can be billed and paid using the existing multiple source drug code. The determination is based on the discussion in the previous paragraph, that is, if there is an existing HCPCS billing code that includes two or more drug products which are rated therapeutically equivalent and meet the remaining conditions of the definition of a multiple source drug, that billing and payment code is a multiple source drug code. Consistent with the statutory language in section 1847A(b)(3) and (6) of the Act, which provides discretion for CMS to assign additional drug products to a multiple source drug code, a section 505(b)(2) drug product can be assigned to the multiple source drug code. The section 505(b)(2) product assigned to the multiple source drug code meets the definition of a multiple source drug in section 1847A(c)(6)(C) of the Act. Thus, for the purpose of payment under Medicare Part B, the section 505(b)(2) drug product can be billed and paid under that existing multiple source code. However, in situations where there is no existing multiple source drug code that describes a section 505(b)(2) drug product, the section 505(b)(2) drug product is typically assigned to its own single source code.

2. Multiple Source Drug and Single Source Drug Codes

Section 1847A of the Act uses the terms drug and drug product. Consistent with the statutory definitions discussed at section 1847A(c)(6)(C) and (D) of the Act and program instruction published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_announcement.pdf*), we have applied the terms multiple source drug and single source drug at the billing and payment code level, meaning that ''drug'' corresponds to a HCPCS or other applicable billing code and its descriptor, which typically includes the active ingredient(s) of the drug. The term ''drug product'' corresponds to individual packages of the drug as identified by the National Drug Code (NDC) or other applicable alternative identifier.

The terms multiple source drug and single source drug are defined, respectively, in section 1847A(c)(6)(C) and (D) of the Act. Section 1847A(c)(6)(C) of the Act states that multiple source drug means, for a calendar quarter, a drug for which there are two or more drug products which are rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''); are pharmaceutically equivalent and bioequivalent, as determined by the FDA; and are sold or marketed in the United States during the quarter. Section 1847A(c)(6)(E) and (F) of the Act establish conditions under which pharmaceutical equivalence and

bioequivalence are met. The definition of multiple source drug in section 1847A of the Act can be interpreted to mean that once a multiple source drug code exists—that is, once there are two or more drug products that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent, and CMS has assigned them to a multiple source drug code—then a subsequent product of the same drug—that is, a product that corresponds to the multiple source drug code's descriptor—can be assigned to such code even if the subsequent drug product is not, itself, therapeutically equivalent, bioequivalent or pharmaceutically equivalent. This is because in this case, the drug is multiple source, meaning that there are two or more products which are rated as therapeutically equivalent of that drug, as evidenced by the fact that the existing products are already assigned to the multiple source drug code. Once a drug product is assigned to a multiple source drug code, the product would not be assigned to a single source drug code because the definition of single source drug at section 1847A(c)(6)(D)(ii) of the Act states, in part, that a single source drug is a drug which is not a multiple source drug. Thus, when assigning drug products to multiple source and single source drug codes for the purpose of payment under section 1847A of the Act, we consider whether the product is described by an existing multiple source drug code first, and if the product is assigned to an existing multiple source drug code, its payment allowance will be determined based on the volume-weighted average ASPs of all drug products assigned to the code, rather than based solely on its own ASP (for example under a new single source code).

Section 1847A(b)(3) and (6) of the Act provide that payment for multiple source drugs is determined for all drug products included within the same multiple source drug billing and payment code. For multiple source drugs, we calculate a volume weighted average sales price across all drug products assigned to a billing and payment code. This typically means that the ASP-based payment amount for a multiple source drug code includes generic and branded drug products within an individual code.

Consistent with section 1847A(b)(3) and (6) of the Act and our interpretation of the definition of multiple source drug in section 1847A(c)(6) of the Act, we assign certain section 505(b)(2) drug products to existing multiple source drug codes. We determine whether to assign section 505(b)(2) drug products to multiple source or single source drug codes by comparing information about the section 505(b)(2) drug product to the descriptors for existing multiple source codes to which the drug products may be assigned for the purposes of payment amount determinations under section 1847A of the Act, as well as information about products already assigned to that descriptor. This information includes the products' active ingredients and labeling, particularly the prescribing information and, if necessary, additional sources such as the FDA's Approval Summary Review, which is a part of the FDA's application review files and is available at *https://www.accessdata.fda.gov/scripts/cder/daf/*, and drug compendia. The FDA's Approval Summary Review can provide additional details about information that is found in the drug's labeling and prescribing information and other compendia can supplement the information that is found in labeling and provide information about off label use of a drug.

Our case by case determination about the assignment of certain section 505(b)(2) drug products to existing multiple source drug codes is based on the factors described in further detail in the bullet points below: First, the products' active ingredient(s), drug name and description; second, the products' labeling information; third, how they are ordered (prescribed) and used clinically. These factors are assessed as a whole, using the information (for example, active ingredient, labeling, compendia, and FDA Approval summary), to determine whether an existing multiple source drug code describes a section 505(b)(2) drug product and whether the product can be assigned to an existing multiple source drug code for the purpose of payment under section 1847A of the Act. The determination is based on the following:

- The active ingredient and drug name of the section 505(b)(2) drug product and other drug products in an existing multiple source drug code.
- The drug description and indications, particularly whether differences such as the salt form, additional ingredients, or uses exist.

The two bullet points above identify the section 505(b)(2) drug product and multiple source drug code and establish what is being compared so that the determination can proceed, if necessary. For example, if the active ingredients and drug names do not correspond, there would not be a reason to assign the section 505(b)(2) drug product to the multiple source drug code or to proceed further. We also note that the active ingredient of a drug is often included in the HCPCS code descriptor that is used to bill a drug product and to pay for it under section 1847A of the Act. The drug description is used, if necessary, to clarify what the actual active ingredient(s) are, whether there are minor differences, such as salt forms and other inactive ingredients that may affect how the product is used. This information may be helpful when considered with the information in the next two groups of bullet points as we consider labeling and uses of the drug products.

- The labeling information (and if necessary other material from sources such as the FDA's Application Review Files, including the FDA's Approval Summary Review, and drug compendia), particularly pharmacokinetics, indications, adverse reactions, drug interactions, contraindications, warnings, precautions and clinical studies.

The bullet point above allows us to determine whether the same information, for example the same studies, were used to support the approval of the section 505(b)(2) drug product and to gauge how much of the labeling information from existing multiple source drug products appears in the section 505(b)(2) drug product's labeling. This information also supports the determination in the next bullet point. The more labeling information that a section 505(b)(2) drug product has in common with drug products in an existing multiple source drug code, the more likely it is that the existing code describes the section 505(b)(2) drug product, such that CMS will assign it to that multiple source drug code for the purpose of payment under section 1847A of the Act.

- The dosage and administration, pharmacokinetics, indications, contraindications, warnings, drug interactions, and adverse reactions.

The bullet point above allows us to determine whether the section 505(b)(2) drug product is ordered and used in patient care in the same way as products assigned to a multiple source drug billing code. The dosage and administration, pharmacokinetics, and indications are particularly important because we consider whether a prescriber writes a prescription for the section 505(b)(2) drug product in the same way as drug products assigned to a multiple source drug code and whether the products could be used for the same uses. Typically, a prescription includes the following information: The drug, dose, route of administration, and frequency. The quantity of a drug (or duration of therapy) and refills are also

a part of a prescription, but are less of a factor for Part B where most drugs are used incident to a physician's services. Typically, drugs used incident to a physician's services are administered and billed as a very limited number of doses, often just one, are administered during a service, and the drug is not dispensed for the patient for use over an extended time period beyond an office visit or outpatient hospital visit. The elements in the bullet point reflect how a drug is used and administered in the care of patients and in turn determine how billing for the drug is accomplished; that is, whether an existing code descriptor describes a section 505(b)(2) drug product and can be used to bill for it.

As a simple example of our approach, if the active ingredient, dose, route of administration and frequency of the section 505(b)(2) drug product are the same as those for drug products in a multiple source drug code, then it is likely that an existing code descriptor describes a section 505(b)(2) drug product and can be used to bill for it. The information does not have to be an exact match, for example different uses of a drug product may require different doses, routes of administration, or frequencies. However, if the section 505(b)(2) drug product and the multiple source drug products in the existing multiple source drug code could both be used for the same indication (potentially by way of off-label use), then billing for both with the existing HCPCS code would still be feasible. In such situations, similarities between labeling information such as whether the same studies were used to establish pharmacokinetic parameters may factor into the assessment. In summary, the information discussed above is used as a whole to determine whether the existing multiple source drug HCPCS code descriptor describes the section 505(b)(2) drug product or if a new HCPCS code would be needed describe the product for payment under Part B.

The information described in the bullet points above is usually sufficient for our determinations, but from time to time we may reach out to the drug manufacturer, seek post marketing data, or review literature sources for additional information to assist us with understanding the information in the bullet points above and to assist with determinations in complicated situations, for example where indications vary, but it appears that the section 505(b)(2) drug product could still be used, administered and billed in the same manner as drug products assigned to an existing multiple source drug code.

We are aware that some section 505(b)(2) drug products are very different from previously approved products that may be used to support their approval. We do not assign all section 505(b)(2) drug products to existing multiple source drug codes. In circumstances where an existing code does not describe the section 505(b)(2) drug product and use of the existing code would not be suitable for billing and payment of the section 505(b)(2) drug product under Part B based on the assessment described above, the section 505(b)(2) drug product would not be assigned to the existing multiple source drug code. The following examples illustrate how we distinguish section 505(b)(2) drug products that are assigned to an existing multiple source drug code from those that are not. If a section 505(b)(2) drug product has the same active ingredient, same dose and dosing interval, and prescribing information and includes the same clinical studies (for example, the same patient number, same response rates and same adverse reaction frequencies) as drug products assigned to an existing multiple source drug code, the section 505(b)(2) drug product would be assigned to the multiple source code. However, if the section 505(b)(2) drug product has different pharmacokinetics, for example if it is a sustained release version of a drug that permits less frequent dosing compared to drug products in an existing multiple source drug code, or if the section 505(b)(2) drug product has additional active ingredients not found in the drug products in an existing multiple source drug code, the section 505(b)(2) drug product would not be described by the existing multiple source drug code. As a result, it would not be considered a multiple source drug under section 1847A(c)(6)(C) of the Act because there would not be at least two drug products for that drug that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent; thus, the section 505(b)(2) drug product would be considered a single source drug and typically assigned to a single source drug code.

3. Codifying Existing Policy for Section 505(b)(2) Drug Products

As we stated in the CY 2021 PFS proposed rule (85 FR 50264 through 50265), our approach (described in section II.L.2 of this final rule) for the payment of section 505(b)(2) drug products has been in place for at least 12 years, and it is also consistent with the concept of paying similar amounts for similar services. It is based on the definitions of multiple source drug and single source drug in section 1847A(c)(6)(C) and (D) of the Act and authority to assign drug products to billing and payment codes in section 1847A(b)(3) and (6) of the Act as discussed in the sections above. We explained that a number of section 505(b)(2) drug products that are described by an existing multiple source drug code are priced significantly higher than comparable products. Two recently introduced section 505(b)(2) drug products that appear to be comparable to drug products in existing multiple source drug codes (using the approach described in the section earlier) have Medicare payment allowances that are approximately 10 times higher than that of the existing multiple source code. We stated that we believe that assigning section 505(b)(2) drug products that are described by existing multiple source drug HCPCS codes to those existing HCPCS codes is consistent with efforts to curb drug prices while limiting opportunities to ''game the regulatory process and the patent system in order to unfairly maintain monopolies.'' [109] We stated that we believe our approach also encourages competition among products that are competitors—that is, when they are described by one billing code and share similar labeling.

We stated our concern about high payments for section 505(b)(2) drug products if they are assigned to unique separate HCPCS codes despite being described by existing multiple source drug codes. We also stated our concern about the effect of high payment amounts on individual beneficiaries' cost sharing payments for these products.

Therefore, for these reasons, in the CY 2021 PFS proposed rule (85 FR 50265) we proposed to codify our long-standing process for assigning certain section 505(b)(2) drug products to existing multiple source drug codes if the section 505(b)(2) products are described by existing multiple source drug codes consistent with our interpretation of the definition of multiple source drug in section 1847A(c)(6)(C) of the Act and the approach described above. Specifically, we proposed that where a section 505(b)(2) product is not itself therapeutically equivalent, pharmaceutically equivalent, or bioequivalent, as determined by FDA, to another drug product, we would nonetheless consider it to meet the definition of multiple source drug if, based on an assessment of its active ingredient, labeling, compendia, and

[109] *https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices/.*

other information, the product is described by the code descriptor for an existing multiple source drug code. That is, we would assess the section 505(b)(2) drug product's active ingredient(s), drug name, and description, whether the section 505(b)(2) drug product's labeling, particularly the prescribing information, includes information from other drug products that are paid under the multiple source drug code, and whether the section 505(b)(2) drug product is used and prescribed in a manner similar to other products in the multiple source drug code, in order to determine whether the section 505(b)(2) drug product is described by an existing multiple source drug code. We would not assign all section 505(b)(2) drug products to multiple source codes and would not assign section 505(b)(2) drug products to a single source drug code exclusively made up of single source drug products. We stated that we would also reevaluate and potentially revise previous payment (and coding) decisions to maintain consistency with our proposed approach, if finalized. Consistent with these proposals, we also proposed to revise the definition of multiple source drug in regulation text at § 414.902 by amending the regulation text to state that multiple source drugs may include drug products described under section 505(b)(2) of the FFDCA and adding § 414.904(k) that describes the framework for our determination as discussed in this section of the preamble.

4. Summary of Comments

The following is a brief summary of comments we received on these proposals. More detailed comments and responses follow this summary. We received approximately 37 timely comments on section 505(b)(2) drug products. In general, commenters, primarily manufacturers, stated that the proposal was contrary to the statute, conflicted with FDA's therapeutic equivalence ratings, would impair access for patients, underpay providers, and dampen innovation. Several comments from beneficiary advocate and provider groups generally repeated the same points, although some comments expressed support for curbing drug prices, particularly if the proposal did not affect patient access. Several comments appeared to take a middle ground that conditionally supported the proposals, particularly if more detail could be provided and if effects on patient access were considered. Several commenters supported the proposals without conditions.

Comment: Several commenters contended that CMS lacks the statutory authority to adopt the proposals in the proposed rule, and some stated that the proposal was not consistent with subregulatory guidance from 2007. These commenters stated that the language in the statute clearly defines multiple and single source drugs, that assigning non-therapeutically equivalent drug products to a multiple source code contradicts the plain language of section 1847A of the Act, and that CMS's proposal is contrary to Congress' intent. Commenters also stated that the definition of multiple source drug in section 1847A(c)(6) of the Act requires each drug product assigned to a multiple source code to be therapeutically equivalent, pharmaceutically equivalent and bioequivalent to another product in the code, and that the only exception is a provision (sometimes referred to as the grandfathering provision) under section 1847A(c)(6)(C)(ii) of the Act.

Response: We disagree that our proposed approach is inconsistent with the statute. The statute allows CMS to assign drug products to an existing multiple source code, and does not require that the code include only products that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent to one another product. As outlined in the proposed rule, the definition of multiple source drug in section 1847A(c)(6)(C) of the Act can be interpreted to mean that once a multiple source drug exists—that is, once there are two or more drug products that are therapeutically equivalent, pharmaceutically equivalent and bioequivalent, and we have assigned them to a multiple source drug code—then a subsequent product of the same drug—that is, a product that corresponds to the multiple source drug's billing code descriptor—can be assigned to such code even if the subsequent drug product is not, itself, therapeutically equivalent, bioequivalent or pharmaceutically equivalent. In this case, the drug is already multiple source, meaning that there are two or more products of that drug which are rated as therapeutically equivalent, as evidenced by the fact that the existing products are already assigned to the multiple source drug code. Once a drug product is assigned to a multiple source drug code, the product would not be assigned to a single source drug code because the definition of single source drug at section 1847A(c)(6)(D)(ii) of the Act states, in part, that a single source drug is a drug which is not a multiple source drug. Also, we are not aware of any sources, such as Committee Reports that describe Congress' intent in detail, that conflict with our interpretation. The proposed approach focuses on assigning drug products to a drug code solely for Part B drug payment purposes and is consistent with the statutory definitions at section 1847A(c)(6)(C) and (D) of the Act. However, we do not agree that statutory language at section 1847A(c)(6)(C)(ii) of the Act about an exception is relevant to this discussion. This grandfathering provision applies only to ''single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003.'' The exception does not apply to multiple source drugs or the assignment of drug products to multiple source drug billing and payment codes.

The proposals are also consistent with the program instruction published in 2007 (*https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf*). In the program instruction, we addressed how we would identify ''single source drugs'' and ''biological products'' using a multi-step process. We did not expressly address how we would identify multiple source drugs. The program instruction is not inconsistent with our proposal because in both cases, the determination of the ''drug'' is reflected at the HCPCS code level. In contrast, the term ''drug product'' corresponds to individual package sizes of the drug as identified by the NDC or other applicable alternative identifier. The proposals published in the CY 2021 PFS proposed rule add to, rather than conflict with, the 2007 program instructions and provide detail about how we approach Medicare Part B payment of section 505(b)(2) drug products.

Comment: A number of commenters stated that our approach is not consistent with or does not take into account FDA's ratings of therapeutic equivalency for drugs and the application of the ratings for interchangeability determinations pertaining to these products.

Response: We disagree with these comments. The therapeutic equivalence ratings published by FDA and its work associated with these ratings pertain to Part B drug payment only to the extent that they are used to define when two or more drug products are therapeutically equivalent, which is relevant to the determination of whether a drug is single source or multiple source as defined in section 1847A of the Act. FDA's therapeutic equivalence ratings do not themselves dictate payment under Medicare Part B.

Relatedly, our proposals for section 505(b)(2) drug products do not affect these ratings or this work; rather, our proposals apply only to drug payments under section 1847A of the Act. This is consistent with the different roles of FDA and CMS—the former assesses a drug product's safety and effectiveness, and the latter administers the Medicare program.

As we discussed in the previous comment response, one condition for meeting the definition of a multiple source drug at section 1847A(c)(6)(C) of the Act is that there be two or more drug products rated as therapeutically equivalent. However, a subsequent product of the same drug—that is, a product that corresponds to the multiple source drug code's descriptor—can be assigned to such code even if the subsequent drug product is not, itself, therapeutically equivalent. In other words, where there are two or more drug products that are rated as therapeutically equivalent in the Orange Book, the drug meets the definition of multiple source drug for purposes of Medicare Part B payment, and this has no bearing on any particular drug product's therapeutic equivalence rating. Where there is a multiple source drug (as defined in section 1847A(c)(6)(C)), other non-therapeutically equivalent drug products of that drug may be assigned to the HCPCS code for purposes of payment under section 1847A of the Act. Section 1847A of the Act does not mention interchangeability as a factor in determining payment for drugs, nor does it explicitly describe how multiple source drug products must be assigned to billing and payment codes or how they must be paid.

We also disagree with comments that our proposal fails to take product interchangeability into account. Payment under Medicare Part B and interchangeability are separate issues—the former pertains to when Medicare will pay for a product, and the latter pertains to drug dispensing and clinical decisions. In Medicare Part B, where most drugs are used incident to a physician's services and are not dispensed through a retail pharmacy, what a provider administers to a patient is often determined by the prescriber or where that prescriber practices. For example, due to space and inventory budget limitations, a physician's office will generally stock a limited range of drug products that are administered incident to a physician's services. Section 1847A of the Act does not specify which drug products physician must stock or provide, nor does it dictate how prescribers may utilize drug products in patient care. Interchangeability governs the range of products that a pharmacist may dispense to fill a prescription and also is not addressed in section 1847A of the Act. Rather, interchangeability and pharmacy substitution are typically addressed in State law and may be affected by factors such as hospital bylaws, inventory and other matters that are outside of CMS' purview. As noted previously, our proposals pertain only to payment under Medicare Part B, and do not purport to dictate which drug products a prescriber may prescribe or a pharmacy may dispense.

Comment: A few commenters noted that the assignment of section 505(b)(2) drug products to multiple source codes was new and had never been applied by CMS. However, other commenters acknowledged CMS' longstanding policy with respect to these drug products.

Response: We disagree with commenters that stated the proposals are a new policy that has not been applied to Part B drug payments. As we stated in the proposed rule, the policy has been in place for at least 12 years. For example, this process has been applied to gemcitabine injection products that were first marketed as Gemzar(R), a sterile lyophilized powder packaged in vials. The brand products were assigned to a HCPCS code (J9201), and once generic gemcitabine products were marketed, they also were assigned to J9201, making J9201 a multiple source drug code. Later, liquid concentrates of gemcitabine injection were approved through the pathway established under section 505(b)(2) of the FFDCA. These concentrated liquid products also were assigned to the existing multiple source HCPCS code, J9201, even though they were not, themselves, therapeutically equivalent to the branded products in J9201. Subsequently marketed lyophilized powder and concentrated liquid gemcitabine injections, as well as gemcitabine products approved under ANDAs also have been assigned to HCPCS code J9201.

ASP–NDC crosswalks that reflect these HCPCS assignments have been available to the public along with the quarterly ASP Drug Pricing files on the CMS website. We began including the concentrated liquid formulations in the ASP NDC crosswalks that were published for January 2012. The January 2012 Drug Pricing Files and the ASP NDC–HCPCS crosswalk are available in the Related Links section at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2012ASPFiles.* Although we do not describe the crosswalks as a complete listing of all NDCs used in pricing determinations, the crosswalks serve as a guide to help the public understand which products are included in the weighted average calculation for a given HCPCS code. The crosswalk files are readily available to the public via the CMS website and illustrate which NDCs are assigned to HCPCS codes for payment under section 1847A of the Act.

Comment: Several commenters discussed potential effects of the proposals on manufacturers. Commenters, primarily manufacturers that seek 505(b)(2) approvals for their products, expressed concerns that the proposals would dampen innovation, result in fewer drug approvals through the pathway, and contribute to a less efficient approval process, which could result in fewer choices for patients and prescribers and a less predictable marketplace. While some commenters expressed concerns about major effects on the industry and appeared to believe that all section 505(b)(2) drug products would be affected by the proposal, others suggested identifying situations where separate payment would be available in a predictable manner. Several commenters stated that if CMS moves forward with the proposal, CMS should exclude products with ''meaningful differences'' from the policy. One commenter encouraged CMS to continue an approach ''that allows for innovation, competition, and ultimately more therapeutic choices for Medicare beneficiaries.''

Response: As mentioned in the proposed rule, we are aware that the section 505(b)(2) pathway has been in existence since the 1980s, well before the implementation of the payment methodology in section 1847A of the Act. We are also aware of the potential advantages of seeking approval through the pathway established under section 505(b)(2) of the FFDCA compared to seeking approval under the section 505(b)(1) pathway. Under the 505(b)(1) pathway, the application contains full reports of investigations of safety and effectiveness that were conducted by or for the applicant or for which the applicant has a right of reference or use. Because the approval of a product through the section 505(b)(2) pathway relies on at least some information from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference, the use of the 505(b)(2) pathway can minimize time, effort and expense associated with bringing a product to the market, although some additional study of the product is typically

required. From experience with the crosswalking process (the assignment of NDCs to HCPCS codes for payment determinations under section 1847A of the Act), we have observed that section 505(b)(2) drug products are heterogeneous. Some of the products are very different from previously marketed products that were used to support the approval through the section 505(b)(2) pathway. For example, the section 505(b)(2) drug product may include additional active ingredients, or may incorporate formulation changes that result in significant changes to the dosing schedule (for example, changing from 3 times per day to once per day administration). However, some section 505(b)(2) drug products are very similar to drug products that are assigned to multiple source drug codes.

The application of our policy to determine assignment of section 505(b)(2) drug products to a multiple or single source drug code has resulted in the assignment of a limited number of these drug products to multiple source drug codes and under our proposal we anticipate that the number of assignments of drug products to multiple source codes would continue to be limited. Many section 505(b)(2) drug products are paid using single source drug codes under section 1847A of the Act. We have examined 23 instances associated with the assignment of section 505(b)(2) drug products to billing codes for payment under section 1847A of the Act during the years 2017 to 2019. Eighteen of the instances led to products being assigned to single source drug codes. Products associated with the remaining five instances were not priced as separately payable Part B drugs (for example, because payment is bundled with physician services). Seventeen of the 18 products that were assigned to single source drug codes are included in either the ASP Drug Pricing Files, OPPS Addendum B or both files (the exception is a product that was not yet marketed). These 17 products include an older antibiotic that was combined with a new ingredient that extended its antibiotic spectrum, a new formulation of a drug that is used in the treatment of opiate use disorder, and novel formulations of older drugs that are specifically designed for less frequent administration or are administered by a different route (such as a drug that was previously approved only as an oral drug and not paid under Part B, but was then approved as a section 505(b)(2) drug product as an injectable drug). Thus we believe that our policy has not led to the frequent assignment of section 505(b)(2) drug products with significant modifications (like an additional active ingredient) to multiple source drug codes. Further, if manufacturers continue to market products that one commenter described as having ''meaningful differences'' from multiple source drugs, we anticipate that section 505(b)(2) drug products approved in the future will not be assigned to multiple source drug codes frequently. For these reasons, we do not believe the commenters' concerns that the policy would have a major negative impact on innovation, access to products or the speed and efficiency of product approval are justified, nor would the policy discourage the use of the section 505(b)(2) pathway for drug approvals.

However, we have concerns about the consistency of how the policy has been applied recently. Of the 18 recently approved section 505(b)(2) drug products discussed above, we believe that two that were mentioned in the proposed rule should be reevaluated to determine whether they should be paid as single source or multiple source drugs. For example, a diluted and ready to administer IV bag of gemcitabine injection was recently approved (*https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208313Orig1s000TOC.cfm*). As discussed in a previous comment's response in this section, gemcitabine injection was originally sold as a lyophilized powder that is reconstituted and then further diluted for intravenous administration. Then concentrated liquids (which have to be further diluted before administration) were approved through the section 505(b)(2) pathway. The lyophilized powder, concentrated liquid and generic gemcitabine products are all assigned to HCPCS code J9201. Payment limits for this HCPCS code appear in the ASP Drug Pricing files and the various products appear in the corresponding ASP NDC–HCPCS crosswalk files; the October 2020 payment limit for HCPCS code J9201 for 2 grams of the drug, a commonly used dose, is $39.57. The newer gemcitabine injection product approved through the section 505(b)(2) pathway, which shares dosing, pharmacokinetics, adverse effect profile, and indications on labeling with the products assigned to J9201, but is packaged in a ready to administer IV bag, has a WAC (as reflected in pharmaceutical pricing compendia as of November 11, 2020) of $760 per 2 grams, about 19 times the payment allowance of J9201. At this time the newest gemcitabine product is not paid under HCPCS code J9201, and we believe that its assignment to a single source drug billing and payment code should be reevaluated.

Applying our proposal to all gemcitabine injection products, that is, the lyophilized powders, the concentrated injection and the newest diluted injection formulation, reveals that all products are gemcitabine injections, all products share the same labeled indications (treatment of ovarian, breast, non-small cell lung, and pancreatic cancers), product labeling is very similar (for example, the clinical studies referred to in the package insert appear to be the same, survival rates, adverse reaction rates, contraindications and warning sections of the labeling include virtually identical information), and based on dosage and administration, pharmacokinetics, indications and other sections of the product labeling, we expect these drug products to be used and prescribed in the same way. The result of the application of our proposal is that we would determine that the new gemcitabine product meets the definition of multiple source drug and assign it to the existing multiple source HCPCS code and the payment allowance for all the products in the code would be based on the volume-weighted average of the ASPs of all the NDCs of such products.

As discussed earlier in this comment response, we believe that this policy approach would not negatively affect innovation. We also believe that our approach could help prevent situations where any change to a product that distinguishes a 505(b)(2) drug product from a previous product approved under an ANDA, no matter how trivial (for the purpose of Medicare Part B drug payment), can result in very high prices and Part B payments for inexpensive, small molecule drugs that are similar to other inexpensive products in the market. Also, assigning section 505(b)(2) drug products to corresponding multiple source drug codes could encourage competition among products that are competitors—that is, when the products are described by one billing code and share similar labeling.

Comment: Several commenters expressed concerns about how grouping potentially expensive to acquire section 505(b)(2) drug products into multiple source drug codes may create situations where a provider's Medicare payment would be less than the acquisition cost and that this situation could lead to drugs not being available through some providers. One commenter pointed out that this could be more problematic for smaller practices.

Response: As discussed in a previous comment response, we believe that the application of our proposal would result in a limited number of section 505(b)(2) drug products being assigned to multiple source drug codes. Also, when products are assigned to HCPCS codes for payment under section 1847A of the Act, the products' sales volume and averages sales price may affect the weighted average ASP-based payment limit.

Since 2005, average sales price-based payment limits described in section 1847A of the Act have been determined using sales volume weighted averages. Each calendar quarter, a product's average sales price as reported by the manufacturer and the number of units sold by the manufacturer are included in the statutorily mandated payment calculation with other products that are assigned to a given HCPCS code. The ASP-based payment limit depends on the manufacturer reported volume of sales for a given product within a code and the reported ASP. Thus, as more units of a product are sold, that product's contribution to the weighted average increases.

We understand that in some cases a payment limit that is determined based on a weighted average can result in payment amounts that are below the acquisition costs of products that are sold at prices that are much higher than the ASP-based payment allowance. However, as noted previously, our policy would apply only to those section 505(b)(2) drug products that meet the definition of multiple source drug based at section 1847A(c)(6)(C), and manufacturers remain free to develop section 505(b)(2) drug products that would not meet the definition of multiple source drugs under our proposed approach, in which case such section 505(b)(2) drug products would not be assigned to multiple source billing and payment codes, and the concern about underpayment relative to acquisition cost would be mitigated. Also, in situations where a section 505(b)(2) drug product is assigned to a multiple source code, the section 505(b)(2) drug product can significantly influence payment limit calculations for a code if it competes successfully with similar products assigned to the multiples source drug code and achieves high sales volume (relative to the other products), particularly in situations where only a few low sales volume products are assigned to the code.

We also note that other factors can also influence acquisition cost. We do not have control over factors that can affect a provider's acquisition costs, for example, high launch prices set by manufacturers, sudden and unexpected price increases from manufacturers, markups from intermediaries such as wholesalers, lack of discounts (including volume discounts to smaller providers) and price differences for various classes of trade.

Comment: Several commenters expressed concern about the proposals' effects on patients. Most of these commenters focused on the effects on manufacturers, such as potential for less innovation by manufacturers leading to fewer drug approvals, fewer options for the treatment of patients, and impaired access. One commenter also requested that we consider the overall financial effects on patients, including effects on drug availability. This commenter expressed concerns about manufacturers' attempts to secure high payments for drugs and recognized CMS' concerns about manufacturers gaming the payment system in a manner that negatively affects consumers and results in diminished competition, but the commenter was also concerned about whether the policy may also have negative effects on patients.

Response: We have replied to concerns about the impact on manufacturers, innovation, providers and effects on access in general in previous comment responses. We do not believe that there is a strong justification for such concerns about access because of the limited scope of the proposals. That is, the proposals would result in limited number of section 505(b)(2) drug products being assigned to multiple source drug codes.

Much of our concern about negative effects on patients is related to increases in Part B drug spending that have been occurring for many years. From 2011 to 2016, Medicare FFS drug spending increased from $17.6 billion to $28 billion under Medicare Part B, representing a compound annual growth rate (CAGR) of 9.8 percent, with per capita spending increasing 54 percent, from $532 to $818. The number of Medicare Part B FFS beneficiaries and the number of these beneficiaries who received a Part B drug increased over the 5-year period (2011 through 2016). However the increase in total Medicare drug spending during this period is more fully explained by increases in the prices of drugs and mix of drugs for those beneficiaries who received them than by increases in Medicare enrollment and drug utilization. The CAGR in the number of Medicare Part B FFS beneficiaries is less than 1 percent between 2011 and 2016 (83 FR 54549 through 50).

We have concerns that if incentives to develop minimally modified products with high prices are not minimized, spending on such products will increase and contribute to increases in overall Part B drug spending. For individual patients, cost sharing amounts for section 505(b)(2) drug products, particularly for patients who do not have supplementary insurance, could increase as illustrated by the gemcitabine example discussed in a previous comment where there is a very substantial (approximately 19 times) difference between payments for a multiple source drug code and a corresponding product approved under the pathway established under section 505(b)(2) of the FFDCA. If similar situations become more common, such differences in payment amounts may contribute to increases in overall spending that in turn contribute to increases in Part B premiums that help fund Part B payments. Increases in Part B drug spending could also lead to increases in premiums for those with supplementary insurance.

Comment: A few commenters supported finalizing the proposals in order to curb drug prices and to pay similar amounts for similar services. The commenters agreed that products recently approved through the pathway established under section 505(b)(2) of the FFDCA were significantly more expensive than existing products and brought up the issue of ''evergreening'' (which includes actions such as securing patents or approvals for minimally modified versions of drugs to preserve high payments) and its effects on generic drug market by way of contribution to higher drug spending for products that do not improve outcome or quality. Not finalizing the proposal was characterized by a commenter as providing incentive for manufacturers to seek more section 505(b)(2) pathway approvals of higher priced products that are comparable to previously approved products. One commenter stated that the case by case determinations described in the proposed rule have been effective, have not sacrificed safety or access, and that continuing this approach would reduce opportunities for manufacturers to game FDA drug labeling in a manner that results in high, single source payments over extended periods of time for multiple source products.

Response: We agree with the commenters and the concern about the potential negative impact on innovation that could occur if all section 505(b)(2) drug products are paid as single source drugs under Part B. Permitting the payment of all section 505(b)(2) drug

products as single source drugs could continue to incentivize the development of minimally modified, high priced products, particularly injectable drug products used incident to a physician's services. This situation could shift manufacturers' focus from innovation to profit and thus contribute to high launch prices, high acquisition and inventory costs for providers, higher cost sharing and premiums in scenarios similar to the newer gemcitabine injection product approved through the section 505(b)(2) pathway that was discussed in an earlier comment response. This newer product shares dosing, pharmacokinetics, adverse effect profile, and indications on labeling with generic products but is packaged in a ready to administer IV bag, has a WAC (as reflected in pharmaceutical pricing compendia as of November 11, 2020) of $760 per 2 grams, about 19 times the payment allowance of the multiple source gemcitabine code, J9201.

Comment: One commenter stated that the proposal will not reduce high launch prices.

Response: We disagree. Although, the effect on launch prices is likely to be limited because we do not anticipate that many section 505(b)(2) drug products will be paid under multiple source codes, in situations where payment under a multiple source drug code occurs, we believe that manufacturers would not have an incentive to set high launch prices.

Comment: Several commenters expressed conditional or partial support for the proposal. This includes commenters who objected to finalizing the proposals for reasons discussed in previous comments but also stated that if CMS nevertheless finalized the proposals, CMS should provide more detail about the framework and the determination process and also should delay finalizing the proposal.

Commenters that suggested a delay in finalizing or implementing the proposals provided a variety of reasons for doing so. Some commenters requested CMS to provide more details about the process, including more specifics on how factors described in the proposal, for example differences in the active ingredient and labeling, might be interpreted and which drug products might be affected. Several commenters also requested that CMS provide more time for assessing the proposals so that the public could better understand them and provide an opportunity, such as through future rulemaking, for public input both on the proposals and on decisions about specific drug products. The current public health emergency (PHE) for COVID–19 was also mentioned by some commenters as an obstacle to engaging with CMS on this issue or responding fully to the proposal, and a reason for why a delay in finalizing the proposal is warranted. Other commenters who expressed concerns about rising drug prices supported the proposals on the condition the beneficiary access was not impaired and that the financial impact on patients is considered.

Response: We believe that we have proposed a clear process that includes a variety of factors such as drug names, labeling and indication to determine whether a section 505(b)(2) drug product meets the definition of multiple source drug at section 1847A(c)(6)(C) of the Act and thus should be assigned to an existing multiple source drug code. The proposals are also consistent with longstanding CMS drug payment policy.

However, we appreciate commenters' concerns about implementing the proposals and requests for additional time for further evaluation and engagement. It appears that some commenters may have misunderstood the limited scope of our proposal because they believe that many 505(b)(2) drug products would be affected. We understand that providing more detail with respect to our proposal may be helpful to a variety of stakeholders and that a better understanding of the policy will assist with planning and more efficient product procurement during a period where time and other resources may be scarce.

Comment: One commenter suggested that if finalized, the policy should be phased in, for example by changing the payment for a drug product by 25 percent increments over a 4-year time period to close the difference between a section 505(b)(2) drug product's current payment and the payment for the HCPCS code to which it would be assigned.

Response: We thank the commenter for this suggestion. However, we do not believe that there is authority under section 1847A of the Act to adjust payment allowances in the manner the commenter suggests.

Comment: Commenters also provided comments on the following issues: Payment to providers for the costs associated with the acquisition of a drug product; payments for the administration of section 505(b)(2) drug products; preferred coverage; formularies as well as the role of utilization management like step therapy and prior authorization for Part B drugs; the application of the process to biologicals; speeding up the coding process so that codes are available at product launch; payments for new technology; and the implementation of MedPAC recommendations.

Response: These comments are considered to be out of scope of the proposed rule, and therefore, we are not addressing in this final rule.

5. Decision

As discussed in the preceding responses to comments, we continue to believe that we have authority to assign certain section 505(b)(2) drug products to existing multiple source drug codes based on an interpretation of section 1847A of the Act and that our approach does not conflict with previously published program instruction or the FDA's therapeutic equivalency ratings.

However, in response to commenters requesting more detail about our proposed approach and requests to delay finalizing a decision, we are not finalizing the section 505(b)(2) drug product proposals or the proposed corresponding regulation text changes for 2021. The delay will also provide time for CMS to further consider this issue. We thank commenters for their responses.

M. Updates To Certified Electronic Health Record Technology Due to the ONC 21st Century Cures Act Final Rule

1. Background

The American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5, enacted February 17, 2009) authorized incentive payments to eligible professionals, eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of Certified Electronic Health Record Technology (CEHRT). In 2010, the Office of the National Coordinator for Health Information Technology (ONC) launched the Health IT Certification Program (ONC Health IT Certification Program) to provide for the certification of health IT. Requirements for certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary. The ONC Health IT Certification Program supports the use of certified health IT under the programs that we administer, including, but not limited to, the Promoting Interoperability Programs (previously known as the Medicare and Medicaid EHR Incentive Programs), the Quality Payment Program (QPP), and the Hospital Inpatient Quality Reporting (IQR) Program. While these programs continue to require the use of certified health IT, the use of certified health IT

has expanded to other government and non-government programs. The Promoting Interoperability Programs and QPP require the use of CEHRT as defined at 42 CFR 495.4 and 414.1305, respectively. Since 2019, in general, this has consisted of EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition (as defined at 45 CFR 170.102) and has been certified to certain other 2015 Edition health IT certification criteria as specified in the definition. Similarly, the Hospital IQR Program began requiring that hospitals use only technology certified to the 2015 Edition certification criteria beginning with the CY 2019 reporting period/FY 2021 payment determination (83 FR 41607).

The ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' final rule (hereinafter referred to as the ''ONC 21st Century Cures Act final rule''), published in the May 1, 2020 **Federal Register** (85 FR 25642 through 25961), finalized a number of updates to the 2015 Edition of health IT certification criteria (hereinafter referred to as the 2015 Edition Cures Update). We believe the 2015 Edition Cures Update will enhance interoperability and patients' access to their electronic health information, consistent with section 4006(a) of the 21st Century Cures Act (Pub. L. 114–255, enacted December 13, 2016). The ONC 21st Century Cures Act final rule revised, added new, and removed certification criteria that establish the capabilities and related standards and implementation specifications for the certification of health IT. In the CY 2021 PFS proposed rule (85 FR 50267), we proposed to require that technology used to meet the CEHRT definitions must be certified in accordance with the updated certification criteria in the ONC 21st Century Cures Act final rule.

The 2015 Edition Cures Update represents a limited set of changes relative to the overall set of health IT certification criteria currently required for the Promoting Interoperability Programs and QPP. These changes incorporate technical standards, including an e-prescribing standard required for alignment with other CMS programs, and other technical updates to existing 2015 Edition functionality used by many health care providers. For example, updates to 2015 Edition certification criteria referencing the United States Core Data for Interoperability (USCDI) standard, rather than the Common Clinical Data Set (CCDS) regulatory definition do not require extensive changes to user-facing aspects of health IT already certified to these criteria (85 FR 25665).

For CY 2019 and subsequent years, the CEHRT definitions for the Promoting Interoperability Programs at § 495.4, and for QPP at § 414.1305, require the use of EHR technology that is certified under the ONC Health IT Certification Program and meets the 2015 Edition Base EHR definition at § 170.102. In addition, the CEHRT definitions require the technology to be certified to certain other 2015 Edition health IT certification criteria, as specified in the definitions, including criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and criteria necessary to report on applicable objectives and measures specified under the MIPS Promoting Interoperability performance category (previously known as the Advancing Care Information performance category). The updates finalized by ONC in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) impact criteria in the different elements of the CEHRT definitions. This includes certification criteria included in the 2015 Edition Base EHR definition, as well as the additional certification criteria necessary to report on applicable objectives and measures to be a meaningful EHR user under the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category.

The ONC 21st Century Cures Act final rule outlines a number of timelines and compliance dates for health IT developers related to the 2015 Edition Cures Update. The final rule finalized the removal of several certification criteria from the 2015 Edition that were included in the Base EHR definition, upon the effective date of the final rule (June 30, 2020). For other certification criteria, the final rule finalized a limited period during which ONC–Authorized Certification Bodies (ONC–ACBs) may continue to issue certificates for these criteria to health IT developers, after which certification will no longer be available.

Where the ONC 21st Century Cures Act final rule finalized updates to existing 2015 Edition certification criteria, or introduced new 2015 Edition certification criteria, ONC generally finalized that health IT developers have 24 months from the publication date of the final rule (until May 2, 2022) to make technology available that is certified to the updated, or new criteria. Subsequently, on April 21, 2020, in response to the PHE for COVID–19, ONC announced additional flexibility for health IT developers subject to the policies in the ONC 21st Century Cures Act final rule (*https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf*). Specifically, ONC announced that it would exercise enforcement discretion regarding new requirements in the ONC 21st Century Cures Act final rule, until 3 months after each initial compliance date or timeline (August 2, 2022).

In response to additional calls for increased flexibility in response to the PHE for COVID–19, ONC published an interim final rule with comment period at 85 FR 70064, on November 4, 2020 entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereinafter the ''ONC interim final rule''). In this rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to new or updated criteria available, ONC extended the timeline until December 31, 2022 (and until December 31, 2023 for § 170.315(b)(10), ''EHI export''). ONC stated that in order to reduce confusion, it has aligned these dates to the calendar year where they impact CMS program participants as aligning these compliance dates to the calendar year, also aligns them to the CMS program annual cycle. As noted in the CY 2021 PFS proposed rule, during this transition period, health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to implementing updates (85 FR 50266).

Below is an overview of the updates finalized in the ONC 21st Century Cures Act final rule that impact certification criteria included in the CEHRT definitions, as well as a discussion of associated timelines finalized in the ONC 21st Century Cures Act final rule, as revised in the ONC interim final rule.

The ONC 21st Century Cures Act final rule finalized removing the following criteria from the 2015 Edition certification criteria upon the effective date of the final rule (June 30, 2020), which included removing the following criteria from the 2015 Edition Base EHR definition (85 FR 25657 through 25660):

- ''Problem list'' at § 170.315(a)(6);
- ''medications'' at § 170.315(a)(7);
- ''medication allergies'' at § 170.315(a)(8); and

• ''smoking status'' at § 170.315(a)(11).

The ONC 21st Century Cures Act final rule noted that the functionality associated with these criteria is now widespread among health IT products, and is expected to remain in products absent certification. Accordingly, ONC sought to reduce burden associated with the certification program by removing these criteria (85 FR 25657 through 25660).

The ONC 21st Century Cures Act final rule also removed the ''data export'' criterion at § 170.315(b)(6) from the Base EHR definition, upon the effective date of the final rule (June 30, 2020) (85 FR 25668). However, this criterion will continue to be available for certification until December 31, 2023, as finalized in the ONC interim final rule (85 FR 70064). The ONC 21st Century Cures Act final rule instead established a new criterion, ''electronic health information export'' at § 170.315(b)(10), which requires a certified health IT module to electronically export all electronic health information (EHI), as defined in § 171.102, that can be stored at the time of certification by the product of which the health IT module is a part. A health IT developer of certified health IT products, which, at the time presented for certification electronically stores EHI, must certify such products to this new criterion and make these products available to their customers by December 31, 2023. However, the new EHI Export criterion is not included in the Base EHR definition (85 FR 25690), and it is not associated with any objectives or measures in the Promoting Interoperability Programs, or the MIPS Promoting Interoperability performance category.

In the ONC 21st Century Cures Act final rule, ONC finalized ''time-limited'' certification for several additional certification criteria associated with measures under the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category from the 2015 Edition:

• ''Drug-formulary and preferred drug list checks'' at § 170.315(a)(10);

• ''secure messaging'' at § 170.315(e)(2); and

• ''patient-specific education resource'' at § 170.315(a)(13).

In order to allow participants in the Medicaid Promoting Interoperability Program to continue to have access to technology meeting 2015 Edition certification criteria to meet the measures for that program, ONC stated in the ONC 21st Century Cures Act final rule that ONC–ACBs may continue to issue certificates for these criteria until January 1, 2022 (85 FR 25660 through 25662).

Specifically, in the proposed rule we noted that the latter two criteria are necessary for participants to meet two of the measures in the Medicaid Promoting Interoperability Program. The ''secure messaging'' criterion at § 170.315(e)(2) is required to meet Objective 6 (Coordination of Care through Patient Engagement) and Measure 2 (Secure Messaging) (80 FR 62852). Similarly, the ''patient-specific education resource'' at § 170.315(a)(13) is necessary to fulfill the requirements of Objective 5 (Patient Electronic Access to Health Information) and Measure 2 (Patient-Specific Education) (80 FR 62846). We did not propose any changes to these measures in the CY 2021 PFS proposed rule (85 FR 50265 through 50272), as the final year of the Medicaid Promoting Interoperability Program is CY 2021. Based on the phased approach that ONC finalized, Medicaid eligible professionals may continue to use certified technology meeting those two criteria in CY 2021, which will enable them to report on these measures for the CY 2021 Medicaid Promoting Interoperability Program EHR reporting period. Health IT developers are encouraged to maintain the certified functionality for those two criteria through CY 2021, even if they move forward with updates to other criteria. Furthermore, the Secure Messaging measure is one of three measures within Objective 6, and eligible professionals need only meet two of the measures (§ 495.24(d)(6)(i)(B)). Even without the secure messaging functionality, an eligible professional could meet the other two measures and fulfill the objective. There is no similar option for the Patient-Specific Education measure, which is required to meet Objective 5.

The ''drug-formulary and preferred drug list checks'' criterion is also currently associated with measures under the Electronic Prescribing objective for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category (80 FR 62882 and 83 FR 59817). As discussed below, since ONC will retire this criterion after January 1, 2022, this criterion would no longer be required for e-Prescribing measures for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category, beginning in CY 2021 (85 FR 25678).

The ONC 21st Century Cures Act final rule also finalized updates to a number of certification criteria, which are currently associated with objectives and measures under the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category, as well as criteria that are included in the 2015 Edition Base EHR definition. In general, ONC finalized that health IT developers have 24 months from the publication date of the final rule to make technology certified to these updated criteria available to their customers (until May 2, 2022). Subsequently, in the ONC interim final rule published on November 4, 2020, ONC further extended these compliance dates until December 31, 2022, in response to the PHE for COVID–19. During this time, developers are expected to continue supporting technology certified to the prior version of the 2015 Edition certification criteria for use by their customers.

The ONC 21st Century Cures Act final rule updated several criteria to include references to the USCDI standard, rather than the existing CCDS definition (85 FR 25670), and implemented related technical updates (85 FR 25671). These include the following criteria:

• ''Transitions of care'' at § 170.315(b)(1);

• ''clinical information reconciliation and incorporation'' at § 170.315(b)(2);

• ''view, download, and transmit to 3rd party'' at § 170.315(e)(1);

• ''transmission to public health agencies—electronic case reporting'' at § 170.315(f)(5); and

• ''application access—all data request'' at § 170.315(g)(9).

The USCDI standard establishes a set of data classes and constituent data elements required to support interoperability nationwide, designed to expand in an iterative and predictable way over time.[110] In finalizing version 1 of the USCDI, the ONC 21st Century Cures Act final rule added three new data classes, ''allergies and intolerances,'' ''clinical notes,'' and ''provenance;'' and added several additional elements to ''patient demographics'' that were not defined in the CCDS (85 FR 25912).

With respect to the use of secure, standards-based application programming interface (APIs), the ONC 21st Century Cures Act final rule finalized a new standards-based API criterion at § 170.315(g)(10), ''standardized API for patient and population services,'' which requires the use of FHIR Release 4 and several implementation specifications (85 FR 25742). Developers must make technology certified to this criterion available by December 31, 2022, as finalized in the ONC interim final rule

[110] For more information about the USCDI, see *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

(85 FR 70064). This criterion replaces the existing ''application access—data category request'' certification criterion at § 170.315(g)(8). However, ONC–ACBs may continue to issue certificates for § 170.315(g)(8) until December 31, 2022, permitting certification to either criterion during this transition period. The ONC 21st Century Cures Act final rule also added the new API criterion at § 170.315(g)(10) to the 2015 Edition Base EHR definition.

The ONC 21st Century Cures Act final rule also revised the ''electronic prescribing'' criterion at § 170.315(b)(3) to reference the NCPDP SCRIPT standard version 2017071 (85 FR 25678). As with the other updated criteria above, health IT developers have until December 31, 2022 to make technology certified to the updated criterion available to their customers, as finalized in the ONC interim final rule (85 FR 70064). However, we note that ONC has discontinued certification of new products to the former electronic prescribing criterion using the NCPDP SCRIPT standard version 10.6, in order to align with CMS requirements for use of the updated NCPDP SCRIPT standard under Part D, adopted as of January 1, 2020 (85 FR 25679). Products that were previously certified may maintain certification status until December 31, 2022 as developers are updating their products, and health care providers may continue to use these certified health IT modules for CMS program participation.

Finally, the ONC 21st Century Cures Act final rule updated the certification criterion for clinical quality measures ''Clinical Quality Measures (CQMs)—Report'' at § 170.315(c)(3), which is included in the CEHRT definitions (85 FR 25686). These updates remove the HL7 QRDA standard requirements from the criterion, and instead require support for the CMS QRDA Implementation Guides, upon the effective date of the final rule (June 30, 2020). In the ONC interim final rule, ONC issued a correction stating that health IT developers would have until December 31, 2022 to make technology available to their customers meeting the updated criterion.

For further discussion, we refer readers to the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961), and section III.M.3.b. of this final rule for discussion specific to the Hospital IQR Program.

As noted above, in general, health IT developers have until the date finalized in the ONC interim final rule, December 31, 2022, to make technology certified to the updated criteria available to their customers. As described in the proposed rule (85 FR 50268), after this date, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified by ONC.

ONC expects and requires that developers will notify customers when technology certified to the updated criteria is available, and that developers will introduce these updates into certified health IT products in the manner most appropriate for their customers, such as through the course of normal maintenance (85 FR 25642). As discussed in the ONC 21st Century Cures Act final rule (85 FR 25666), health care providers may use the Certified Health IT Product List (CHPL) to identify the specific certification status of a product at any given time. The CHPL distinguishes certification to the existing 2015 Edition certification criteria from certification to the updated criteria adopted in the ONC 21st Century Cures Act final rule, by referring to the new and revised criteria as the 2015 Edition Cures Update, allowing health care providers to identify when a specific Health IT Module was updated. (*https://chpl.healthit.gov/*)

2. Updates to 2015 Edition Certified Electronic Health Record Technology Requirements in the Promoting Interoperability Programs and Quality Payment Program, Due to the ONC 21st Century Cures Act Final Rule

In consideration of the updates made to 2015 Edition certification criteria as described in the CY 2021 PFS proposed rule (85 FR 50265 through 50272), we proposed that the technology used by health care providers to satisfy the definitions of CEHRT at §§ 495.4 and 414.1305 must be certified under the ONC Health IT Certification Program, in accordance with the updated 2015 Edition certification criteria as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642). We explained this includes technology used to meet the 2015 Edition Base EHR definition at § 170.102, technology certified to the criteria necessary to be a meaningful EHR user under the Promoting Interoperability Programs, and technology certified to the criteria necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, as specified in the CEHRT definitions.

As discussed above, the ONC 21st Century Cures Act final rule finalized compliance dates for health IT developers, and established which versions of certification criteria meet the certification requirements under the ONC Health IT Certification Program based on those compliance dates. In other words, the ONC 21st Century Cures Act final rule established timelines for (1) a transition period where technology certified to the prior or the updated versions of the same certification criteria would be considered certified, and (2) the date for which technology certified to only the updated version of the certification criteria would be considered certified. A health care provider must use technology certified under the ONC Health IT Certification Program to meet the CEHRT definitions. Therefore, we proposed that health care providers participating in the Promoting Interoperability Programs or QPP would be required to use only technology considered certified under the ONC Health IT Certification Program, according to the timelines finalized in the ONC 21st Century Cures Act final rule. For updated and new certification criteria included in the CEHRT definitions in §§ 495.4 and 414.1305, ONC finalized that health IT may be certified to the current 2015 Edition certification criteria or the 2015 Edition Cures Update criteria for a period of 24 months, as described in timelines finalized in the ONC 21st Century Cures Act final rule (85 FR 25670). ONC then announced an additional 3 months during which ONC stated it would exercise enforcement discretion in response to the PHE for COVID–19 and continue to allow health IT certified to either version of the criteria to be considered certified. We explained in the proposed rule that under our proposal, during that time period (up to 27 months from May 1, 2020, or until August 2, 2022), program participants would be able to use technology certified to either version, and that technology would be considered certified under the ONC Health IT Certification Program. Subsequently, in ONC's interim final rule, ONC extended the compliance dates for certification criteria finalized in the ONC 21st Century Cures Act final rule, finalizing that health IT may be certified to either the existing 2015 Edition certification criteria or the 2015 Edition Cures Update until December 31, 2022. As the ONC interim final rule extended compliance dates for the updated certification criteria until December 31, 2022, technology certified by ONC under the ONC Health IT Certification Program to the existing 2015 Edition certification criteria, or certified to the 2015 Edition and updated to the 2015 Edition Cures Update will now be considered certified by ONC under the

ONC Health IT Certification Program until December 31, 2022.

While the ONC 21st Century Cures Act final rule did not finalize a new Edition of certification criteria, this approach is similar to the prior policy for transition periods between Editions. For example, during the transition period in which the ONC Health IT Certification Program included both the 2014 Edition and the 2015 Edition, a health IT module certified to either Edition was considered certified, and technology certified to either Edition, or a combination of the two, could be used by health care providers to meet CEHRT definitions and demonstrate meaningful use (see 82 FR 38490 for a discussion of the CY 2018 transition between 2014 and 2015 Editions for eligible hospitals and CAHs). After the end of the transition period, only health IT certified to the 2015 Edition could be used by health care providers to meet the CEHRT definitions and demonstrate meaningful use, and health IT modules certified to only the 2014 Edition were no longer considered certified under the ONC Health IT Certification Program. In the same manner, after the current transition period ends, health care providers must use technology certified to only the updated version of the certification criteria finalized by ONC for the ONC Health IT Certification Program to meet the CEHRT definitions and demonstrate meaningful use.

Health care providers should refer to the Certification Criteria and Conditions and Maintenance of Certification requirements in 45 CFR part 170 for details about the updated certification criteria and timelines for health IT developers associated with the criteria. The ONC Health IT Certification Program regulations specify the requirements for what health IT developers must make available to customers and the associated timelines.

In previous rulemaking, to assist readers in identifying the requirements of CEHRT for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category objectives and measures, we provided tables identifying the 2015 Edition certification criteria required to meet those objectives and measures (see 83 FR 59817 for the MIPS Promoting Interoperability performance category). We noted two instances in which updates in the ONC 21st Century Cures Act final rule affect information we have provided in past rulemaking regarding the certification criteria that support specific Promoting Interoperability objectives and measures.

First, we noted that the ONC 21st Century Cures Act final rule is retiring the ''drug-formulary and preferred drug list checks'' criterion at § 170.315(a)(10), which is currently identified as supporting measures under the Electronic Prescribing objective (80 FR 62882 and 83 FR 59817). ONC finalized that this criterion requires certification until January 1, 2022, before being retired (85 FR 25667). We noted that removing this criterion from the Certification Program will have negligible impact on health care providers. As discussed in prior rulemaking, health care providers have noted that formulary checks are a promising approach. However, the utility of the specific functionality that is certified is not necessarily consistently applicable for all prescriptions (80 FR 62833). In addition, as it does not remove the product from the market, any health care providers who are using the current functionality may continue to use this technology for their own purposes. Accordingly, we noted that this certification criterion would no longer be associated with the measures under the Electronic Prescribing objective for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category, beginning with the CY 2021 reporting and performance periods.

Second, we stated that under the new API certification criterion, ''standardized API for patient and population services'' at § 170.315(g)(10), which requires the use of FHIR Release 4, health IT developers have 24 months from the publication date of the ONC 21st Century Cures Act final rule to make technology available that is certified to this new criterion, which is part of the 2015 Edition Base EHR definition. We stated that after 24 months, ONC will retire the current ''application access—data category request'' at § 170.315(g)(8), which is currently identified as supporting the ''Provide Patients Electronic Access to Their Health Information'' measure (80 FR 62882 and 83 FR 59817). We stated that health IT meeting either criteria are considered certified during the 24-month period. Table 42, shows that either the existing criterion at § 170.315(g)(8), or the newly finalized criterion at § 170.315(g)(10), could be used by health care providers to complete the actions of the ''Provide Patients Electronic Access to Their Health Information'' measure for the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category. Allowing health care providers the flexibility of using EHR technology that is certified to either criterion during this transition period would allow early adopters of the newly finalized criterion at § 170.315(g)(10), as well as those using technology meeting the existing certification criterion, to be able to meet the requirements of the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category. As discussed above, in the ONC interim final rule, ONC updated compliance dates finalized in the ONC 21st Century Cures Act final rule to extend the 24-month period described above to December 31, 2022.

In light of the changes described above with respect to the ''e-Prescribing'' and ''Provide Patients Electronic Access to Their Health Information'' measures we included Table 42 in the CY 2021 PFS proposed rule (85 FR 50270), shown below. Table 42 provided details on the measures for the Promoting Interoperability Programs for eligible hospitals and CAHs and the MIPS Promoting Interoperability performance category, and the certification criteria that support each measure. We also included in Table 42 the certification criteria that support the reporting of eCQMs. We noted that Table 42 is only applicable for the measures under the Promoting Interoperability Programs and for the Promoting Interoperability performance category of MIPS. Table 42 does not include all of the updated certification criteria included in the CEHRT definition as discussed in the CY 2021 PFS proposed rule (85 FR 50265 through 50272). Last, Table 42 has been updated to include the Health Information Exchange (HIE)(alternative) Bi-Directional Exchange measure, as this was finalized in section IV.A.3.c.(4)(c)(ii)(B) of this final rule, under the MIPS Promoting Interoperability performance category. For further discussion of changes to criteria under the CEHRT definition, we referred readers to the ONC 21st Century Cures Act final rule (85 FR 25667).

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TABLE 42: Medicare Promoting Interoperability Objectives and Measures, and 2015 Edition Certification Criteria

Objective	Measure	2015 Edition
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Bonus: Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)[3]	Health Information Exchange (HIE) Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria: § 170.315(b)(1) Transitions of care § 170.315(b)(2) Clinical information reconciliation and incorporation § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party § 170.315(g)(7) Application access — patient selection § 170.315(g)(8) Application access — data category request § 170.315(g)(9) Application access — all data request § 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(4)[1] Transmission to cancer registries § 170.315(f)(6)[2] Transmission to public health agencies — antimicrobial use and resistance reporting § 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting[2]	§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible professionals, and eligible hospitals and CAHs	§ 170.315(c)(1) § 170.315(c)(2) § 170.315(c)(3)(i) and (ii) § 170.315(c)(4) [4] (optional)

[1] = Specific to Eligible Clinicians (MIPS Promoting Interoperability performance category)
[2] = Specific to Eligible Hospitals and CAHs (Promoting Interoperability Programs)
[3] = Specific to Eligible Clinicians, finalized in section IV.A.3.c.(4)(c)(ii)(B) of this final rule (MIPS Promoting Interoperability performance category)
[4] = In the CY 2021 PFS proposed rule, (c)(4) was inadvertently listed as (c)(3); correction noted here

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In the CY 2021 PFS proposed rule, we proposed to revise two definitions under § 414.1305 (85 FR 50270). First, under the definitions of CEHRT, we proposed to replace the reference to the ''Advancing Care Information'' performance category with the ''Promoting Interoperability'' performance category, to reflect the performance category name change that we made previously (83 FR 59785). Second, under the definition of Meaningful EHR user for MIPS, we proposed to replace the reference to the ''Advancing Care Information'' performance category with the ''Promoting Interoperability''

performance category, to reflect the performance category name change that we made previously (83 FR 59785).

We sought public comments on all of these proposals.

Comment: Many commenters supported CMS' proposal that the technology used by health care providers to satisfy the definitions of CEHRT must be certified under the ONC Health IT Certification Program in accordance with the updated 2015 Edition certification criteria, as finalized in the ONC 21st Century Cures Act final rule. Commenters indicated the update would harmonize requirements, create more efficiencies, and facilitate true interoperability between EHRs. Commenters were also in favor of eliminating inconsistencies and reducing costs by having the ability to use technology certified to the existing 2015 Edition certification criteria, technology certified to the 2015 Edition Cures Update, or a combination of the two. One commenter observed that the alignment with the ONC 21st Century Cures Act final rule would reduce provider confusion.

Response: We agree that this proposal will reduce confusion for health care providers, continue with our efforts to promote interoperability, and reduce burden by streamlining efforts across programs, and components of the Department.

Comment: Several commenters expressed appreciation that, during the transition period, health care providers will have the flexibility to meet the CEHRT definition using technology certified to the existing 2015 Edition certification criteria, technology certified to the 2015 Edition Cures Update, or a combination of the two. Further, commenters stated that this alignment would reduce administrative burden, eliminate redundancies, streamline objectives and measures, ensure health care providers are using up-to-date technology, and encourage continued efforts to align reporting requirements across care settings.

Response: We agree that health care providers participating in the Promoting Interoperability Programs and QPP will have flexibility during this transition period to use EHR technology certified to the existing 2015 Edition certification criteria, technology certified to the 2015 Edition and updated to the 2015 Edition Cures Update, or a combination of EHR technologies. We also agree with commenters that this alignment will reduce administrative burden, and support our efforts to achieve alignment across programs, care settings, and components of the Department.

Comment: Several commenters stated that the August 2, 2022 compliance date discussed in the CY 2021 PFS proposed rule occurs in the middle of a program year and would create additional challenges and complexity for planning. Commenters also expressed concern that the proposed mid-year requirement would limit reporting flexibility for providers participating in the Hospital IQR Program, the Advanced-APM track within QPP, and those opting to use eCQMs under MIPS. These commenters requested guidance regarding the relationship between the deadline and annual reporting requirements.

Response: We appreciate commenters' concerns that the August 2, 2022 compliance date discussed in the CY 2021 PFS proposed rule may introduce additional complexity for stakeholders who manage technology upgrades and program reporting based on the calendar year.

As noted above, the ONC interim final rule has extended the compliance dates for health IT developers associated with the updated certification criteria finalized in the ONC 21st Century Cures Act final rule. Specifically, ONC has extended compliance dates that originally fell 24-months after the publication of the ONC 21st Century Cures Act final rule, to December 31, 2022. This means that technology meeting the existing 2015 Edition criteria will be considered certified under the ONC Health IT Certification Program through the end of 2022.

With the extension of the compliance dates in the ONC interim final rule, we believe it is appropriate to align the transition period during which health care providers participating in the Promoting Interoperability Programs or QPP may use technology certified to either the existing or updated 2015 Edition certification criteria, with the extended compliance date of December 31, 2022. We believe that this extension of the transition period to include all of 2022 will address commenter concerns regarding the complexities associated with a mid-year transition date. We are therefore finalizing a modification to our proposal, and extending the transition period to the new December 31, 2022 compliance date as finalized in the ONC interim final rule. After this date, only certified technology updated to the 2015 Edition Cures Update will be considered certified and may be used by health care providers to meet the definitions of CEHRT for the Promoting Interoperability Programs and QPP.

However, we reiterate that health care providers would not be required to demonstrate that they are using updated technology to meet the CEHRT definitions immediately upon the transition date of December 31, 2022. In accordance with the reporting and performance period requirements of the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category, participants are only required to use technology meeting the CEHRT definitions during a self-selected reporting or performance period of a minimum of any consecutive 90 days in CY 2022 (85 FR 58966 through 58967 and section IV.A.3.c.(4)(b) of this final rule, respectively). For instance, under this final policy, a health care provider could demonstrate meaningful use for any consecutive 90-days during CY 2022 using either technology certified to the existing 2015 Edition, or certified technology that has been updated to the 2015 Edition Cures Update, or a combination of non-updated and updated certified health IT modules to meet the CEHRT definition. Under the MIPS Promoting Interoperability performance category, as described in section IV.A.3.c.(4)(b) of this final rule, a MIPS eligible clinician could then choose a performance period of any consecutive 90 days to demonstrate meaningful use during 2023, up to the final 90 days of 2023. The MIPS eligible clinician would not be required to demonstrate meaningful use of technology meeting the 2015 Edition Cures Update until the 90-day performance period they have selected. Moreover, we remind readers that a MIPS eligible clinician is not required to report on possession of certified technology for the 90-day performance period they have selected, but instead, they are required to report on how many times they used certified technology for the completion of the action defined by each measure. Although we have not yet established an EHR reporting period in 2023 for eligible hospitals and CAHs under the Promoting Interoperability Program, we may consider adopting another 90-day period for 2023 in future rulemaking.

With regard to alignment with other CMS programs that also require or reference the use of certified EHR technology, we expect to collaborate with these programs in the future to ensure alignment across CMS programs, and that the timelines for implementation discussed in this final rule are not adversely impacted by other CMS program requirements.

Comment: Many commenters did not support our proposal to require the use of technology certified to the 2015 Edition Cures Update, due to concerns with health IT vendors. Specifically, commenters are concerned with vendors

being able to complete, and providers being able to adopt and implement, the changes associated with the 2015 Edition Cures Update by August 2, 2022, when only updated technology would be considered certified under the ONC Health IT Certification Program.

Commenters specifically expressed concern that in aligning deadlines between health care providers and vendors, there would not be sufficient time for health care providers to adopt and implement the newly available technology. Some commenters requested additional time beyond the vendor deadline to select and implement certified health IT, test the new technology, customize the new technology for their specific practices, update workflows, and train staff.

A few commenters expressed concern that complications associated with transitioning between versions of certified technology could negatively affect patient care, and lead to potential patient harm. Several commenters urged CMS to extend the transition period for using technology certified to either the current 2015 Edition or the 2015 Edition Cures Update for CMS reporting and incentive-based programs. As alternatives, commenters recommended January 2023, August 2023, January 2024, and August 2024 as potential deadlines.

Response: We appreciate commenters' concerns related to the effort required for health care providers to adopt and implement updated technology to meet the CEHRT definition, after it is made available by health IT developers. However, we disagree that our proposal would not permit adequate time for implementing and using the 2015 Edition Cures Update in a manner similar to what commenters are requesting.

Under our proposed rule, we stated that a health care provider must use technology that is considered certified under the ONC Health IT Certification Program to meet the CEHRT definitions, in accordance with updates to the 2015 Edition of health IT certification criteria, as finalized in the ONC 21st Century Cures Act final rule. In our proposed rule, we stated that this proposal would allow health care providers to use either technology certified to the existing 2015 Edition certification criteria, technology certified to the 2015 Edition Cures Update, or a combination of the two, prior to the date established by ONC, regardless of the health care provider choosing to update their certified technology in a phased-in approach, or at one time. Specifically, we stated that during CY 2022, a health care provider implementing updates in a phased approach could plan to use a combination of updated and non-updated certified health IT for any consecutive 90-day reporting or performance period prior to August 2, 2022, and then complete their first reporting or performance period using only updated health IT modules in CY 2023. Similarly, we stated that if a health care provider was planning to update all of their certified technology at one time in order to engage in a more extensive testing and implementation period during CY 2022, they could complete their 90-day reporting or performance period for CY 2022, prior to August 2, 2022 using non-updated health IT, and then complete their first reporting or performance period using only updated health IT modules in CY 2023 (85 FR 50268).

Under the revised compliance dates finalized in the ONC interim final rule, both technology certified to the existing 2015 Edition and technology certified to the 2015 Edition Cures Update would now be considered certified until December 31, 2022. As noted above, we are finalizing that health care providers may use health IT certified to the existing 2015 Edition certification criteria, certified health IT updated to the 2015 Edition Cures Update, or a combination of updated and not-yet updated health IT modules, for the full year in CY 2022. For a reporting or performance period *after* December 31, 2022, health care providers would need to use only technology certified to the 2015 Edition Cures update to meet the CEHRT definitions.

We believe the additional flexibility finalized in the ONC interim final rule as well as the performance period flexibilities permitted under the MIPS Promoting Interoperability performance category, as described in section IV.A.3.c.(4)(b) of this final rule, will allow sufficient time for health IT developers to make updated products available for health care providers to demonstrate meaningful use. This timeframe would allow developers and MIPS eligible clinicians as much as 3 years and 5 months (or, 41 months total) from the publication of ONC's 21st Century Cures Act final rule, before a MIPS eligible clinician seeking to demonstrate meaningful use would be required to use technology meeting the 2015 Edition Cures Update for their 90-day performance period in CY 2023 under the Promoting Interoperability performance category. We believe this is a sufficient amount of time for MIPS eligible clinicians to implement and use updated technology after it is made available by health IT developers. Historically, commenters have requested a total of 36 months from the publication of a new Edition of health IT certification criteria to the time it is required for use by health care providers participating in CMS programs. As discussed in the proposed rule, updates to the certification criteria that ONC finalized in the ONC 21st Century Cures Act final rule do not constitute a full new Edition of technology (85 FR 25665), as the scope of updates did not warrant implementation of an entirely new Edition of certification criteria (85 FR 25664 through 25665). Although we have not yet established an EHR reporting period in 2023 for eligible hospitals and CAHs under the Promoting Interoperability Program, we may consider adopting another 90-day period for 2023 in future rulemaking.

The updates finalized in the ONC 21st Century Cures Act final rule are limited in scope to build on existing functionality and standards in technology certified to the 2015 Edition, which participants in CMS programs have been using as part of clinical and administrative workflows since the 2019 program year. Specifically, as described in the ONC 21st Century Cures Act final rule (85 FR 25665), updates to the technology that require additional technical development by health IT developers, and which impact participants in CMS programs, include: (1) Updating eCQM and e-prescribing criteria to align with existing CMS requirements; (2) modifying existing interoperability criteria to reference the USCDI standard; and (3) updating certification of the API functionality for patient access. For eCQMs, the updates required in the ONC 21st Century Cures Act final rule bring the criterion in line with the updates already required for CMS quality programs, which are implemented on an annual basis. For the e-prescribing criterion, the updates required in the ONC 21st Century Cures Act final rule bring the criterion in line with the requirements for the Medicare Part D program, which required use of an updated e-prescribing standard beginning on January 1, 2020 (84 FR 23832). For the USCDI updates, ONC noted that the updates to the common clinical data set (CCDS) to create the USCDI were intentionally limited to a modest expansion that most health IT developers already supported, were already working toward, or should be capable of updating their health IT to support in a timely manner (85 FR 25665). Additionally, while there may be some development burden on health IT developers to update current criteria from the CCDS to the USCDI, there would be limited burden on health care

providers to send or receive additional data types or to provide additional data points to patients using the same health IT capabilities that currently support these workflows. Similarly, since 2019, health care providers with systems certified to 2015 Edition certification criteria that participate in the Promoting Interoperability programs or the Promoting Interoperability performance category in MIPS have implemented workflows for patients to access their information using API technologies certified to the 2015 Edition for the purposes of reporting for the ''Provide Patients Electronic Access to their Health Information'' measure. The update to the FHIR-based API should not be a significant change to these workflows for the provider, as these changes are technical modifications within the system rather than significant changes to clinical or administrative workflows.

Therefore, while implementation and testing of updates in the 2015 Edition Cures Update will be necessary, the updates to the eCQM and e-prescribing criteria are already being implemented under existing CMS programs. In addition, we believe the updates for the USCDI and API will be largely seamless for health care providers and will not require substantial redesign of existing clinical and administrative workflows for health IT users. Instead, the majority of the burden associated with these updates falls on health IT developers of certified health IT, as discussed in the regulatory impact analysis in the ONC 21st Century Cures Act final rule (85 FR 25912).

Regarding recommendations from commenters that we establish separate deadlines for health care providers to use technology meeting the 2015 Edition Cures Update, we do not believe that such timelines would be consistent with the level of burden described above or with HHS priorities to advance interoperability in a timely fashion. For instance, if we adopted the recommendation to not require health care providers to use updated technology until 2024, as recommended by some commenters, this could mean that a health care provider would not implement and use certified technology updated to the 2015 Edition Cures Update until 4 years after the publication of updated criteria in the ONC 21st Century Cures Act final rule. Therefore, the benefits of technology updates such as FHIR-based API capabilities, which can be implemented today, would not be available to patients for over 4 years from their inclusion in the ONC Health IT Certification Program. We do not believe that such a lengthy delay in improving patient access to their health information would be consistent with our priorities for the Promoting Interoperability Programs or QPP.

We also wish to emphasize that, under the ONC 21st Century Cures Act final rule, health IT developers may make technology meeting updated criteria available to health care providers at any time prior to the compliance dates finalized in the ONC interim final rule, and may begin to support health care providers in implementing these updates. Our policy would allow health care providers to use either technology certified to the current 2015 Edition, technology certified to the 2015 Edition and updated to 2015 Edition Cures Update, or a combination of the two, to meet the CEHRT definitions beginning with the 2020 reporting and performance periods upon the effective date of this final rule.

We declined to set an independent additional deadline for health care providers participating in the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category to use updated technology, as we believe that existing flexibility around when health care providers must demonstrate meaningful use during the calendar year will provide sufficient time for health care providers to implement and use updated certified technology. Moreover, we believe that any further extension of timeframes beyond what we have discussed in this final rule would result in unacceptable delays in making important technology updates available, which HHS has determined are critical for improving interoperability across the nation in a timely fashion and improving the quality of care for patients.

Comment: Several commenters expressed concern that updated 2015 Edition certified health IT would be cost prohibitive, and recommended that CMS allow additional time for health care providers to implement these updates, so that they would have an opportunity to recover from the financial effects of the PHE for COVID–19 before being required to implement technology meeting the 2015 Edition Cures Update. A few commenters stated that aligning deadlines between CMS and ONC could lead to significant financial burdens in an already compromised environment. Commenters expressed concern with vendors making excessive charges to clients to guarantee meeting required deadlines, or, vendors deciding not to issue an updated product thereby reducing market competition, and potentially further increasing the cost for available products. Several commenters stated that the costs to cover such expansive EHR upgrades were not approved in this fiscal years' budget, leaving little room for unexpected high costs.

Response: We appreciate commenters' concerns regarding the financial impact of the PHE for COVID–19 on health care providers. We proposed that participants in the Promoting Interoperability Programs and QPP be required to use technology considered certified under the ONC Health IT Certification Program to meet the CEHRT definitions, consistent with the timelines finalized in the ONC 21st Century Cures Act final rule. As discussed above, the ONC interim final rule published in the November 4, 2020 **Federal Register** provided additional flexibility by extending compliance dates for updated certification criteria finalized in the ONC 21st Century Cures Act final rule to December 31, 2022. To align with this change, we are finalizing our proposal with a modified timeframe, as discussed in our previous responses to comments. We believe this extended timeframe will offer health care providers additional flexibility to manage the financial impacts of the PHE for COVID–19 with respect to when they implement and begin using technology updated to the 2015 Edition Cures Update.

Regarding pass through and development costs, we would like to reiterate a few points as discussed above. First, with the extended timeline, health care providers have the ability to use technology certified to the existing 2015 Edition certification criteria or updated to the 2015 Edition Cures Update to demonstrate meaningful use, starting from the effective date of this final rule. Moreover, in many cases, we believe these updates will be implemented by health IT developers as part of routine cyclical updates, such as the annual updates to CMS eCQMs. We believe the ability to implement these changes through routine service and maintenance updates will reduce the pressure on health care providers to meet an expedited timeline. Second, as discussed above, the required updates are based on existing capabilities that vendors have already deployed as part of the 2015 Edition, reducing the likelihood that developers will not pursue updates to their products. For health care providers who have concerns regarding their respective vendor, we again want to encourage the use of CHPL. As discussed above, the CHPL distinguishes certification to the existing 2015 Edition certification criteria from certification to the updated

criteria adopted in the ONC 21st Century Cures Act final rule, by referring to the new and revised criteria as the 2015 Edition Cures Update, allowing health care providers to identify when a specific health IT module was updated. (*https://chpl.healthit.gov/*) Last, to understand the impact on health IT developers associated with updating health IT products, we refer readers to the impact analysis presented in the ONC 21st Century Cures Act final rule at 85 FR 25912.

Comment: A few commenters were supportive of our proposals, but asked that CMS and ONC continue to monitor the PHE for COVID–19, and adjust compliance deadlines as appropriate. A few concerns commenters shared surrounding the PHE for COVID–19 included administrative burdens for health care providers, potential risks to patients and their safety, and the financial burden for those already struggling financially and administratively amidst the PHE for COVID–19. As an alternative, commenters suggested implementing two separate timelines, allowing additional time to recoup financial costs and recover from the PHE for COVID–19. The first timeline being for developers to make updated 2015 Edition products available as finalized under the ONC 21st Century Cures Act final rule, immediately followed by a second timeline specifically for health care providers to adopt and implement these updated products.

Response: We appreciate the concerns raised by commenters, but respectfully disagree. As mentioned above, our alignment with the additional flexibility finalized in the ONC interim final rule, coupled with the existing flexibilities permitted under the MIPS performance period requirements for the Promoting Interoperability performance category described in section IV.A.3.c.(4)(b) of this final rule, allows developers and MIPS eligible clinicians as much as 3 years and 5 months from the publication of ONC's 21st Century Cures Act final rule before they must use certified technology updated to the 2015 Edition Cures Update. Given the limited scope of the updates and the importance of supporting patient access and care coordination, we believe a single aligned timeline for developers to make updates available and for subsequent provider implementation and use is appropriate. Health care providers have the option to use either technology certified to the existing 2015 Edition, or certified technology that has been updated to the 2015 Edition Cures Update, or a combination of non-updated and updated certified health IT modules through December 31, 2022, with the ability to choose a phased-in, or one time approach to implementing these updates. Additionally, as discussed above, MIPS eligible clinicians are only required to use technology meeting the CEHRT definition during any self-selected performance period of a minimum of any consecutive 90-days, including the last 90-days of 2023, for the Promoting Interoperability performance category in CY 2023 (see section IV.A.3.c.(4)(b) of this final rule). Although we have not yet established an EHR reporting period in 2023 for eligible hospitals and CAHs under the Promoting Interoperability Program, we may consider adopting another 90-day period for 2023 in future rulemaking.

Regarding recommendations that we establish two separate implementation deadlines (one for health IT developers, and one for health care providers), we do not believe that such timelines would be consistent with the level of burden previously discussed, with HHS priorities to advance interoperability in a timely fashion, or our efforts to maintain alignment across programs and components of the Department. We further believe that a single timeline for health care provider use of updated technologies that is aligned to the compliance timelines for health IT developers allows for the most efficient transition for health care providers in planning and executing implementation of updates in preparation for a reporting period in CY 2023.

Comment: One commenter supported the alignment between CMS and ONC, but shared concerns with the ability of all health care providers to meet the proposed deadlines. The commenter instead suggested that early adopters be rewarded with bonus points and/or counting this as an improvement activity.

Response: We will take these suggestions under consideration for future rulemaking.

Comment: Several commenters urged CMS to work with ONC to ensure that health care providers are not held accountable for delays in implementation or adoption caused by the health IT vendors. One commenter said that health care providers cannot control vendor compliance, and urged CMS to work with ONC to ensure that health care providers are not harmed, either by being penalized for vendor non-compliance or through high pass-through costs.

Response: We remind commenters that under the Promoting Interoperability Programs for eligible hospitals and CAHs, CMS may grant, on a case-by-case basis, hardship exceptions for extreme and uncontrollable circumstances, which may include vendor issues or issues related to decertified EHR technology. Information on the hardship exception request process is available on the CMS Promoting Interoperability web page at *https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/PaymentAdj_Hardship*. Eligible clinicians participating in the MIPS Promoting Interoperability performance category may submit a hardship exception request through the QPP website at *https://qpp.cms.gov/login*. For more information on the hardship exception process under MIPS, please also refer to *https://qpp.cms.gov/mips/exception-applications*.

Comment: Some commenters were not supportive of CMS' proposal to require updates to 2015 Edition certified health IT in accordance with the timeline set forth in the ONC 21st Century Cures Act final rule to meet the CEHRT definitions. Commenters expressed concern with, and lack of confidence in, any presumption that technology updated in accordance with the 2015 Edition Cures Update will facilitate seamless interoperability, as these updates encompass a significant development effort. Commenters encouraged CMS to consider alternative means to the proposed timelines.

Commenters urged CMS to work in concert with federal partners that are working to address the same issues now to ensure its approach aligns with theirs, and to minimize compliance burdens on affected stakeholders. One commenter recommended that CMS engage clinicians in developing the requirements for future updates to certification criteria for health IT referenced by the CEHRT definitions.

Response: We respectfully disagree with commenters that the updates to certification criteria finalized in the ONC 21st Century Cures Act final rule will not help to improve interoperability for health care providers and patients. As discussed in the CY 2021 PFS proposed rule, the updates to 2015 Edition certification criteria are primarily focused on incorporating standards that are broadly supported across industry as important steps to improve interoperability. For instance, the USCDI version 1, which is referenced in several updated certification criteria, adds clinical notes and provenance as data elements to the existing CCDS based on significant feedback from the industry. Both the free text portion of the clinical notes

and the provenance of data have been identified by clinicians as data that is important *to clinicians* but is often missing during electronic health information exchange.

Similarly, we believe implementation and use of technology certified to the new certification criterion for a standards-based API in the 2015 Edition Cures Update will help to create an environment that promotes innovation for software developers to connect new tools and services that create efficiencies for health care providers throughout their course of care delivery. By enabling access to data through the new, standards-based API, clinicians will have increased access to applications that can help support use cases for population health analytics, clinical decision support, patient education, as well as to conduct administrative and financial tasks. For further information, we refer readers to the discussion of the benefits associated with increased interoperability enabled by APIs in the ONC 21st Century Cures Act final rule (85 FR 25922).

In response to commenters who expressed concerns that this alignment will not result in a seamless transition, we respectfully disagree and note that this approach avoids potential negative consequences of misalignment. As an example, not aligning the requirements for the use of certified technology under the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category with the updated 2015 Edition certification criteria finalized in the ONC 21st Century Cures Act final rule could lead to increased stakeholder confusion on how to meet individual program requirements, gaps in availability of essential functionality and standards, and lack of adoption of updated technology that supports patient safety and quality outcomes. This would increase burden by requiring health care providers to maintain the same health IT, but applied differently to two different program areas.

In response to commenters requesting that CMS continue to work alongside Federal partners to ensure that we approach overlapping issues similarly, we agree. CMS and ONC will continue to work together keeping HHS' priorities to advance interoperability in a timely fashion as a priority. The theme of alignment is also integral across program areas, across components of the Department, and across the care-continuum. We will continue to work together, and continue to highlight these areas of alignment for health care providers.

For commenters recommending that CMS engage clinicians in developing the requirements for future updates to CEHRT, we appreciate this suggestion. Health care providers are welcome to submit suggestions via the Promoting Interoperability Call for Measures, for eligible hospitals and CAHs, or eligible clinicians. Health care providers are also encouraged to submit comments and suggestions in responses to proposed rules including the annual IPPS and PFS proposed rules. We also encourage health care providers to listen to, participate in, and submit questions or comments through Promoting Interoperability webinars for hospitals and CAHs, and eligible clinicians.

Comment: Several commenters supported revising the two definitions referencing the ''Advancing Care Information'' performance category, and changing this to read the ''Promoting Interoperability'' performance category under § 414.1305.

Response: We would like to thank commenters for their support.

Comment: One commenter recommended that CMS remove the 45 CFR 170.315(c)(2) and (3) criteria from the CEHRT definition for MIPS and QPP, to allow more eligible clinicians to participate in A–APMs and other-Payer A–APMs that use CQM collection types without leveraging eCQM functionality. It was suggested that CMS and ONC make the CQM criteria optional for those who choose to use the eCQM collection type. The commenter stated this would allow additional eligible clinician types to use certified criteria as appropriate for their respective fields, without needing to possess and maintain technology that is not necessary.

Response: We thank commenters for their input, and note that the CEHRT definitions already provide this type of flexibility for health care providers to obtain and implement only those criteria that they need to use based on specific program measures and submission methods. The CEHRT definitions do require the 45 CFR 170.315(c)(1) criterion, which is a part of the 2015 Edition Base EHR definition. However, implementation and use of both the 45 CFR 170.315(c)(2) criterion and the 45 CFR 170.315(c)(3) criterion is contingent upon what is necessary to report on applicable objectives and measures. These two criteria are required if the health care provider is reporting eCQMs directly from their EHR for their program participation. However, the criteria are not required if they are not required by the specific CQM reporting option that the health care provider chooses.

After consideration of the public comments received, we are finalizing our proposals with a modification to align the transition period during which health care providers participating in the Promoting Interoperability Programs or QPP may use technology certified to either the existing or updated 2015 Edition certification criteria, with the December 31, 2022 date established in the ONC interim final rule for health IT developers to make updated certified health IT available.

This will allow health care providers to use either not yet-updated technology certified to the existing 2015 Edition, or certified technology that has been updated to the 2015 Edition Cures Update, or a combination of non-updated and updated certified health IT modules, starting from the effective date of this final rule through the end of CY 2022. Health care providers would then be required to use only certified technology updated to the 2015 Edition Cures Update for a performance period in CY 2023. As discussed in our responses to comments, we note that, consistent with the MIPS Promoting Interoperability performance category performance period described in section IV.A.3.c.(4)(b) of this final rule, a MIPS eligible clinician is not required to demonstrate use of updated technology beginning on January 1, 2023. Rather, a MIPS eligible clinician participating in the Promoting Interoperability performance category may select a performance period of any consecutive 90-days as late as the last 90-days in 2023 to meet the CEHRT definitions using technology meeting the 2015 Edition Cures Update. Although we have not yet established an EHR reporting period in 2023 for eligible hospitals and CAHs under the Promoting Interoperability Program, we may consider adopting another 90-day period for 2023 in future rulemaking.

3. Changes to Certification Requirements Under the Hospital IQR Program Due to the 21st Century Cures Act Final Rule

a. Background and Previously Finalized Certification Requirements

To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program, previously referred to as the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861) and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181) for detailed discussions of the history of the Hospital IQR Program, including the

statutory history, and to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609), and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509) for the measures we have previously adopted for the Hospital IQR Program measure set for the FY 2022 payment determination and subsequent years. We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

The Hospital IQR Program strives to put patients first by empowering patients to make decisions about their own healthcare along with their clinicians using information from data driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care, while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across HHS, we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves. The Hospital IQR Program measures assess clinical processes, patient safety and adverse events, patient experiences with care, care coordination, and clinical outcomes, as well as cost of care.

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period. Hospital IQR Program file format requirements have progressed over time to support quality reporting based on data submitted from EHRs that use relevant, up-to-date, standards-based structured data capture. We updated our requirements with the adoption of health IT certified to new Editions of certification criteria referenced in the CEHRT definition, originally requiring hospitals submitting eCQM data to use technology certified to the 2014 Edition certification criteria (79 FR 50252) and evolving to the current requirement that hospitals use technology certified to the 2015 Edition certification criteria for reporting eCQMs and hybrid measures (83 FR 41604 through 41607, and 84 FR 42507). In order to ease the transition between Editions of certified health IT, the Hospital IQR Program offered flexibility in file submission requirements, allowing the use of either the 2014 Edition or the 2015 Edition for multiple reporting periods (80 FR 49705 through 49708; 81 FR 57169 through 57170; 82 FR 38397 through 38391). As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57111), our goal is to align electronic quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, as much as feasible so that the reporting burden on healthcare providers will be reduced (82 FR 38392). In the past we noted that aligning the eCQM submission requirements of the Hospital IQR Program and the Promoting Interoperability Programs reduces burden for hospitals as they may report once and fulfill the requirements of both programs (84 FR 42599). We intend to continue to align the eCQM reporting requirements for the Hospital IQR Program and Promoting Interoperability Programs to reduce reporting burden (84 FR 42598 through 42601; 82 FR 38479).

b. Revisions to the Existing Certification Requirements

Recently, through the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) published on May 1, 2020, ONC updated the 2015 Edition of health IT certification criteria (''2015 Edition Cures Update''). Specifically, the ONC 21st Century Cures Act final rule finalized updates to existing 2015 Edition certification criteria and introduced new 2015 Edition criteria. As noted in section III.M.1. of this final rule, in general, the ONC 21st Century Cures Act final rule provided that health IT developers have up to 24 months from May 1, 2020 to make technology certified to the updated and/or new criteria available to their customers. During this period, health IT developers are expected to continue supporting technology certified to the prior version of the certification criteria for use by their customers prior to updating their products (85 FR 25642 through 25961).

In April 2020, ONC announced its intention to exercise enforcement discretion as to the compliance dates finalized in the ONC 21st Century Cures Act final rule in response to the PHE for COVID–19.[111] As a result, where the ONC 21st Century Cures Act final rule required health IT developers to make technology meeting new and updated certification criteria available by May 2, 2022, ONC stated developers taking advantage of enforcement discretion would be permitted to delay making updated certified technology available until 3 months after each initial compliance date or timeline.

Given the Hospital IQR Program's history of updating file submission requirements, we understand that transitioning to technology certified to a new Edition, or to an updated version of the same Edition of certification criteria, can be complex. Nevertheless, we believe that there are many benefits to using relevant, up-to-date, standards-based structured data capture with an EHR to support electronic clinical quality measurement. In addition, we believe it is important to continue to align with the eCQM reporting requirements for the Promoting Interoperability Programs (82 FR 38479, 84 FR 42598).

Therefore, in the CY 2021 PFS proposed rule (85 FR 50270 through 50272), for the Hospital IQR Program beginning with the CY 2020 reporting period/FY 2022 payment determination [112] and for subsequent years, we proposed to expand flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition criteria as was previously finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41537 through 41608), or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961). We are clarifying in this final rule that this proposed flexibility applies to all Hospital IQR Program measures which use EHR data elements to calculate measure rates, including eCQMs and hybrid measures. We also refer readers to sections III.M.1. and III.M.2. of this final rule for background and more details about the 2015 Edition Cures Update. We proposed to adopt this flexible approach in order to encourage hospitals to implement the most up-to-date, standards-based structured data capture while also maintaining alignment with the Promoting Interoperability Program proposal. We noted that the proposal would allow hospitals that are early adopters of certified health IT that has

[111] *https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf.*

[112] We note that the CY 2021 PFS proposed rule stated that this proposal would begin with CY 2020 reporting period/FY 2023 payment determination (85 FR 50271). We are clarifying that this proposal will begin with the CY 2020 reporting period, which corresponds with the FY 2022 payment determination.

been updated to the 2015 Edition Cures Update to implement those changes while still meeting Hospital IQR Program requirements. We also noted that we will revisit this topic in future rulemaking as for further alignment with the ONC 21st Century Cures Act final rule. We sought public comment on our proposal.

We noted that, among other changes and of particular relevance to hospitals that participate in the Hospital IQR Program, the ONC 21st Century Cures Act final rule revises the clinical quality measurement criterion at § 170.315(c)(3) to refer to CMS QRDA Implementation Guides and removes the Health Level 7 (HL7®) QRDA standard requirements (85 FR 25645). Under the Hospital IQR Program, we previously encouraged health IT developers to test any updates on an annual basis, including any updates to the eCQMs and eCQM reporting requirements for the Hospital IQR Program, based on the CMS QRDA I Implementation Guide for Hospital Quality Reporting (CMS Implementation Guide for QRDA) (82 FR 38393). The CMS Implementation Guide for QRDA, program specific performance calculation guidance, and eCQM electronic specifications and guidance documents are available on the eCQI Resource Center website at *https://ecqi.healthit.gov/*. To be clear, the ONC 21st Century Cures Act final rule removes the HL7® QRDA standards from the relevant health IT certification criteria, which now refers directly to the CMS Implementation Guides for QRDA standards bringing their requirements into closer alignment with what we encourage under the Hospital IQR Program. Based on our data, the majority of Hospital IQR Program participants already use the CMS QRDA I Implementation Guide for Hospital Quality Reporting for submission of eCQMs to the Hospital IQR Program. We noted that we believe this update results in health IT developers no longer needing to maintain certification to the Health Level 7 (HL7®) QRDA base standards in addition to using the CMS QRDA I Implementation Guide for the Hospital IQR Reporting.

Since publication of the CY 2021 PFS proposed rule, in response to additional calls for increased flexibility in response to the PHE for COVID–19, on November 4th, 2020 ONC issued an interim final rule with comment entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereafter, ''ONC interim final rule'') (85 FR 70066). In the ONC interim final rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to updated criteria available to their customers, ONC extended the timeline until December 31, 2022 (85 FR 70064). After that date, technology that has not been updated in accordance with the 2015 Edition Cures Update will no longer be considered certified.

The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for our proposal to expand flexibility to allow hospitals to use either: (1) Technology certified to the 2015 Edition as was previously finalized in the FY 2019 IPPS/LTCH final rule (83 FR 41537 through 41608); or (2) certified technology updated consistent with the 2015 Edition Cures Update as finalized in the ONC 21st Century Cures Act final rule (85 FR 25642 through 25961) for the CY 2020 reporting period/FY 2022 payment determination and for subsequent years. A few commenters expressed their support and noted that CMS should consider the timeline for fully implementing the technology upgrades associated with the 2015 Edition Cures Update when considering requirements for future program years. One commenter noted their support for the required use of the CMS QRDA I Implementation Guide that will occur as a result of using the 2015 Edition Cures Update because it reduces burden on EHR developers.

Response: We agree that the standardization to use the QRDA I Implementation Guide will help in burden reduction for EHR developers. We will consider the timeline for fully implementing the technology upgrades associated with the 2015 Edition Cures Update when determining requirements for future program years. As noted above, in this final rule we are finalizing the proposed flexibility, which applies to all Hospital IQR Program measures, which use EHR data elements to calculate measure rates, including eCQMs and hybrid measures.

Comment: A few commenters did not support our proposal due to concerns with the timeline and effort for health IT developers to certify and for providers to adopt the changes associated with the 2015 Edition Cures Update. These commenters specifically expressed concern that aligning the deadline for providers to adopt technology certified to the 2015 Edition Cures Update with the deadline for vendors to have this Edition available would not provide sufficient time for providers to adopt the newly available version. Some commenters noted that they require additional time beyond the vendor deadline to select and implement certified health IT, test the new technology, customize the health IT for their specific practices, and update workflows and train staff. The commenters urged CMS to extend the flexibility for using both technology certified to the current 2015 Edition and certified technology updated consistent with the 2015 Edition Cures Update as acceptable versions to be used for CMS reporting and incentive-based programs through CY 2023 or later.

Response: We emphasize that the proposal to allow hospitals to use either technology certified to the 2015 Edition or certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY 2020 reporting period/FY 2022 payment determination allows for greater flexibility. We want to avoid penalizing providers participating in the Hospital IQR Program who wish to adopt the updated technology earlier than the mandated deadline for the ONC Health IT Certification Program finalized by ONC by ensuring the providers who adopt early are still in compliance with Hospital IQR Program data submission requirements. We clarify that, for the Hospital IQR Program, beginning with the CY 2020 reporting period/FY 2022 payment determination, using certified technology updated to the 2015 Edition Cures Update is an acceptable option, but so is use of technology certified to the 2015 Edition certification criteria. For those that cannot use certified technology updated to the 2015 Edition Cures Update, technology certified to the 2015 Edition continues to be acceptable.

We understand commenters' concerns related to the effort it will take for providers to customize their health IT for their specific practices and to potentially update workflows and train staff when adopting updated certified technology once it is made available by health IT developers; however, we expect the burden of updating these criteria for providers to be no greater than that already required to comply with CMS annual updates. We recommend readers review section III.M.2. of this final rule, and the ONC 21st Century Cures Act final rule (85 FR 25667) for greater understanding of the scope of these updates and how this scope was considered in establishing the timelines for developer update.

Furthermore, as noted above, since publication of the CY 2021 PFS proposed rule, in response to additional calls for increased flexibility in response to the PHE for COVID–19, on November 4, 2020 ONC issued an interim final rule with comment entitled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (hereafter, ''ONC interim final rule'') (85 FR 70066). In the ONC interim final rule, ONC finalized extended compliance dates for certain 2015 Edition certification criteria. Specifically, where the ONC 21st Century Cures Act final rule provided that developers of certified health IT have 24 months from the publication date of the final rule to make technology certified to updated criteria available to their customers, ONC extended the timeline until December 31, 2022 (85 FR 70064).

Comment: One commenter noted that hospital and delivery systems are experiencing disruptions due to the PHE for COVID–19, which makes digital updates difficult during this time.

Response: We reiterate that our policy is intended to expand flexibility and avoid penalizing providers participating in the Hospital IQR Program who wish to adopt the updated technology earlier than the mandated deadline finalized by ONC by ensuring the providers who adopt early are still in compliance with Hospital IQR Program data submission requirements. We will accept data using either technology certified to the 2015 Edition criteria or certified technology updated consistent with the 2015 Edition Cures Update beginning with the CY2020 reporting period/FY 2022 payment determination.

In addition, if a hospital experiences an extraordinary circumstance that prevents it from reporting eCQMs they are able to submit an individual extraordinary circumstances exception (ECE) request under the Hospital IQR Program. Specifically, in the FY 2016 IPPS/LTCH PPS final rule, we finalized a policy, effective starting with the FY 2018 payment determination, to allow hospitals to utilize the existing ECE form (OMB control number 0938–1022 (expiration date December 31, 2022)) to request an exception to the Hospital IQR Program's eCQM reporting requirement for the applicable program year based on hardships preventing hospitals from electronically reporting (80 FR 49695, 49713). We stated that such hardships could include, but are not limited to, infrastructure challenges (hospitals must demonstrate that they are in an area without sufficient internet access or face insurmountable barriers to obtaining infrastructure) or unforeseen circumstances, such as vendor issues outside of the hospital's control (including a vendor product losing certification (80 FR 49695, 49713)). We assess a hospital's request on an individual basis to determine if an exception is merited (80 FR 49695, 49713). We also refer stakeholders to additional eCQM ECE resources on QualityNet.[113] We also note that, in response to the PHE for COVID–19, ONC announced additional flexibility for health IT developers. Specifically, in the ONC interim final rule, ONC further extended the deadline for health IT developers to make technology certified to the updated criteria available to their customers until December, 31, 2022 (85 FR 70064).

Comment: A few commenters noted that the August 2, 2022 deadline for making technology meeting new and updated certification criteria available occurs in the middle of a program year, and therefore, limits flexibility for providers, including those participating in the Hospital IQR Program. These commenters requested guidance regarding the relationship between the deadline and annual reporting requirements for various programs including the Hospital IQR Program.

Response: In the proposed rule we discussed ONC's compliance date of August 2, 2022 for health IT developers to make updated certified health IT products available to their customers.[114] However, as mentioned above, since publication of the CY 2021 PFS proposed rule, ONC issued an interim final rule, which extended the date for health IT developers to make technology certified to the updated criteria available to their customers until December 31st, 2022 (85 FR 70064). For the CY 2022 reporting period/FY 2024 payment determination, hospitals must report the required number of quarters of eCQM data from the January 1, 2021 to December 31, 2022 reporting period, by 2 months following the close of the calendar year. (85 FR 58940). We refer readers to QualityNet.org for more information related to important dates and deadlines for the Hospital IQR Program.[115] We believe the change finalized in the ONC interim final rule, which aligns the compliance date for updating certified health IT under the ONC Health IT Certification Program with the calendar year, addresses the commenters' concern regarding misalignment with the annual reporting requirements for the Hospital IQR program.

After consideration of the public comments, we are finalizing our proposal as proposed.

N. Establishing New Code Categories

1. Background

Currently, there are four existing Level II HCPCS codes for buprenorphine/naloxone products (J0572–J0575), which describe groupings of products by different strengths as indicated on their FDA labels. When many payers assign a single payment rate to a single code, they typically do so under the expectation that the products can be substituted for one another in most clinical scenarios. As discussed in the CY 2021 PFS proposed rule (85 FR 50272), we have received feedback from stakeholders that there is variability in bioequivalence between the products within the range of strengths listed in each code descriptor, meaning that products within a current code are not necessarily substitutes for one another. Therefore, to facilitate more accurate coding and more specific reporting of the variety of buprenorphine/naloxone products on the market, we proposed an expanded series of codes to identify buprenorphine/naloxone products.

Specifically, we proposed to establish 15 new code categories for use to report all currently marketed buprenorphine/naloxone products, based on strength as well as therapeutic equivalence reflected in Table 43.

[113] See *https://www.qualitynet.org/inpatient/measures/ecqm/participation#tab2.*

[114] *https://www.healthit.gov/cures/sites/default/files/cures/2020-04/Enforcement_Discretion.pdf.*

[115] QualityNet.org, Hospital IQR Program Participation. Available at *https://www.qualitynet.org/inpatient/iqr/participation.*

TABLE 43: Proposed New Code Categories

HCPCS	Description
JXXX1	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 2mg; 0.5mg
JXXX2	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 4mg; 1mg
JXXX3	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 8mg; 2mg
JXXX4	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal, sublingual 12mg; 3mg
JXXX5	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 2.1mg; 0.3mg (Bunavail)
JXXX6	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 4.2mg; 0.7mg (Bunavail)
JXXX7	Buprenorphine Hydrochloride; Naloxone Hydrochloride film; buccal 6.3mg; 1.0mg (Bunavail)
JXXX8	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual 2mg; 0.5mg
JXXX9	Buprenorphine Hydrochloride; Naloxone Hydrochloride; tablet; sublingual 8mg; 2mg
JXX10	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 0.7mg; 0.18mg (Zubsolv)
JXX11	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 1.4mg; 0.36mg (Zubsolv)
JXX12	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 2.9mg; 0.71mg (Zubsolv)
JXX13	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 5.7mg; 1.4mg (Zubsolv)
JXX14	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 8.6mg; 2.1mg (Zubsolv)
JXX15	Buprenorphine Hydrochloride; Naloxone Hydrochloride tablet; sublingual; 11.4mg; 2.9mg (Zubsolv)

As the existing 4 codes would be replaced with more specific codes in the new code series, we also proposed to discontinue the existing codes in Table 44.

TABLE 44: Codes CMS Proposed to Discontinue

HCPCS	Description
J0572	Buprenorphine/naloxone, oral, less than or equal to 3 mg buprenorphine
J0573	Buprenorphine/naloxone, oral, greater than 3 mg, but less than or equal to 6 mg buprenorphine
J0574	Buprenorphine/naloxone, oral, greater than 6 mg, but less than or equal to 10 mg buprenorphine
J0575	Buprenorphine/naloxone, oral, greater than 10 mg buprenorphine

The new code series would permit physicians and clinics to accurately bill insurers for the drug and dose utilized. For example, state Medicaid agencies would be able to more easily identify the drug dispensed, which would facilitate more efficient and accurate rebate invoicing for the Medicaid Drug Rebate Program. The expanded code series would also facilitate more specific and meaningful tracking of utilization of buprenorphine/naloxone products within and across their respective health insurance programs. We noted that these coding proposals would not change Medicare coverage or payment policies for oral or sublingual buprenorphine codes. The drug products described by these codes are not separately payable under Medicare Part B.

We received the following comments on the proposal to establish new code categories.

Comment: Several commenters supported our proposal to establish new code categories.

Response: We appreciate the comments in support of establishing the new code categories.

Comment: A few commenters suggested retaining the existing four codes and recommended that we not establish new code categories, on the basis that the proposed, expanded list of codes may result in confusion and additional work on the part of providers.

Response: We appreciate the comment in support of retaining the existing code categories and not establishing new code categories. As discussed below, in order to further consider the effects of an expanded code series, we have decided not to finalize our proposals at this time.

As a result of our review of the comments, some in favor of more granular coding and some in favor of less granular coding, we would like to further consider the appropriate level of coding granularity for buprenorphine/naloxone products. Thus, we have decided not to finalize our proposal to establish the 15 new code categories set forth in Table 43 or our proposal to discontinue the existing four HCPCS

codes (J0572, J0573, J0574 and J0575) listed in Table 44 at this time. The existing four codes in Table 44 will remain in effect on January 1, 2021.

O. Medicare Diabetes Prevention Program (MDPP)

In the CY 2021 PFS proposed rule (85 FR 50074), we proposed to amend our regulation at § 410.79(e) to describe the policies that will apply during certain emergencies (Emergency Policy). In addition, we proposed to amend § 424.210 to modify the definition of ''beneficiary engagement period'' and to address beneficiary engagement incentives that are furnished to MDPP beneficiaries who are receiving MDPP services virtually pursuant to the Emergency Policy.

1. Revisions to § 410.79(b)

We proposed to amend the Medicare Diabetes Prevention Program (MDPP) expanded model to revise certain MDPP policies adopted in the March 31st COVID–19 IFC (85 FR 19230) that would apply during the remainder of the PHE for COVID–19 and/or any future emergency period, and in an emergency area, as such terms are defined in section 1135(g) of the Act, where the Secretary has authorized section 1135 waivers for such emergency area and period (hereinafter referred to as an ''1135 waiver event'') where such 1135 waiver event may cause a disruption to in-person MDPP services (hereinafter referred to as an ''applicable 1135 waiver event''). We proposed that we would determine that an 1135 waiver event could disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include avoiding the transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries or MDPP coaches during an 1135 waiver event. We proposed that if we determine that an 1135 waiver event may disrupt in-person MDPP services, we would notify all impacted MDPP suppliers via email and other means as appropriate. Such notice would include the effective date when flexibilities described in § 410.79(e) would be available. We proposed that the applicable 1135 waiver event would end on the earlier of the end of the emergency period (as defined in section 1135(g) of the Act) or the date we determine that the 1135 waiver event no longer disrupts in-person MDPP services under the proposed standard described above.

We temporarily amended the MDPP expanded model to revise certain MDPP policies in the March 31st COVID–19 IFC. These changes apply only during the PHE for COVID–19. The March 31st COVID–19 IFC permits certain beneficiaries to obtain the set of MDPP services more than once per lifetime, waives the 5 percent weight loss eligibility requirements, and allows certain MDPP suppliers to either suspend the delivery of services or deliver virtual MDPP sessions on a temporary basis. We believe that establishing an Emergency Policy that applies more broadly will improve the current flexibilities for the remainder of the PHE for COVID–19 and provide MDPP suppliers and MDPP beneficiaries with flexibilities to address any future applicable 1135 waiver events.

The changes proposed in the CY 2021 PFS proposed rule would preserve the March 31st COVID–19 IFC MDPP flexibilities and apply them to future section 1135 waiver events, provide for additional flexibilities that would apply during the PHE for COVID–19 and future 1135 waiver events, clarify certain policies adopted in the IFC, and prospectively end a flexibility that would become unnecessary in light of our other proposals. We stated that the proposed flexibilities, if finalized, would supersede the flexibilities adopted in the March 31st COVID–19 IFC for the PHE for COVID–19. Thus, the proposed changes would be available for the remainder of the PHE for COVID–19 and for all future applicable 1135 waiver events, effective January 1, 2021.

We proposed these changes to address MDPP supplier and MDPP beneficiary needs in response to the PHE for COVID–19 and any future 1135 waiver events that result in an interruption to expanded model services delivered by MDPP suppliers and preventing MDPP beneficiaries from attending in-person sessions. Throughout the original rulemaking for the MDPP expanded model, we sought to ensure that the set of MDPP services would be delivered in-person, in a classroom-based setting, within an established timeline. During that rulemaking, CMS prioritized establishing a structured service that, when delivered within the confines of the rule, would create the least risk of fraud and abuse, increase the likelihood of success for beneficiaries, and maintain the integrity of the data collected for evaluation purposes. Based on lessons learned during the PHE for COVID–19, we proposed to allow temporary flexibilities that prioritize availability and continuity of services for MDPP suppliers and beneficiaries affected by extreme and uncontrollable circumstances that CMS determines may disrupt in-person MDPP services during an applicable 1135 waiver event using the standard articulated above. The overall intent of the proposed Emergency Policy is to minimize disruption of services for MDPP suppliers and beneficiaries.

The proposed flexibilities would be applicable to MDPP beneficiaries and MDPP suppliers (as such terms are defined in § 410.79(b)) as described herein. Our Emergency Policy does not permit an MDPP supplier to furnish MDPP services virtually during the PHE for COVID–19 or an applicable 1135 waiver event unless the MDPP supplier's preliminary or full CDC Diabetes Prevention Recognition Program (DPRP) recognition authorizes the supplier to furnish services in-person. The MDPP supplier requirements at § 424.205 set forth parameters for suppliers to enroll in Medicare, including having any preliminary recognition established by the CDC for the purposes of the DPRP or full CDC DPRP recognition. The DPRP refers to a program administered by the CDC that recognizes organizations that are able to furnish the National Diabetes Prevention Program (National DPP) services, follows a CDC-approved curriculum, and meets CDC's performance standards and reporting requirements. The CDC assigns to each DPRP-recognized supplier an organizational code that specifies the service delivery mode (for example, in-person, online, distance learning, or combination). Because MDPP services are covered under Medicare only when they are furnished at least in part in-person, a supplier that does not have an organizational code authorizing in-person services (''virtual-only suppliers'') may not provide MDPP services, either virtually or in-person. We do not believe it is appropriate to permit virtual-only suppliers to furnish MDPP services when the proposed Emergency Policy is in effect. This is because MDPP suppliers must remain prepared to resume delivery of MDPP services in-person to start new cohorts and to serve beneficiaries who wish to return to in-person services when the proposed Emergency Policy is no longer in effect. Given the difficulty of predicting when the PHE for COVID–19 or any applicable 1135 waiver event will end, virtual-only suppliers may not have sufficient time to obtain the CDC's authorization to furnish in-person

services. Permitting virtual-only suppliers to furnish MDPP services during the PHE for COVID–19 or an applicable 1135 waiver event could disrupt the provision of services to MDPP beneficiaries when services resume on an in-person basis. Virtual only suppliers are not permitted to provide the set of MDPP services because MDPP beneficiaries may elect to return to in-person services after the PHE for COVID–19 or other applicable 1135 waiver event ends, and MDPP suppliers need to be able to accommodate their request. In addition, we are still requiring the MDPP suppliers to resume furnishing in-person the set of MDPP services after the applicable 1135 waiver event.

We proposed to amend the MDPP regulations to provide for certain changes, including allowing MDPP suppliers to start new cohorts during the remainder of the PHE for COVID–19 or a future applicable 1135 waiver event and allowing MDPP suppliers to either deliver MDPP services virtually, or suspend in-person services and resume services at a later date during an applicable 1135 waiver event. The proposed changes would permit certain MDPP beneficiaries to obtain the set of MDPP services more than once per lifetime, for the limited purposes of allowing a suspension in service due to an applicable 1135 waiver event and to provide the flexibilities that will allow MDPP beneficiaries to maintain eligibility for MDPP services despite a break in attendance.

In the March 31st COVID–19 IFC, we stated that we would allow MDPP suppliers to either deliver MDPP services virtually or suspend in-person services and resume services at a later date. In addition, we also provided in the March 31st COVID–19 IFC that the once per lifetime requirement waiver is only applicable to MDPP beneficiaries whose sessions were suspended or cancelled due to the PHE for COVID–19 (that is, MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020). However, we do not believe it is necessary to permit all MDPP beneficiaries to restart the set of MDPP services in all applicable 1135 waiver events. Therefore, we proposed that MDPP beneficiaries who elect to receive MDPP services virtually in accordance with the MDPP Emergency Policy are not eligible to restart the set of MDPP services at a later date. As proposed, the policy would ensure that MDPP beneficiaries who continue to receive the set of MDPP services virtually during an applicable 1135 waiver event cannot repeat the set of MDPP services at a later date, in accordance with the general once per lifetime limitation for the set of MDPP services established in § 410.79(c)(1)(i)(B).

We proposed the following approach for permitting MDPP beneficiaries to resume or restart the set of MDPP services in the event in-person sessions are suspended, and the MDPP beneficiary does not elect to receive MDPP services virtually. MDPP beneficiaries who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event would be eligible to restart the set of MDPP services at the beginning, or resume with the most recent attendance session of record, after the applicable 1135 waiver event has ended. Beneficiaries who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event would be eligible to restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or would be permitted to resume with the most recent attendance session of record. MDPP beneficiaries who are in the second year of the set of MDPP services would not be allowed to restart the set of MDPP services at the beginning.

We noted that we do not believe allowing MDPP beneficiaries who are already in the ongoing maintenance phase of MDPP to restart from the beginning aligns with the performance-based payment strategy upon which the expanded model relies to achieve savings. MDPP suppliers with beneficiaries who have successfully completed over half of the set of MDPP services have already benefited from the bulk of the permitted total performance-based payments. Allowing MDPP beneficiaries in the ongoing maintenance interval phase to restart the expanded model would result in an MDPP supplier being reimbursed for close to double the intended payment amount. Not only might this have a negative impact on the long term expanded model savings, this could result in beneficiaries being unfairly coerced into electing to start over instead of resuming the set of MDPP services where they left off. The proposal would apply prospectively only. Under the current MDPP regulations, as amended in the March 31st COVID–19 IFC, we waived the once per lifetime requirement for MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020 and whose sessions were suspended or canceled due to the PHE for COVID–19 to obtain the set of MDPP services more than once per lifetime by electing to restart the set of MDPP services or resume with the most recent attendance session of record. We proposed to retain that flexibility for those MDPP beneficiaries who were receiving the set of MDPP services as of March 1, 2020 (and as discussed in greater detail below, are modifying this flexibility to apply to MDPP beneficiaries who were receiving the set of MDPP services as of March 31, 2020). Finally, we proposed that beneficiaries who elect to suspend the set of MDPP services at the start of an applicable 1135 waiver event and subsequently choose to restart the MDPP set of services at the beginning or to resume with the most recent attendance session of record, may only make such an election once per applicable 1135 waiver event. The proposed policy was intended to ensure that MDPP beneficiaries may not suspend and re-start the MDPP set of services multiple times during the same applicable 1135 waiver event, which would be contrary to the overall goal of the MDPP Emergency Policy, and to the goals of the MDPP expanded model as a whole.

We proposed that the limit placed on the number of virtual make-up sessions described at § 410.79 would not apply during the remainder of the PHE for COVID–19 or during any future applicable 1135 waiver event, so long as the virtual services are furnished in a manner that is consistent with the CDC DPRP standards for virtual sessions, follow the CDC-approved National DPP curriculum requirements, and the supplier has an in-person DPRP organizational code.

We proposed to amend the regulations to clarify that all sessions, including the first core session, may be offered virtually, not as ''virtual make-up sessions,'' but as a virtual class consistent with the in-person class curriculum, during the remainder of the PHE for COVID–19 and any future applicable 1135 waiver event. The MDPP supplier could still only furnish a maximum of one session on the same day as a regularly scheduled session and a maximum of one virtual make-up session per week to the MDPP beneficiary. We proposed that virtual sessions may be furnished to achieve both attendance goals and achieve weight-loss goals in the event that a qualifying weight measurement was obtained by one of the methods described herein. We proposed that an MDPP supplier may offer to an MDPP beneficiary: 16 virtual sessions offered weekly during the core session period; 6 virtual sessions offered monthly during the core maintenance session interval periods; and 12 virtual sessions offered monthly during the ongoing

maintenance session interval periods. MDPP suppliers may only furnish a maximum of one regularly scheduled session virtually and a maximum of one virtual make-up session per week to an MDPP beneficiary. As proposed, the number of allowable virtual core sessions would increase from 15 to 16. This change is due to the added proposed flexibility to allow MDPP suppliers to obtain weight measurements remotely (as described below) and to deliver the first core session virtually.

Under these temporary flexibilities, we proposed that the requirement for in-person attendance at the first core-session would not apply. We proposed that during the remainder of the PHE for COVID–19 and any future applicable 1135 waiver events, MDPP suppliers may obtain weight measurements from MDPP beneficiaries through the following methods: (1) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations; (2) via digital technology, such as scales that transmit weights securely via wireless or cellular transmission (commonly referred to as ''Bluetooth™ enabled''); or (3) self-reported weight measurements from a participant's own at-home digital scale. We proposed that self-reported weights must be submitted via video, by the MDPP beneficiary to the MDPP supplier. The video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session. Due to this additional flexibility, we proposed that the waiver of the minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in § 410.79(e)(3)(iv) of the March 31st COVID–19 IFC (85 FR 19230) be ended. Thus, effective January 1, 2021, all MDPP beneficiaries would be required to achieve and maintain the required 5 percent weight loss goal in order to be eligible for the ongoing maintenance sessions, even if the PHE for COVID–19 remains in place as of that date.

We proposed to amend § 410.79(e). We sought comment on these proposals. We received public comments on the proposed changes to § 410.79(b). The following is a summary of the comments we received and our responses.

Comment: Several commenters requested clarification regarding whether beneficiaries are required to use digital scales to collect their body weights at home. Commenters expressed concern that some participants in MDPP would be unable to document their weight because they do not have either digital scales or smart phones to capture a photograph or video of their weight on a digital scale. For example, several commenters indicated that requiring beneficiaries to capture their weights via a digital scale by video, and then sending the video in a HIPAA-compliant manner to their MDPP supplier, may prove too burdensome for patients and create additional barriers to MDPP participation. Furthermore, commenters stated that MDPP beneficiaries may have limited access or ability to use the technology required to meet this method of reporting. These commenters contended that if beneficiaries are unable to present in-person for their MDPP sessions or secure digital transmissions of their weights, this could limit them from meeting the eligibility requirements to participate. Several commenters requested that we consider other options of self-reporting such as allowing patients to take their weight at home on the date of the MDPP session and report via a telehealth visit, via a phone call to the MDPP supplier, or securely communicate the weight measurement thru the Electronic Health Record secure messaging portal.

Response: We agree with the commenters that some beneficiaries may lack access to scales and phones with photograph or video capabilities. We proposed additional methods by which MDPP suppliers may obtain weight measurements from beneficiaries and allowing MDPP suppliers to obtain weight measurement from MDPP beneficiaries either in-person or via the use of technology, such as a Bluetooth-enabled scale or self-reported weight measurements using the MDPP beneficiary's digital scale and video technology.

After considering these comments, we are modifying the proposed § 410.79(e)(3)(iii)(C) to allow MDPP suppliers to accept self-reported MDPP beneficiary weight measurements via a photograph of their digital scale. In addition, § 424.210 allows MDPP suppliers to furnish MDPP beneficiaries with certain engagement incentives, including technological tools such as Bluetooth-enabled scales that support the goals of the expanded model and satisfy other conditions. We believe these options allow for MDPP beneficiaries with varying resources and comfort with technology to have their weight measured, and to participate in virtual MDPP services, in most circumstances. We also note that virtual participation in MDPP during an applicable 1135 event is voluntary. Beneficiaries may suspend and restart the set of MDPP services at a later date consistent with the policies we are adopting in this rule.

Comment: Multiple commenters urged CMS to add the MDPP set of services to the Medicare telehealth list, either temporarily during the PHE for COVID–19 or permanently. Commenters stated that access to telehealth services is critical beyond the PHE for COVID–19, as it helps address barriers such as program delivery in rural areas and transportation issues. Commenters stated that research shows that Medicare beneficiaries with prediabetes are at high risk for many chronic and comorbid conditions, including COVID–19. These commenters stated that many beneficiaries will not participate in in-person prediabetes prevention programs during the PHE due to social distancing rules or stay-at-home directives. The commenters noted that access for Medicare beneficiaries to telehealth MDPP services are essential during this PHE for access to MDPP services that can increase and maintain healthy lifestyles to prevent diabetes and comorbidities.

Similarly, other commenters urged CMS to increase access to virtual MDPP generally, or to make the flexibilities finalized in the March 31st COVID–19 IFC or in this rule applicable to circumstances outside of the PHE for COVID–19 or an applicable 1135 waiver event. One commenter states that, given the length of the current public health emergency, it is likely that additional data on satisfaction and efficacy of virtual DPP options will soon be available. Another commenter urged CMS to undertake a renewed actuarial analysis of virtual MDPP. This commenter also encouraged CMS to permit Medicare Advantage (MA) plans to use virtual MDPP encounters, in addition to in-person MDPP encounters, and to permit virtual DPP programs to register as Medicare suppliers in order to meet network adequacy requirements and satisfy the requirement to provide MDPP services.

Response: We appreciate the interest in adding the set of MDPP services to the Medicare telehealth list and allowing access to virtual MDPP outside the PHE for COVID–19 or other applicable 1135 waiver event. Inclusion of MDPP services on the Medicare telehealth list is not appropriate because virtual MDPP services do not qualify as telehealth services. The provisions we are finalizing in this rule are intended to ensure that beneficiaries participating in the set of MDPP services during the PHE for COVID–19 or any future applicable 1135 waiver event can maintain consistent access to care via virtual delivery of services with

minimal disruption throughout their entire set of MDPP services. The MDPP expanded model was actuarially certified for primarily in-person delivery. We are not allowing additional virtual delivery of the set of MDPP services beyond the Emergency Policy described in this final rule. We continue to explore options for making virtual MDPP services more widely available.

Comment: In general, commenters agreed that the final rule should permit MDPP beneficiaries to continue to participate in MDPP virtually during applicable 1135 waiver events. Other commenters indicated that beneficiaries should have a choice between receiving MDPP services virtually and waiting for in-person sessions to resume. In addition, beneficiaries who initially elect to receive MDPP services virtually, but later determine that virtual services do not work for them (for example, due to technological challenges, if the MDPP supplier is unable to offer a high quality program virtually, or if virtual services are not an effective tool for the beneficiary), or unforeseeable circumstances occur that do not allow them to continue or be successful virtually, they should have the option to suspend services at that time and resume in-person sessions at a later date.

Response: We agree with the suggestions made in this comment and are modifying our policy regarding the election of virtual services and its impact on the once-per-lifetime benefit for those beneficiaries receiving the MDPP set of services on or after January 1, 2021 during an applicable 1135 event or PHE. The final rule includes modifications that support the provision of virtual MDPP services and permit new cohorts to start. We are modifying our policy in this rule to allow MDPP beneficiaries participating in the set of MDPP services during the PHE for COVID–19 or any future applicable 1135 waiver event to continue receiving the set of MDPP services virtually even after the PHE for COVID–19 or other applicable 1135 waiver event ends. Please note that MDPP beneficiaries who opt to continue to receive the set of MDPP services virtually during an applicable 1135 waiver event cannot repeat the set of MDPP services at a later date, in accordance with the general once per lifetime limitation for the set of MDPP services established in § 410.79(c)(1)(i)(B). However, MDPP beneficiaries may decide to suspend virtual MDPP services and later resume the set of in-person MDPP services with the most recent attendance session of record once in-person services are available.

In addition, this rule allows certain beneficiaries to restart the set of MDPP services at the beginning. MDPP beneficiaries who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event are eligible to restart the set of MDPP services at the beginning, or resume with the most recent attendance session of record, after the applicable 1135 waiver event has ended. MDPP beneficiaries who are in the second year of the set of MDPP services as of the start of the applicable 1135 waiver event, are only permitted to restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or resume the set of MDPP services at the most recent attendance session of record. MDPP beneficiaries who are in the second year of the set of MDPP services are not allowed to restart the set of MDPP services at the beginning.

In the March 31st COVID–19 IFC, we waived the once per lifetime requirement for MDPP beneficiaries who were receiving the set of MDPP services as of March 1st, 2020 (changed in this rule to March 31st, 2020) and whose sessions were suspended or canceled due to the PHE for COVID–19. These MDPP beneficiaries may obtain the set of MDPP services more than once per lifetime by electing to restart the set of MDPP services. Alternatively, these MDPP beneficiaries can resume with the most recent attendance session of record, in which case they would not be eligible to restart thereafter. Finally, MDPP beneficiaries who suspend the set of MDPP services at the start of an applicable 1135 waiver event (or after virtual services have started) and subsequently choose to restart the MDPP set of services (to the extent they are eligible to do so) or resume with the most recent attendance session of record, may only make such an election once per applicable 1135 waiver event. Table B–N 45 summarizes the beneficiary options during an applicable 1135 waiver event.

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TABLE 45: Summary of MDPP Beneficiary Options during an Applicable 1135 Waiver Event

Beneficiary MDPP Status	Supplier Response to 1135 Waiver Event	During 1135 Waiver Event	1135 Waiver event ends and in-person services resume
Beneficiary is in first 12 months of MDPP set of Services when 1135 waiver event begins	Supplier Suspends MDPP set of services during 1135 waiver event	N/A	**Option 1**: Beneficiary may restart MDPP set of services at the first core session OR **Option 2**: Beneficiary may resume the set of MDPP services with the most recent attendance session of record
Beneficiary is in first 12 months of MDPP set of Services when 1135 waiver event begins	Supplier switches to virtual delivery of MDPP during 1135 waiver event	Beneficiary opts to switch to the virtual MDPP set of services . Once virtual services have started, the beneficiary may suspend MDPP services at any time.	**Option 1**: Beneficiary may continue receiving services virtually until the conclusion of their services OR **Option 2**: Beneficiary may resume the set of in-person services with the most recent attendance session of record. If beneficiary received any part of the MDPP set of services virtually during an applicable 1135 waiver event, s/he cannot restart the set of MDPP services.
Beneficiary is in first 12 months of MDPP set of Services when 1135 waiver event begins	Supplier switches to virtual delivery of MDPP during 1135 waiver event	Beneficiary opts to suspend in-person MDPP set of services and does not switch to the virtual MDPP set of services.	**Option 1**: Beneficiary may restart in-person MDPP set of services at the first core session OR **Option 2**: Beneficiary may resume the set of in-person MDPP services with the most recent attendance session of record
Beneficiary is in 2nd Year of MDPP set of Services when 1135 waiver event begins	Supplier suspends MDPP set of services during 1135 waiver event	N/A	**Option 1:** Beneficiary may resume the set of MDPP services with the most recent attendance session of record. OR **Option 2**: Beneficiary may restart the set of MDPP services at the ongoing maintenance interval in which s/he was participating at the start of the applicable 1135 waiver event.

Beneficiary MDPP Status	Supplier Response to 1135 Waiver Event	During 1135 Waiver Event	1135 Waiver event ends and in-person services resume
Beneficiary is in 2nd Year of MDPP set of Services when 1135 waiver event begins	Supplier switches to virtual delivery of MDPP during 1135 waiver event	Beneficiary opts to switch to the virtual MDPP set of services. Once virtual services have started, the beneficiary may suspend virtual MDPP services at any time.	**Option 1**: Beneficiary may continue receiving services virtually until the conclusion of their services. OR **Option 2**: Beneficiary may resume the set of in-person services with the most recent attendance session of record. If the beneficiary received any part of the MDPP set of services virtually during an applicable 1135 waiver event, s/he cannot restart the set of MDPP services at the ongoing maintenance interval in which s/he was participating at the start of the applicable 1135 waiver event.
Beneficiary is in 2nd Year of MDPP set of Services when 1135 waiver event begins	Supplier switches to virtual delivery of MDPP during 1135 waiver event	Beneficiary opts to suspend in-person MDPP set of services and does not switch to virtual MDPP services.	**Option 1**: Beneficiary may resume the set of MDPP services with the most recent attendance session of record. OR **Option 2**: Beneficiary may restart the set of MDPP services at the ongoing maintenance interval in which s/he was participating at the start of the applicable 1135 waiver event.
Beneficiary starts MDPP set of Services during an 1135 Waiver Event	Supplier offers to start new cohorts using virtual delivery of MDPP during 1135 waiver event	Beneficiary enrolls in MDPP and receives virtual delivery of MDPP services. Once virtual services have started, the beneficiary may suspend virtual MDPP services at any time.	**Option 1**: Beneficiary may continue receiving services virtually until the conclusion of their services. OR **Option 2**: Beneficiary may resume the set of in-person services with the most recent attendance session of record. If beneficiary received any part of the MDPP set of services virtually during an applicable 1135 waiver event, s/he cannot restart the set of MDPP services.

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In addition, the rule permits MDPP suppliers to start new cohorts during the PHE for COVID–19 and any future applicable 1135 waiver events as long as

a weight measurement for MDPP beneficiaries in the cohort can be obtained during the first core session. We proposed additional methods by which MDPP suppliers may obtain weight measurements from MDPP beneficiaries by allowing MDPP suppliers to obtain weight measurement from MDPP beneficiaries either in-person or via the use of technology, such as a Bluetooth-enabled scale or self-reported weight measurements using the MDPP beneficiary's digital scale and photograph or video technology.

Finally, taking into account comments concerning beneficiaries' access to scales that transmit weights securely via wireless or cellular transmission (commonly referred to as ''Bluetooth™ enabled'' or phones with video capabilities we are modifying proposed § 410.79(e)(3)(iii)(C) to allow MDPP suppliers to accept self-reported MDPP beneficiary weight measurements via a photograph with time stamp of their digital scale. When appropriate, in accordance with the §§ 414.84 and 410.79, MDPP suppliers may use the weight measurements obtained through any of the methods outlined in § 410.79(e)(3)(iii)(C) to submit claims to CMS for reimbursement for the first core session and any weight-loss based performance goals achieved during the set of MDPP services. Collectively, the flexibilities permitted during the PHE for COVID–19 or other applicable 1135 waiver events will allow beneficiaries with options to access the set of MDPP services in a manner that best suits their particular circumstances.

Comment: Several commenters supported our proposal to allow MDPP suppliers the option to deliver sessions virtually, or to suspend in-person services and resume in-person services at a later date. These commenters also supported the proposal that the limit placed on the number of virtual make-up sessions would not apply during the remainder of the PHE for COVID–19 or during any future applicable 1135 waiver events, and the proposed waiver of the once per lifetime limit that is applicable during the PHE for COVID–19 or an applicable 1135 waiver event. Multiple commenters urged CMS to remove the once-per-lifetime limit for MDPP services altogether and the 5 percent weight loss requirement for the ongoing maintenance period in Year 2. One commenter opposed ending the waiver of the minimum weight loss requirement for the ongoing maintenance sessions during applicable 1135 waiver events. They indicated that more individuals are struggling with weight loss/maintenance for many reasons. For example, many are not able to attend gyms or engage in other physical activity that puts them at risk for infection. These commenters stated that during the PHE for COVID–19, beneficiaries may not have the transportation options to travel to areas with healthy food options. One commenter encouraged CMS to continue this flexibility until July 2021 at a minimum to account for the next wave of the virus, combined with uncertainty in our economy, reopening, and the availability of a vaccine. Another commenter expressed concern about the ongoing health disparities during the PHE for COVID–19 in relation to a beneficiary's ability to meet the 5 percent weight loss requirement, referencing stress and anxiety that may have significant effects on weight loss. Another commenter advocated that the final rule not require beneficiaries to meet eligibility requirements for MDPP services again, regardless of whether they restart at the beginning or resume with the most recent attendance session of record. For an example, if a beneficiary lost weight or reduced their A1C or blood glucose value from MDPP class participation prior to the PHE, then under the proposed rule, they might not be eligible to restart MDPP when the PHE ends because they no longer meet the eligibility requirements.

Response: The provisions we are finalizing in this rule are intended to ensure that MDPP services can continue to be delivered during the remainder of the PHE for COVID–19 and any future applicable 1135 waiver events. We agree that the PHE for COVID–19 presents unique challenges to beneficiaries in terms of meeting and maintaining a 5 percent weight loss. However, the provisions we are finalizing in this rule permit virtual delivery of services, the virtual collection of body weight measurements, and provide access to appropriate beneficiary incentives, which collectively provide sufficient flexibilities to give MDPP beneficiaries the skills to successfully achieve the 5 percent weight loss goal. MDPP beneficiaries receiving the set of MDPP services prior to January 1, 2021 will not need to meet the 5 percent weight loss goal to resume the set of MDPP services with the most recent attendance session of record or to continue into the second year of set of MDPP services. Beneficiary eligibility will not be impacted by any changes to the beneficiary's body mass index (BMI) or reduction in hemoglobin A1c, fasting plasma glucose, or 2-hour plasma glucose test values achieved during the set of MDPP services or the intervening time in which a beneficiary has suspended the set of MDPP services. Beneficiaries who elect to suspend MDPP services may restart or resume services as described in the rule. Beneficiaries are eligible to restart or resume services regardless of their weight measurement or glucose level as of the date on which they elect to restart or resume services. Beneficiaries are encouraged to continue practicing the skills they have learned in the set of MDPP services to maintain a healthy lifestyle until they can restart or resume services.

Effective January 1, 2021, the 5 percent weight loss eligibility waiver described in § 410.14(g)(3)(iv) will end for MDPP beneficiaries starting after this date. However, the 5 percent weight loss eligibility waiver will remain in effect for MDPP beneficiaries who were receiving the set of MDPP services prior to January 1, 2021. MDPP beneficiaries who were receiving MDPP services prior to January 1, 2021 are not required to meet or maintain a 5 percent weight loss to maintain eligibility for the ongoing maintenance year and may resume or restart services without meeting the 5 percent weight loss requirement.

However, MDPP beneficiaries who start the set of MDPP services on or after January 1, 2021 will be required to meet and maintain the 5 percent weight loss goal to be eligible for the ongoing maintenance year described in § 410.79(c)(1)(ii)(B) and (c)(1)(iii)(B). The waiver of the requirement for beneficiaries to achieve 5 percent weight loss was intended to be a temporary flexibility to account for various state and local lock-down orders that prevented MDPP suppliers from obtaining weight measurements from beneficiaries to verify eligibility. The flexibilities we are finalizing in this final rule establish new remote and virtual methods for obtaining weight measurements. As such, the waiver of the 5 percent weight loss requirement is no longer necessary for the administration of the MDPP set of services. We are finalizing this policy as proposed.

When submitting claims to CMS for MDPP services, MDPP suppliers should use the following weight measurements as the baseline weight for purposes of determining all weight-loss achievements: For an MDPP beneficiary who began receiving the set of MDPP services before March 31, 2020, has suspended services during an applicable 1135 waiver event, and then elects to restart the set of MDPP services at the first core session, the MDPP supplier must record a new baseline weight on the date of first core session that restarts

the set of MDPP services. For an MDPP beneficiary who began receiving the set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, and then resumes the set of MDPP services either as the most recent attendance session of record or during the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session. For MDPP beneficiaries who were receiving MDPP services prior to January 1, 2021, as noted previously, the waiver of the 5 percent weight loss requirement still applies, so MDPP suppliers should submit a claim during each interval of the ongoing maintenance sessions in which the beneficiary has attended two sessions using the ''Attend 2 sessions (with at least 5% WL)'' HCPCS/G-codes.

Comment: One commenter stated that CMS' proposed policy of not allowing beneficiaries who elect to receive MDPP services virtually to restart the set of MDPP services at a later date is too restrictive. The commenter stated that this provision will contribute to health disparities because not all beneficiaries will be able to engage successfully in virtual MDPP sessions, such as issues with technology or internet connections. The commenter requested more flexibility in this policy and recommended that CMS allow beneficiaries who elect to receive MDPP services virtually retain eligibility to participate in in-person MDPP services after the end of the PHE for COVID–19 or applicable 1135 waiver event. The commenter also requested that CMS provide the opportunity to change an election if an applicable 1135 waiver event extends beyond a certain length (for example, greater than 6 months). Another commenter stated that there are many scenarios where an MDPP beneficiary would elect to receive virtual services but due to unforeseen circumstances those virtual session were not of a quality to impart the benefit of MDPP (for example, issues with technology, smart phone/computer availability, bandwidth). The commenter indicated many accounts from MDPP suppliers working in the field about in-person sessions that were moved to virtual sessions; some MDPP beneficiaries ''stuck with it'' while the barriers were too much for others and they had to drop out.

Response: We agree that prohibiting beneficiaries who elect to receive MDPP services virtually to restart the set of MDPP services at a later date is too restrictive. As such, we are amending our policy to allow MDPP beneficiaries receiving the MDPP set of services virtually, to suspend MDPP services and later resume the set of in-person MDPP services with the most recent attendance session of record once in-person services are available. However, we note that MDPP beneficiaries who opt to receive the set of MDPP services virtually during an applicable 1135 waiver event cannot repeat the set of MDPP services at a later date, in accordance with the general once per lifetime limitation for the set of MDPP services established in § 410.79(c)(1)(i)(B).

Comment: One commenter supported our proposal to allow MDPP suppliers to suspend in-person delivery of the set of MDPP services as necessary and resume upon the effective end date of the applicable 1135 waiver event or the date that CMS determines the 1135 waiver event no longer disrupts in-person MDPP services. The commenter requested additional flexibilities to accommodate a PHE or 1135 waiver event that may affect different populations of individuals, states or regions in different ways, with different timelines. The commenter stated that when CMS makes such a determination, the consequences may not only be different across regions/communities but may affect beneficiaries at both the cohort and individual level. The commenter expressed concern that CMS's decision could be arbitrary as it applies to a specific community. For example, if an MDPP beneficiary completes two virtual sessions but then may be required to return to in-person sessions before it is safe to do so in their area. The commenter recommended that CMS allow MDPP beneficiaries engaged in a virtual cohort of MDPP beneficiaries to continue virtual sessions until the end of the cohort, and not mandate a return to in-person MDPP services for cohorts in progress. The commenter also requested more clarification of how CMS will determine an applicable 1135 waiver event no longer disrupts in-person MDPP services. Another commenter requested a grace period to allow time for MDPP suppliers to transition back into providing in-person services.

Response: We agree that the impact of an applicable 1135 waiver event on in-person MDPP services can vary by population and locations. We disagree that decisions regarding the timeline to return to in-person services would be an arbitrary decision made by CMS. The emergency period is defined in section 1135(g) of the Act and in general, the emergency period for an 1135 waiver event lasts until the affected geographic area is substantially recovered from the event. In response to these comments, we are making one modification to the proposed provisions outlined in the proposed rule to address the concerns about the return to in-person services at the end of an applicable 1135 waiver event. During the PHE for COVID–19 or any future applicable 1135 waiver event, we will allow beneficiaries who switch to virtual MDPP or begin the set of MDPP services virtually to elect to continue receiving services virtually until the conclusion of their services. Our prior policy that MDPP is primarily an in-person service has had to be modified to accommodate the nature and length of the current PHE for COVID–19. While MDPP is still primarily an in-person service, allowing MDPP beneficiaries who switch to or begin the MDPP set of services virtually during an applicable 1135 waiver event to continue receiving the services virtually will allow the MDPP beneficiaries affected by an applicable 1135 waiver event to receive the set of services in a consistent modality. In response to the comment requesting a grace period after the end of the applicable 1135 event, we do not believe that an additional grace period would be necessary in most cases, given that the emergency period of an 1135 waiver event typically lasts for a duration that would permit affected providers to resume normal operations. However, we provided in our proposed regulation text at § 410.79(e)(3)(v) that MDPP suppliers could suspend in-person delivery of the set of MDPP services until the effective date of the 1135 waiver event (that is, the end of the emergency period under section 1135(g) of the Act) or upon a date specified by CMS. Therefore, our proposed regulation text contemplated that we could provide a grace period beyond the end of the emergency period. We anticipate that we would grant a grace period, which we would anticipate would not be longer than 90 days after the end of emergency period, if an MDPP supplier can demonstrate that it needs additional time to resume in-person services for reasons related to health, safety, or side availability or suitability. These flexibilities recognize that the effects of the PHE for COVID–19 or future applicable 1135 waiver events can vary in intensity based on location.

Comment: One commenter stated that their MDPP coaches have shared that many beneficiaries do not have video capability. Several commenters requested that beneficiaries be able to send in a photo of their weight

measurement instead. The commenter also expressed concerns with requesting a weight via email, which may not be compliant with HIPAA, and that requiring printed or faxed documentation will be a barrier for participants, because many people do not have access to printing or faxing when participating in the MDPP set of services from home.

Response: We agree that some MDPP beneficiaries may lack the technology required to provide a video or live feed of their weight measurement. In response to these comments, we are modifying the allowable weight measurement methodologies to include photo documentation. This final rule broadens the methods by which MDPP suppliers may obtain weight measurements from MDPP beneficiaries by allowing MDPP suppliers to obtain weight measurement from MDPP beneficiaries either in-person or via the use of technology, such as a Bluetooth-enabled scale or self-reported weight measurements using the MDPP beneficiary's digital scale and video technology. We are modifying proposed § 410.79(e)(3)(iii)(C) to allow MDPP suppliers to accept self-reported MDPP beneficiary weight measurements via a date stamped photograph or video recording of the beneficiary's weight with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session. A beneficiary may communicate his/her own information to a provider without violating the Health Insurance Portability and Accountability Act (HIPAA). Beneficiaries who are not comfortable transmitting their health information in this format can choose to suspend the set of MDPP services until in-person services are available. We encourage suppliers to utilize HIPAA compliant communication platforms. However, it is the organization's responsibility to comply with any federal, state, and/or local laws governing individual-level identifiable data, including those laws related to HIPAA, data collection, data storage, data use, and disclosure.

Comment: One commenter urged CMS to reconsider the timeframe for which flexibilities under the March 31st COVID–19 IFC are available. The commenter stated that there are MDPP beneficiaries who began receiving services between March 1, 2020, and March 15, 2020 because state timelines for shelter-in-place requirements varied across the country, but that most requirements were effective as of March 15, 2020. The commenter requested clarification that the flexibilities available under this final rule include participants who began the MDPP set of services between March 1 and March 15, 2020. This commenter also requested greater clarification between the requirements for beneficiaries who are in the ongoing maintenance phase of the MDPP set of services during the PHE for COVID–19 and any future 1135 waiver events, and questioned whether beneficiaries have until December 31, 2020 to restart the program, or if after that date, such beneficiaries will no longer have that flexibility.

Response: We agree with the commenter's recommendation. In response, we have made a modification to the regulation text at proposed § 410.79(e)(3)(v)(A) to specify that any beneficiary who began MDPP services on or before March 31, 2020—the effective date of the March 31st COVID–19 IFC—can elect to restart the set of MDPP services at the beginning or resume with the most recent attendance session of record upon the MDPP supplier's resumption of services. The modification to the date will extend the March 31st COVD–19 IFC flexibilities to all MDPP beneficiaries who started the MDPP set of services prior to the effective date of the March 31st COVID–19 IFC.

To clarify the requirements for MDPP beneficiaries who are in the ongoing maintenance phase: MDPP beneficiaries enrolled in the set of MDPP services prior to January 1, 2021 will not need to meet the 5 percent weight loss eligibility requirement to resume the set of MDPP services.

Effective January 1, 2021, the 5 percent weight loss eligibility waiver described in § 410.14(c)(3)(vi) will end for all MDPP beneficiaries starting after this date. However, the 5 percent weight loss eligibility waiver will remain in effect for MDPP beneficiaries who were receiving the set of MDPP services prior to January 1, 2021. MDPP beneficiaries who were receiving MDPP services prior to January 1, 2021 are not required to meet or maintain a 5 percent weight loss to maintain eligibility for the ongoing maintenance year and may resume or restart services without meeting the 5 percent weight loss requirement. However, MDPP beneficiaries who start the set of MDPP services on or after January 1, 2021 will be required to meet and maintain the 5 percent weight loss goal to be eligible for the ongoing maintenance year described in § 410.79(c)(1)(ii)(B) and (c)(1)(iii)(B).

The changes we are adopting in this final rule are effective January 1, 2021 and apply to the remainder of the PHE for COVID–19 and any future applicable 1135 waiver event. This means that MDPP beneficiaries who were receiving MDPP services as of March 31, 2020 may elect once to restart the set of MDPP services at the first core session, or resume in-person with their most recent session attendance of record as a result of the PHE for COVID–19 once at any time during the remainder of their set of MDPP services. However, MDPP beneficiaries who begin the set of MDPP services on or after January 1, 2021 will only be permitted to elect to restart the program at the first core session during the first 12 months of the set of MDPP services (and only if they do not switch to virtual MDPP services, if offered, during the applicable 1135 waiver event). MDPP beneficiaries who have restarted the set of MDPP services as a result of the PHE for COVID–19, and reside in an area that is subsequently impacted by a future 1135 waiver event, may elect to suspend in-person services, switch to virtual services, and restart or resume in-person services as provided in this rule.

Comment: One commenter supported the proposal to clarify that all MDPP sessions, including the first core session, may be offered virtually, not as ''virtual make-up sessions,'' but as virtual classes consistent with the in-person class curriculum. The commenter requested that CMS work with CDC on how MDPP suppliers should report this delivery type to the CDC, given that CDC has instructed in-person MDPP suppliers to report session delivery as virtual make-up sessions.

Response: In accordance with this rule, all MDPP sessions may be offered virtually, including the first core session, during an applicable 1135 waiver event. MDPP suppliers may also furnish virtual make-up sessions consistent with the § 410.79(d). All claims submitted to CMS for payment for MDPP services delivered virtually must include the Virtual Modifier ''VM'' on the claims submission form. We will work with CDC to ensure clarity and alignment for MDPP suppliers when reporting session delivery type to CDC.

Comment: One commenter suggested the following additional changes to the MDPP expanded model: (1) Address regulatory barriers to organizations becoming suppliers, including the requirement for Medicare suppliers to submit Social Security Numbers (SSN) to CMS, which raises privacy concerns for some organizations, and has resulted in some organizations choosing not to move forward with Medicare supplier enrollment; (2) revise the reimbursement structure to front-load

payments to ensure suppliers' upfront costs of serving the Medicare population, given that many MDPP suppliers are community-based organizations with scarce resources to wait for outcomes-based payments; (3) align the program model with the model test and the evidence, which would result in changing MDPP to a 1-year model that aligns with the CDC's NDPP curriculum; and (5) address special populations to avoid cherry picking, taking into account the socioeconomic barriers that prevent low-income individuals from achieving the full 5 percent weight loss required for ongoing maintenance services. The commenter requested that CMS offer modest relief from the 5 percent weight loss requirement, or provide payment adjustments to enable MDPP suppliers to address barriers beneficiaries face to participating in MDPP, such as a lack of transportation.

Response: We appreciate the commenter's recommendations but they are outside the scope of this final rule. We will consider these recommendations in the future.

After consideration of the comments received, we are finalizing our proposals with the following modifications:

- We will add allowable virtual weight measurement methods. In addition to the methods proposed, MDPP beneficiaries may self-report their weights in the following ways: By submitting a time and date-stamped photo or video of their home scale with their current weight measurement, or by using synchronous, online video technology such as video chatting or video conferencing with an MDPP coach, where the coach can clearly observe the self-recorded weight of the beneficiary. The second change is ensuring that flexibilities initially finalized in the March 31st COVID–19 IFC (85 FR 19230) are extended to all beneficiaries who were receiving MDPP services as of March 31, 2020, in order to include those beneficiaries who started MDPP services in the month of March, given that state shelter-in-place orders varied significantly.
- We will allow beneficiaries who begin the set of MDPP services virtually, or who change from in-person MDPP services to virtual during the PHE for COVID–19 or an applicable 1135 waiver event, to continue the MDPP set of services virtually, even after the PHE or 1135 waiver event has concluded.
- We added § 410.79(e)(3)(v)(B) to the rule to clarify the baseline weight measurement that must be used by an MDPP supplier when an MDPP beneficiary restarts or resumes the set of MDPP services following a suspension in services.
- We are updating the cross reference, § 410.79(e)(4)(iii), found in the proposed rule in paragraph (e)(3)(ii) to correctly reflect the proper cross reference at paragraph (e)(3)(iii).
- We are making a few edits for technical clarity. We edited the proposed paragraph (e)(3)(v) to remove the phrase ''must be furnished in compliance with the requirements in accordance with'' and will replace it with ''must be furnished in accordance with.'' We edited paragraphs (e)(3)(v)(B) and (C) to include ''and who elect not to continue with MDPP services virtually.'' In addition, we edited paragraph (e)(3)(v)(D) to improve the clarity.
- Finally, we did not intend to eliminate the waiver as specified in paragraph (e)(3)(iii), of the minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in paragraphs (c)(1)(ii)(B) and (c)(1)(iii)(B) for MDPP beneficiaries who were receiving the MDPP set of services prior to January 1, 2021. As such we have added the language into the final rule, redesignted as paragraph (e)(3)(vi)

2. Revisions to § 424.210

Under § 424.210(b), an MDPP supplier may furnish in-kind beneficiary engagement incentives to an MDPP beneficiary if certain requirements are satisfied. Among other requirements, the in-kind item or service must be furnished only during the ''engagement incentive period.'' The definition of ''engagement incentive period'' at § 424.210(a) states that the period begins when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary, and it ends on the earliest of the following: (1) When the MDPP services period ends as described in § 410.79(c)(3); (2) when the MDPP supplier knows the MDPP beneficiary will no longer be receiving MDPP services from the MDPP supplier; or (3) the MDPP supplier has not had direct contact, either in-person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period. We recognize that the disruption to MDPP services caused by an applicable 1135 waiver event may cause an MDPP supplier not to have contact with an MDPP beneficiary for more than 90 consecutive calendar days. Therefore, we proposed to amend the definition of ''engagement incentive period'' to further qualify when the period ends in the case of the PHE for COVID–19 or an applicable 1135 waiver event. Specifically, we proposed to amend paragraph (iii) in the definition of ''engagement incentive period'' to state that the MDPP supplier has not had direct contact, either in person, by telephone, or via other telecommunications technology, with the MDPP beneficiary for more than 90 consecutive calendar days during the MDPP services period, unless the lack of direct contact is due to the suspension or cancellation of MDPP services under § 410.79(e) and the MDPP services are eventually resumed or restarted in accordance with § 410.79(e).

We solicited comments on when the engagement incentive period should end if the MDPP services are not eventually resumed. We noted that we were considering whether we should deem the incentive engagement period to end if the applicable 1135 waiver event or the PHE for COVID–19 remains in effect for a certain period of time, such as 1 year. At that point, for purposes of beneficiary engagement incentives, it may be more appropriate to terminate the engagement incentive period and permit a new engagement incentive period to begin if services are resumed or restarted in accordance with § 410.79(e). Alternatively, we noted that the engagement incentive period can also end when the MDPP supplier knows that the MDPP beneficiary will no longer be receiving services from the MDPP supplier. We solicited comments on whether that provision eliminates any need to further clarify in regulation text when the engagement incentive period ends if MDPP services are not eventually resumed or restarted.

We also proposed to amend § 424.210(b) to add a requirement governing the provision of an in-kind item or service as a beneficiary engagement incentive during the PHE for COVID–19 or during an applicable section 1135 waiver event. Specifically, we proposed that if the item or service is furnished during the PHE for COVID–19 or an applicable 1135 waiver event that CMS has determined may disrupt in-person MDPP services, and the item or service is furnished to an MDPP beneficiary who is receiving MDPP services virtually, the MDPP beneficiary must be capable of using the item or service during the PHE for COVID–19 or the applicable 1135 waiver event, as applicable. We proposed this usability requirement to deter abuse and to ensure that the incentives furnished during an applicable 1135 waiver event will achieve their intended purpose and serve the goals of the MDPP expanded model. We stated that usable beneficiary engagement incentives would include

vouchers for healthy food, wearable technology or ''wearables'' used to monitor an MDPP beneficiary's health such as heart rate, calories burned, or steps walked. We also noted that gym memberships during lockdowns and stay-at-home orders would not constitute beneficiary engagement incentives that are usable during an applicable 1135 waiver event. We solicited comments on whether this additional requirement is necessary in light of other requirements set forth in § 424.210(b).

Finally, for purposes of the proposed usability requirement at § 424.210(b)(9), we proposed to define ''COVID–19 Public Health Emergency'' to mean the emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, related to the PHE for COVID–19 declared by the Secretary on January 31, 2020. Effective October 23, 2020, the Secretary renewed the January 31, 2020 determination that was previously renewed on April 21, 2020, that a PHE exists and has existed since January 27, 2020. Similarly, we proposed to define ''1135 waiver event'' to mean an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized waivers under section 1135 of the Act. We noted that these definitions were consistent with how we proposed to define the terms for purposes of § 410.79(e).

The following is a summary of the public comments we received and our responses.

Comment: One commenter appreciated the flexibility of the proposed change to paragraph (iii) of the definition, indicating that the engagement incentive period should not automatically end if an MDPP supplier's failure to have direct contact with an MDPP beneficiary for more than 90 days was due to the suspension or cancellation of MDPP services during an applicable 1135 waiver event and the MDPP services were resumed during such 1135 waiver event. The commenter stated that the final rule should clarify when the engagement incentive period ends if MDPP services are not eventually resumed. The commenter supported the addition of a provision under which the engagement incentive period would be deemed to end if MDPP services are not resumed or restarted within 1 year after the PHE for COVID–19 or applicable 1135 waiver event has been in effect. The commenter also stated that, if MDPP services are thereafter resumed or restarted, CMS should permit a new engagement incentive period to begin.

Response: After further consideration, we are not finalizing the proposed changes to paragraph (iii) of the definition of engagement incentive period. That provision will continue to specify that the engagement incentive period will end if the MDPP supplier has not had direct contact with the MDPP beneficiary, whether in person, by telephone, or via other telecommunications technology, for more than 90 consecutive calendar days during the MDPP services period. Under this provision, the engagement incentive period will not end with respect to an MDPP beneficiary who begins to receive MDPP services virtually within 90 days after the occurrence of an 1135 waiver event that CMS determines is likely to disrupt the furnishing of in-person MDPP services. We are mindful of the potential for abuse with beneficiary incentives, and in the absence of any continued direct contact with the MDPP beneficiary for 90 days during an applicable 1135 waiver event, we do not believe that the MDPP supplier should be permitted to furnish additional beneficiary engagement incentives. However, we note that the existing definition of engagement incentive period specifies that the period begins ''when an MDPP supplier furnishes any MDPP service to an MDPP eligible beneficiary.'' Accordingly, even if an MDPP beneficiary's engagement incentive period ends during an applicable 1135 waiver event due to lack of direct contact with the MDPP supplier, the beneficiary would begin a new engagement incentive period consistent with the existing definition when he or she resumes or restarts MDPP services in accordance with § 410.79(e).

Comment: One commenter stated that revising the definition of engagement incentive period as proposed would increase the recordkeeping and tracking burden on MDPP suppliers, who the commenter asserted will need to track the start and end dates of the PHE or 1135 waiver event, the election of the MDPP beneficiary to suspend or cancel MDPP services, the date of the resumption or restart of services, and more. The commenter requested that CMS specify the documentation and tracking requirements for this change.

Response: As noted above, we are not finalizing the proposed changes to the definition of engagement incentive period. We did not propose and are not finalizing any modifications to the documentation requirements described in § 424.210(e). However, we note that § 424.210(e) requires MDPP suppliers to maintain documentation regarding in-kind items and services furnished as beneficiary engagement incentives, including the date on which the item or services was furnished and whether it was furnished during the engagement incentive period. In addition, it is a prudent business practice to document compliance with Medicare regulations, and the information cited by the commenter would be relevant to compliance with § 410.79 and § 424.210.

Comment: One commenter did not believe that the usability requirement at proposed § 424.210(b)(9) was necessary considering the other requirements set forth in § 424.210(b), but stated that if the requirement is retained in the final rule, it should be revised for clarity. Specifically, this commenter questioned whether a beneficiary engagement incentive that is furnished during an 1135 waiver event must be usable by the MDPP beneficiary for the remaining duration of the 1135 waiver event or only at the time the incentive is furnished. As an example, the commenter noted that an MDPP supplier might provide a gym membership voucher during an 1135 waiver event at a time when gyms are open, but the membership could become unusable at a later time during the 1135 waiver event. The commenter advocated that if the final rule includes a requirement regarding the usability of an incentive during the PHE for COVID–19 or an 1135 waiver event, the requirement should expressly state that the MDPP beneficiary must be capable of using the item or service ''at the time of delivery.'' Another commenter requested clarification that that a gym membership would satisfy the proposed usability requirement even if it was furnished when a lockdown or stay-at-home order was in effect, as long as the gym offered virtual fitness classes. In addition, a commenter sought clarification that in-kind items or services that may be useable in one region may not be useable in another region. The commenter expressed concern that documenting compliance with the usability requirement would place undue burden on MDPP suppliers.

Response: Upon further review, we agree that the usability requirement is not necessary in light of other requirements set forth at § 424.210(b). Specifically, under paragraph (b)(2), the in-kind beneficiary engagement incentive must be reasonably connected to the CDC-approved DPP curriculum furnished to the MDPP beneficiary during a core session, core maintenance session, or ongoing maintenance session. In addition, under paragraph (b)(3), the in-kind beneficiary engagement incentive must be a ''preventive care item or service'' or an

item or service that advances a clinical goal for an MDPP beneficiary by engaging him or her in better managing his or her own health. We would not consider either of these requirements to be satisfied if the MDPP beneficiary is incapable of using the item or service at the time it is furnished. Accordingly, because an unusable in-kind item or service could not satisfy all of the conditions set forth at paragraph (b), it is not necessary to finalize the additional proposed requirement for in-kind items and services furnished to an MDPP beneficiary who is receiving MDPP services virtually during the PHE for COVID–19 or an 1135 waiver event. Because we are not finalizing the proposed usability requirement, the commenters' remaining concerns are moot and need not be addressed.

Comment: One commenter supported the proposed definitions of ''COVID–19 Public Health Emergency'' and ''1135 waiver event.''

Response: We appreciate the commenter's support. However, as finalized, § 424.210 does not refer to either term. Accordingly, we are not finalizing these definitions.

After consideration of the comments received, we are not finalizing the proposed usability requirement nor the proposed definitions of ''COVID–19 Public Health Emergency'' and ''1135 waiver event'' proposed at § 424.210(b).

IV. Summary of the Quality Payment Program Proposed Provisions, Analysis of and Responses to Public Comments, and Provisions of the Final Rule

A. CY 2021 Updates to the Quality Payment Program

1. Executive Summary

a. Overview

This section of the final rule sets forth changes to the Quality Payment Program starting January 1, 2021, except as otherwise noted for specific provisions. The 2021 performance period/2023 payment year of the Quality Payment Program continues a transition as we build on the first few years of implementation of the Quality Payment Program to focus better on our measurement efforts, and to reduce barriers to entry into Advanced APMs.

Participation in the Quality Payment Program rose in the third year. We saw 99.99 percent of eligible clinicians participate in MIPS in 2019 with 954,614 eligible clinicians receiving a payment adjustment, which exceeded our 2018 participation rates. In addition, 97.6 percent of eligible clinicians participating in MIPS received a positive payment adjustment for 2021 based on 2019 performance year results. Regarding performance in Advanced APMs, for the 2019 QP Performance Period, 195,564 eligible clinicians earned Qualifying APM Participant (QP) status while another 27,995 eligible clinicians earned partial QP status.[116] We note that due to the Public Health Emergency (PHE) for COVID–19, 65,237 (or about 6.83 percent of 954,614) MIPS eligible clinicians received reweighting for performance year 2019 of one or more MIPS performance categories due to our MIPS extreme and uncontrollable circumstances policy.

We plan to continue developing Quality Payment Program policies that more effectively reward high-quality treatment of patients and increase opportunities for Advanced APM participation. We are moving forward with MIPS Value Pathways (MVPs) policy development as MVPs allow for a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a specialty, medical condition, or a particular population. The MVPs use promoting interoperability as a foundational element and incorporate population health claims-based measures as feasible along with relevant measures and activities for the quality, cost, and improvement activities performance categories. We intended to begin transitioning to MVPs in the 2021 MIPS performance year; however, due to the PHE for COVID–19 and resultant need for clinician focus on the response, our timeline changed accordingly such that the proposal for initial MVPs is delayed until at least the 2022 performance year. In addition, we support clinicians on the front lines by providing burden relief via extreme and uncontrollable circumstances policy exceptions for 2019, 2020 and 2021.

In response to the PHE for COVID–19, a number of additional flexibilities were issued via interim final rules with comment periods (IFCs) (85 FR 19276 through 19278, 85 FR 27617, and 85 FR 54847 through 54851). We extended the deadline for applying for reweighting due to extreme and uncontrollable circumstances for the 2019 performance period from December 31, 2019 to April 30, 2020 in order to provide greater flexibility for clinicians impacted by the PHE for COVID–19 and modified our existing policy for the 2019 performance period such that MIPS data submissions would not effectively void a reweighting application. We added a new ''COVID–19 Clinical Trials'' improvement activity to the CY 2020 Improvement Activities Inventory, applicable beginning January 2020 that would provide high-weighted credit in the Improvement Activities performance category and then modified the activity in the third IFC (March 31st COVID–19 IFC (85 FR 19276 through 19277)). We provided QCDRs an additional year, by 2022, to meet the QCDR measure requirements of measure testing and data collection. Due to COVID–19 we also modified our definition of primary care services used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey to include online and telephone digital E/M codes, and remote evaluation of patient video/images and virtual check in codes. These included previously finalized ''face-face'' codes that are instead furnished using audio/video, real-time, interactive communications technology instead of in person in light of the PHE. We are finalizing all IFC policies except for the COVID–19 Clinical Trials activity for 2020, which is finalized with a modification as presented in the third IFC. See section IV.A.3.c.(3)(b) of this final rule for the modified COVID–19 Clinical Trials activity for CY 2020 as described in the September 2, 2020 IFC (85 FR 54848 through 54851).

As we make long-term improvements, evolve MIPS policies, and plan to implement MVPs in the future, we support our objectives within the Patients Over Paperwork initiative and the National Quality Roadmap.[117] [118] In carrying out these initiatives, we are removing regulatory obstacles that get in the way of health care clinicians spending time with patients. As we develop MVP policies, we look to reduce MIPS reporting burden and increase efficiencies.

On May 15, 2020 the Department of Health and Human Services published the National Quality Roadmap (*https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf*) as directed by E.O. 13877, Improving Price and Quality Transparency in American Healthcare to Put Patients First. The purpose of the Roadmap is to improve patient outcomes through enhanced effectiveness and efficiency of the healthcare quality system. The Roadmap is a means to accelerate change and advance the Administration's goals of ''improving transparency, reducing provider burden, allowing informed

[116] QPP Participation in 2019: Results at-a-Glance released 10/27/2020 at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1190/QPP%202019%20Participation%20Results%20Infographic.pdf*.

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

[118] *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf*.

consumer decision-making, and ultimately improving the health of all Americans''. The Roadmap, which provides a public-private partnership opportunity, describes a strategy for establishing, adopting, and publishing common quality measurements, aligning inpatient and outpatient measures, and eliminating low-value or counterproductive measures. Specific actions are identified to drive change through coordinated governance and oversight, modernized data collection and reporting, and aligned measures reformation in federal quality programs. One of the actions called for is a systematic review of federal quality reporting and value-based payment programs, to identify opportunities leading to recommendations to reduce burden, promote efficiency and effectiveness, and accelerate the shift to value. The Roadmap also calls for stakeholder engagement through public convening and a Request for Information. Actions will be undertaken with the underpinning of the following principles:

- Quality Information is Available and Meaningful.
- Balance Administrative Burden with the Goal of Obtaining Meaningful Information.
- Alignment of Measurement Priorities.
- Cohesive Measurement Stewardship.
- Reward Innovation and Improvement.
- Leverage What Works and Reform the Rest.

The planned implementation of MVPs is noted in the Roadmap and we look forward to recommendations resulting from other Roadmap activities for streamlining quality reporting and value-based purchasing programs that can inform the implementation of the MVPs and promote alignment of quality measures across federal programs.

As we work within MIPS to reduce barriers to clinician participation in Advanced APMs and meet CMS pay for value objectives, we are aligned with the Health Care Payment Learning & Action Network goal to accelerate the percentage of health care payments tied to quality and value in each market segment through the adoption of two-sided risk APMs.[119] MVPs will link quality and cost performance measurement and help clinicians begin to assess their ability to take on risk as in APMs.

In the May 1, 2020 **Federal Register**, HHS published two transformative rules: The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (85 FR 25642 through 25961); and the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, and Health Care Providers final rule (85 FR 25510 through 25640) that will give patients unprecedented safe, secure access to their health data. The two rules implement interoperability and patient access provisions of the bipartisan 21st Century Cures Act (Cures Act) and support the MyHealthEData initiative. MyHealthEData is designed to empower patients around a common aim, giving every patient access to their medical information so they can make better healthcare decisions. We expect that these rules, once implemented, will complement our future MVPs in providing more meaningful information to clinicians and patients.

b. Summary of Major Provisions

(1) Major MIPS Provisions

The MIPS program aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. Within MIPS we intend to pay for health care services in a way that drives value by linking performance on cost, quality, and the patient's experience of care. We believe implementing the MVP framework will move MIPS along the ''path to value,'' transforming the MIPS program by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes, and by promoting robust and accessible healthcare data, and interoperability. In the CY 2020 PFS proposed rule (84 FR 40732 through 40745), we offered our vision of an MVP framework for a new evolution of the MIPS program based on this concept.

As discussed in the CY 2021 PFS proposed rule at 85 FR 50277, we have built the MIPS program to provide broad flexibility for clinician choice of measures and activities, data collection and submission types, and individual or group level participation. While these flexibilities contributed to very high participation levels, we believe the flexibility has inadvertently resulted in a complex MIPS experience for clinicians that is not producing the level of robust clinician performance information we envision that would meet patient needs and support clinician care improvements. We have heard from clinicians that MIPS requirements are confusing, burdensome, and that it is difficult to choose measures from the several hundred MIPS and QCDR quality measures that are meaningful to their practices and have a direct benefit to patients. We have also heard concerns from stakeholders that MIPS does not allow for sufficient differentiation of performance across practices due in part to clinician quality measure selection bias. These aspects detract from the program's ability to effectively measure and compare performance, provide meaningful feedback, and incentivize quality. MVPs are intended to lead to a simplified MIPS clinician experience, improve value, reduce burden, and better inform patient choice in selecting clinicians. We noted that the MVP framework would connect measures and activities across the 4 MIPS performance categories, incorporate a set of administrative claims-based quality measures that focus on population health, provide data and feedback to clinicians, and enhance information provided to patients. We intend to focus the future of MIPS on MVP implementation. We are finalizing proposed provisions as discussed in section IV.A.3. of this final rule related to:

- Developing MVPs
- Implementing the APM Performance Pathway (APP) for APM participant MIPS eligible clinicians to report to MIPS
- Updating the MIPS performance measures and activities; cost and quality category weights; and scoring policies
- Terminating the APM scoring standard.

(a) MIPS Value Pathways and APM Performance Pathway

We are finalizing the proposed MVP framework guiding principles as discussed in section IV.A.3.a.(1) of this final rule and the proposed MVP development criteria and processes as discussed in section IV.A.3.a.(2) of this final rule as we look towards the 2022 performance period to begin MVP implementation. We are finalizing in section IV.A.3.b. of this final rule each of the proposed quality measures included in the APP quality measure set effective January 1, 2021. We are also delaying the sunsetting of the CMS Web Interface by one year and allowing APM entities to report via the CMS Web Interface measure set for the 2021 MIPS

[119] *https://hcp-lan.org/.*

performance period. Submitters reporting through the APP will be scored on the ACO MCC measure, Hospital-wide Readmission measure, and CAHPS for MIPS survey, if available for that submitter type. In addition, each submitter will also be required to report on either the three eCQMs/MIPS CQMs or, for APM Entities, the Web Interface. The APP will be a voluntary pathway for reporting and scoring under MIPS that allows APM participants to receive an improvement activities credit and have the cost performance category reweighted. We are finalizing proposed MIPS performance category weighting and scoring in the APP and a scoring hierarchy that recognizes the APP in section IV.A.3.e.(2) of this final rule. We are also finalizing in section IV.A.3.c.(5)(a) of this final rule the elimination of the APM scoring standard for the 2021 performance year beginning January 1, 2021. This allows APM participants to participate in MIPS as individuals, groups, Virtual Groups, or APM Entities, with reporting through any MIPS reporting and scoring pathway, see section IV.A.3.b.(3) of this final rule. We are also finalizing in section IV.A.3.c.(5)(e) of this final rule, an extreme and uncontrollable circumstances exception policy proposal that would be applicable to APM Entities beginning with the 2022 MIPS payment year.

In response to our MVP RFI in the 2020 PFS proposed rule (84 FR 40732 through 40745), we received a number of comments about the opportunity to participate in the development of MVPs and concerns about the speed of a transition to a new MVP framework. We have taken these concerns into consideration when developing the proposed MVP policies. We had stated our intent to begin the transition to MVPs in 2021 by introducing initial MVPs, however, we noted at 85 FR 50284 through 50285 that due to the PHE for COVID–19, the timeline has changed. As we move forward with the transformation of the MIPS program in a manner that does not take away from the nation's response to the PHE for COVID–19, we limited the MVP-related proposals to those necessary for the collaborative development of MVPs.

We are finalizing in section IV.A.3.a.(2) of this final rule, the proposed process for collaboration on the development of MVPs that builds on our discussions with clinician experts about developing MVPs for future MIPS rulemaking. We believe that collaboration with clinician experts will build a more cohesive and comprehensive set of MVPs. We are finalizing the proposed process for MVP candidate submissions in section IV.A.3.a.(2)(a)(iii) of this final rule.

We recognize that the transition to MVPs will take time and we will continue to evaluate the readiness of clinicians in making this transition, while balancing our strong interest in improving measurement and making MIPS more focused on value.

(b) Other MIPS and APM Policies

We are finalizing with modification our web interface and quality measure proposals as discussed in sections IV.A.3.c.(1)(c) and IV.A.3.c.(1)(d) of this final rule, respectively, after consideration of comments. Additionally, are finalizing in section IV.A.3.d.(1)(b) of this final rule the proposed continuation of policies for scoring quality measures based on achievement, as well as policies for measures that do not meet case minimum, data completeness requirements, or have a benchmark. For the Promoting Interoperability performance category, we are finalizing the proposed new optional Health Information Exchange (HIE) bi-directional exchange measure as discussed in section IV.A.3.c.(4)(c)(ii)B of this final rule.

Additionally, after considering public comments, we are finalizing the following provisions for MIPS beginning with the 2021 performance period in this final rule.

- As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing our proposal to remove the CMS Web Interface submission method under MIPS for groups and virtual groups with a one year delay. Specifically, we will sunset the Web Interface in 2022 instead of 2021.
- As discussed in section IV.A.3.c.(1)(d) of this final rule, we are finalizing the proposals to incorporate 2 new administrative claims outcome quality measures, address substantive changes to 112 existing MIPS quality measures, address changes to specialty sets, remove measures from specific specialty sets. We are finalizing a modified proposal to remove 11 instead of 14 quality measures from the MIPS program. We refer readers to Table Group C of Appendix 1 for a list of final quality measures and further information. Retaining three additional measures means that we are finalizing a modified proposed total of 209 rather than 206 quality measures starting in the 2021 performance year.
- As discussed in sections IV.A.3.c.(1)(e) and IV.A.3.c.(2)(b) of this final rule, we are finalizing the proposals to include services provided via telehealth in quality and cost measurement.
- As discussed in section IV.A.3.c.(2)(a) of this final rule, we are finalizing the proposals that the cost performance category will make up 20 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act, and the quality performance category weight will be 40 percent and 30 percent for each of those years, respectively (see section IV.A.3.c.(1)(b) of this final rule). For the 2023 MIPS payment year, we are finalizing the proposed performance category redistribution policies discussed in section IV.A.3.d.(2)(b)(iii) of this final rule.
- As discussed in section IV.A.3.c.(3)(b) of this final rule, we are finalizing our proposals to: (1) Allow an exception to the Annual Call for Activities nomination period timeframe during a PHE; (2) add a new criterion for nominating new improvement activities; (3) implement a process for HHS-nominated improvement activities; and (4) modify two existing improvement activities. We are also finalizing policies from IFCs and the removal of one obsolete improvement activity and policies from IFCs.
- As discussed in section IV.A.3.c.(4) of this final rule, we are finalizing the proposals that establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year, for the 2024 MIPS payment year and each subsequent MIPS payment year; update two Promoting Interoperability measures; and continue reweighting the Promoting Interoperability performance category for non-physician MIPS eligible clinicians for the 2021 performance period. We are finalizing at section IV.A.3.c.(4)(c)(ii) of this final rule the proposal to add a new Promoting Interoperability performance category Health Information Exchange (HIE) bi-directional exchange measure that would allow an eligible clinician to attest to participation in bi-directional exchange through an HIE using CEHRT functionality.
- As discussed in section IV.A.3.d.(1)(b) of this final rule, we are finalizing the proposed continuation of quality category scoring and bonus policies that add flexibility for when measure specification or coding changes occur during the performance year and continue improvement scoring of the

quality performance category comparing clinicians to a 30 percent baseline score if clinicians scored 30 percent or less. We are finalizing in section IV.A.3.d.(1)(b)(iii) of this final rule the proposal for an exception to the 20-case minimum for all administrative claims-based measures. The exception states that for administrative claims-based measures, the minimum case requirement is specified in the annual list of MIPS measures.

- As discussed in section IV.A.3.d.(2)(a)(iii) of this final rule, we are finalizing the proposal to increase the maximum number of points available for the complex patient bonus for one year, the 2020 performance period/2022 MIPS payment year, due to the increase in patient complexity resulting from the PHE for COVID–19.
- As discussed in section IV.A.3.g. of this final rule, we are finalizing the proposals to modify third party intermediary requirements, remedial actions and termination policies. We are also finalizing policies issued via IFC.
- As discussed in section IV.A.4.b. and IV.A.4.c. of this final rule, we are finalizing the proposals that clarify the APM Incentive Payment amount calculation basis and implement a hierarchy for recipient TIN affiliation identification when making the APM Incentive Payment. We are also finalizing proposed provisions in section IV.A.4.c. of this final rule that provide a process for requesting updated APM Incentive Payment information in situations where a payee TIN cannot be identified, and address in section IV.A.4.d. of this final rule situations where the QP's APM Incentive Payment was determined based solely on supplemental services payments and no Medicare claims for covered professional services were submitted during the incentive payment base period.
- As discussed in section IV.A.4.e.(3) of this final rule, we are finalizing the proposed change to the methodology for addressing prospectively aligned beneficiaries for Threshold Score calculations and QP determinations and establish a targeted review process in section IV.A.4.e.(4) of this final rule for QP determinations.

After consideration of public comments, we are not finalizing the following proposals:

- As discussed in sections IV.A.3.d.(1)(b)(ii) and IV.A.3.d.(1)(b)(v) of this final rule, we are not finalizing using performance period benchmark policies for performance year 2021 and will instead continue with the existing policy to use historical benchmarks and our topped out scoring policy after considering comments and the impact of the PHE for COVID–19.
- As discussed in section IV.A.3.e.(3) of this final rule, we are not finalizing the proposal to reduce the performance threshold for the 2021 MIPS performance period/2023 MIPS payment year from 60 points to 50 points, as we believe that we best incentivize clinician performance through retaining the previously finalized performance threshold of 60 points.

2. Definitions

At § 414.1305, we are finalizing definitions of the following terms:

- Attestation (revision).
- Certified Electronic Health Record Technology (CEHRT) (revision).
- Collection type (revision).
- Full TIN APM (deletion).
- Low volume threshold (revision).
- Meaningful EHR user for MIPS (revision).
- MIPS APM (revision).
- Physician Compare (addition).
- Primary Care Services (addition).
- Submission type (revision).

These terms and definitions are discussed in detail in the relevant sections of this final rule.

3. MIPS Program Details

a. Transforming MIPS: MIPS Value Pathways

(1) Overview

We are finalizing proposed updates to the MIPS Value Pathways (MVP) guiding principles (see 85 FR 50280 through 50281) and MVP development criteria and process (see 85 FR 50281 through 50284) that will guide MVP implementation beginning with the 2022 MIPS performance period/2024 MIPS payment year.

In the CY 2020 PFS final rule, we stated our intent to apply the MVP framework in PY 2021 (84 FR 62946); however, due to the PHE for COVID–19, our timeline has changed (see 85 FR 50284 through 50285). We want to move forward with the transformation of the MIPS program in a manner that does not take away from the nation's response to the PHE for COVID–19, and so have limited our MVP related proposals in this rule to guidance necessary for the collaborative development of MVPs. We deferred MVP implementation to a future year. In particular, we intend to propose an initial set of MVPs and implementation policies in our CY 2022 rulemaking cycle. We continue to envision a transformed MIPS program that increasingly makes MVPs available to clinicians with a burden reduction focus.

We intend to implement the MVPs while maintaining the MIPS participation options established through rulemaking for MIPS performance years 1 through 5. For purposes of this discussion, we refer to the established MIPS participation options collectively as ''traditional MIPS''.

As described in earlier rulemaking (84 FR 40732 through 40734), we are moving to MVPs to improve value, reduce burden, help patients compare clinician performance to inform patient choice in selecting clinicians, and reduce barriers to movement into APMs. We refer to ''value'' as a measurement of quality and patient experience of care as related to cost, and intend to promote value by paying for health care services in a manner that directly links performance on cost, quality, and the patient's experience of care. The MVP framework will move MIPS forward on the path to value through connecting the MIPS performance categories and by better informing and empowering patients to make decisions about their healthcare and helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability.

We believe that MVPs can help address previous feedback from clinicians that MIPS is too complex and burdensome. Feedback related to confusing MIPS requirements, inadequate alignment of the MIPS performance categories, need for better performance comparability across all clinicians and for more meaningful data for patients has informed development of the MVP framework. MVPs will make MIPS more meaningful by allowing a more cohesive participation experience by connecting activities and measures from the 4 MIPS performance categories that are relevant to a patient population, standardizing performance measurement of a specialty or a medical condition, and reducing the siloed nature of the traditional MIPS participation experience. We intend that MVPs help clinicians and practices prepare to take on and manage financial risk, as in Advanced APMs, as they build out their quality infrastructures that align with the MIPS performance categories and gain experience with cost measurement. Performance measure reporting for specific populations as in MVPs encourages practices to build an infrastructure with capabilities to compile and analyze population health data, a critical capability in assuming and managing risk. We believe that experience with MVPs, in which there is aligned measurement of quality (of care and of experience of care) and cost,

continuous improvement/innovation within the practice, and efficient management and transfers of information, will help remove barriers to APM participation. We refer readers to the infographic at *https://qpp.cms.gov/mips/mips-value-pathways*, which provides an overview of our vision for the MIPS path to value future state (see 85 FR 50279).

We envisioned that MVPs will be optional for clinicians when the included measures and activities within the MVP are applicable and available to their practice. Over the course of future performance periods as we transition to MVPs, the traditional MIPS participation option will continue to be available. We noted that we believe MVP reporting will reduce selection burden associated with choosing MIPS quality measures and activities to report; reduce reporting burden associated with fewer MIPS quality measures, cost measures and/or improvement activities to report than the traditional MIPS participation method; and further align across performance categories the measures and activities identified by specialists and patients as being meaningful and relevant. We noted that we intended to build a robust inventory of MVPs which are meaningful to clinicians and expect that in the future we may propose that all MIPS eligible clinicians would be required to participate in MIPS either through an MVP or an APM Performance Pathway (APP).

In the CY 2021 PFS proposed rule (85 FR 50280 through 50281), we proposed to update the MVP guiding principles from the CY 2020 PFS proposed rule (84 FR 40734) to incorporate RFI comments and the evolution of the MVP framework. We refer readers to the CY 2021 PFS proposed rule for a discussion of the RFI comments. We proposed to add a new fifth guiding principle pointing to an important Meaningful Measures element of our future vision for reducing MVP reporting burden; the use of digital performance measure data submission technologies to indicate our commitment to leveraging digital innovations that reduce MIPS related clinician burden. Digital Quality Measures (dQMs) originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems. We refer readers to the CY 2021 PFS proposed rule (85 FR 50280) for a discussion of dQMs. We proposed to retain guiding principle 4 (84 FR 40734) and update guiding principles 1, 2, 3 and 5, as shown in italics, so that the guiding principles for MVPs reflect the following:

1. MVPs should consist of limited, *connected complementary* sets of measures and activities that are meaningful to clinicians, which will reduce clinician burden, *align* scoring, and lead to sufficient comparative data.

2. MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care; *MVPs will enhance this comparative performance data as they allow subgroup reporting that comprehensively reflects the services provided by multispecialty groups.*

3. MVPs should include measures *selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included,* to encourage performance improvements in high priority areas.

4. MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement.

5. MVPs should support the transition to digital quality measures.

We described our proposed method of creating MVPs in the CY 2020 PFS proposed rule (85 FR 50281 through 50283). We noted that we intend to grow the number of available MVPs using the processes described in that section, maximizing our opportunity for expert input on the most meaningful measures and activities.

We noted that we continue our efforts to improve the healthcare of Medicare patients by allowing clinicians to focus on providing care for their patients and the measures and activities that best reflect their care. We also noted that we look forward to continuing to work with stakeholders to improve the program and implement the vision of MVPs.

We received public comments on this proposal. The comments we received and our responses are set forth below.

Comment: Many commenters supported the MVP guiding principles as proposed with some commenters voicing support for all the guiding principles and some commenters highlighting support for subsets of the guiding principles. Commenters voiced a number of reasons for their support of the guiding principles related to moving towards MVP goals of burden reduction, meaningful performance measurement, capturing the patient voice, and/or moving to higher value care.

Response: We appreciate the commenters' support of MVP guiding principles that will move us towards our goals of improving value, reducing burden, helping patients compare clinician performance to inform patient choice in selecting clinicians, and reducing barriers to movement into APMs. We agree with commenters that the MVP guiding principles will help realize these goals.

Comment: While agreeing with the proposed and existing MVP guiding principles, a few commenters had questions about how they would be operationalized. A few commenters supported guiding principle 4. A few commenters questioned how MVPs would help reduce barriers to APM participation and one commenter suggested that we work with specialty societies to develop implementation approaches such as an APM blueprint with guidance for clinicians and further cost measure development. A few commenters voiced a concern that many medical specialties, for example, dermatology, do not have any APMs to work towards.

Response: We appreciate the support for previously finalized guiding principle 4, MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement. Experience with MVPs that measure quality of care and patient experience of care, cost, continuous practice improvement, and effective management and transfers of health information will help to reduce barriers to APM participation (84 FR 40732 through 40733 and 84 FR 62947). We believe that MVPs, which better align cost and quality measurement and use measures meaningful to clinician practice performance, will help clinicians develop skills and processes that increase their readiness for APM participation. This experience with MVPs may stimulate clinician care improvement processes, a growth of data handling infrastructures, and increase clinician understanding of delivery of high value care. That is, MVP experience with cost and quality measurement may help improve clinician readiness to take on financial risk in APMs. This increased clinician understanding of the quality and cost relationship and improvement approaches derived through MVP use may increase clinician confidence and capacity to engage in APMs. We intend to develop MVPs in collaboration with stakeholders that align with the guiding principles. We anticipate these low burden, meaningful MVPs will move clinicians along the value continuum and facilitate movement into APMs by leveraging APM measures where feasible, and linking cost and quality. We acknowledge, that given the number

of Advanced APMs that are now available and the large number of specialty types, some specialists do not currently have an APM they could participate in. New APMs continue to be developed both inside and external to CMS and we envision that the number of APMs will grow in the future. We encourage specialists to collaborate with CMS and within the Health Care Payment Learning Action Network (HCPLAN) to help drive progress towards value-based care. We will continue to engage with stakeholders, including specialty societies, on how MVPs may reduce barriers to APM participation in the future. We are holding a MVP Town Hall meeting on January 7, 2021 (see 85 FR 74729 through 74730) that will provide stakeholders with an opportunity to provide feedback on MVP topics, including how MVPs can help reduce barriers to APM participation.

Comment: One commenter suggested that in guiding principle 1 the term ''limited'' could be used to define MVPs too narrowly and exclude specialties from being assessed on relevant episodes of care and that we should balance the interests of multiple specialties under each proposed MVP.

Response: The word ''limited'' in this guiding principles means that the number of performance measures and activities in each MVP will be small as compared to, for example, the more than 200 MIPS quality measures a clinician may choose from, we do not use ''limited'' here to constrict the overall number of MVPs as the commenter suggests. While the ''limited'' wording was in our previously finalized guiding principle 1, we proposed adding the words ''connected complementary'' to describe MVP sets of measures and activities that are meaningful to clinicians including specialists. We intend to balance performance measurement standardization with measures that are meaningful to clinicians as we develop MVPs in collaboration with stakeholders.

Comment: A few commenters voiced their support for the concept of subgroup reporting as proposed in guiding principle 2, due to the flexibility it provides to specialists and the more meaningful performance data that results. A few commenters suggested that subgroup reporting be extended to traditional MIPS. A few commenters supported subgroup reporting only if it is optional for multispecialty groups and suggested that incentives be created for subgroup reporting to counter the additional reporting burden. A few commenters expressed interest in the potential of subgroup reporting as related to their specific specialties, which include anesthesiologists, electrophysiologists, endocrinologists, occupational therapists, and otolaryngologists. One commenter provided conditional support of the subgroup reporting concept depending on how a combined final score would be calculated and whether feedback would be provided at the pathway level for subspecialties to be able to receive tailored feedback. One commenter suggested a transition period to incentivize subgroup participation.

Response: We appreciate the support of proposed guiding principle 2. We envision subgroup reporting would be implemented as an option for multispecialty groups reporting MVPs in the future. We did not propose to add a subgroup reporting option to traditional MIPS and believe that the subgroup reporting option within MVPs is sufficient as we expect that eventually the majority of MIPS clinicians will transition to MVP reporting in the future. We have not proposed the details of subgroup reporting, data feedback, scoring or incentives for subgroup reporting but will consider all comments on subgroup reporting as we develop and propose MVP subgroup reporting implementation policies in the future. In terms of a transition period, we intend to implement MVPs incrementally with voluntary participation, which we believe will allow clinicians to transition, as they are ready, into MVP and subgroup reporting.

Comment: Several commenters did not support the concept of subgroup reporting due to concerns related to added program complexity, added burden, and the need for clinicians to compare the scoring advantages of group, subgroup, and individual reporting. One commenter suggested that some specialties may not have a corresponding MVP to report and it may be unrealistic to report performance data on the entire multispecialty group. One commenter suggested that it is possible to develop or identify measures that could result in valuable comparative data comparing a few MVPs but believes that it may be challenging to identify measures that are comparable across all MVPs. One commenter had a concern that a future requirement for subgroup reporting that requires a minimum percent clinician representation would be burdensome and discourage MVP participation. One commenter suggested that testing the attribution methodology for sub-group reporting is critical. One commenter suggested that subgroup reporting would deter team-based care, increase competition, and produce unintended consequences. This commenter suggested that applying Promoting Interoperability requirements to a subgroup rather than a group would discourage MVP selection.

Response: Multispecialty groups, especially groups with many clinicians, often provide an array of services that may not be captured in a single set of measures or in a single MVP. We proposed a modified MVP Guiding Principle 2 as we intend to propose subgroup MVP reporting in the future which would allow clinicians who want to voluntarily report measures that better represent the services they provide to do so. Regarding measure challenges related to comparable measures across all MVPs, within traditional MIPS we require performance measure and activity reporting across four categories (quality, costs, Promoting Interoperability, and improvement activities) and believe there is opportunity to improve comparative data within MVPs as we move in the direction of standardization. We agree with the commenter that it may be challenging to identify measures that are comparable across all MVPs but believe that a future state where clinicians who deliver similar services and report the same MVP will be an improvement over traditional MIPS where wide choices of performance measures and activities, produce challenges in obtaining comparative data. We intend to work with stakeholders to develop MVPs that include meaningful measures and build a portfolio of MVPs that improve comparative data within and across MVPs. We have not proposed implementation details or any minimum criteria for subgroup reporting. We acknowledge that since we plan to incrementally implement MVPs in future years, that some specialties will not initially have a respective MVP. The policies related to operational aspects of subgroup MVP reporting will be developed through future rulemaking with input from stakeholders and we will seek to mitigate concerns such as those voiced by commenters that include complexity, burden, attribution challenges, Promoting Interoperability requirements, unintended consequences, and whether subgroup reporting incentives are warranted. We are holding a MVP Town Hall meeting on January 7, 2021 (see 85 FR 74729 through 74730) that will provide stakeholders with an opportunity to provide feedback on MVP topics, including subgroup reporting.

Comment: A few commenters suggested that the group reporting option continue to be available. One commenter suggested there could be undue burden on multi-specialty groups when each specialty/clinician reported separately and this resulted in separate payment adjustments, as it would be difficult to keep up with the scoring methodology and payment adjustments and would also create confusion for consumers in determining how well a group is performing.

Response: As we implement MVPs and propose to implement subgroup reporting, we intend to continue the group reporting option. We thank the commenters for their feedback and understand their concerns around reporting, scoring, and payment adjustment. We believe that the statute requires CMS, to the extent feasible, to make group reporting comprehensive. We would balance more comprehensive reporting with concerns about complex reporting and scoring and separate payment adjustments. Though we are considering if, in a future state, it would be feasible to require multispecialty groups to report through subgroups and therefore not report as a single group, we do not believe that it would be feasible in the initial years. We are holding a MVP Town Hall meeting on January 7, 2021 (see 85 FR 74729 through 74730) that will provide stakeholders with an opportunity to provide feedback on MVP topics, including subgroup reporting.

Comment: One commenter requested that CMS place a cap on the amount of measures that any one TIN would have to report. One commenter stated their belief that it will be difficult for developers and CMS to meet the 2nd guiding principle of providing valuable information to patients and caregivers if the MVP components are not meaningful to patients and caregivers.

Response: We do not believe that the suggested cap on number of measures a TIN must report is necessary as subgroup reporting will be optional for multispecialty groups during the MVP transition years. We intend that MVP components be meaningful to patients and caregivers and refer the commenter to our MVP development criteria finalized in section IV.A.3.a.(2)(a)(i) of this final rule that ensures meaningful MVPs that are comprehensible and understandable.

Comment: One commenter voiced concern related to linking cost and quality measurement in MVPs for specialties that rarely receive attribution in the cost performance category and urged CMS to be transparent in our cost attribution methodology.

Response: Regarding the commenter concern about linkage of specialty cost and quality measurement challenges in MVPs, as referenced in guiding principle 4, we refer the commenter to MVP Development criteria, section IV.A.3.a.(2)(a)(i) where we state that in cases where there are not relevant cost measures for a specific type of care being provided, a broadly applicable cost measure should be considered for MVP inclusion. We are also interested in focused feedback on what additional cost measures should be prioritized for future development and inclusion in the MVP candidate.

Comment: One commenter recommended that CMS revise guiding principle 2 to read: MVPs should include measures and activities that would result in providing comparative performance data that is valuable to patients and caregivers in evaluating clinician performance and making choices about their care ''and their overall health and well-being.''

Response: We expect the guiding principles to work together to promote our overall goals and we include a meaningful measures principle which looks to improve clinician performance. While MVP comparative data will help patients make clinician selection choices, it is not clear that the comparative data would be available at a level that explicitly helps patients' over-all health and well-being. Therefore, we are not adding the suggested wording to guiding principle 2.

Comment: One commenter encouraged CMS to provide additional guiding principle 2 guidance on how ''sufficient comparative data'' will be ensured, for example, by using single or a limited set of sources to aggregate, analyze and submit data within a given domain.

Response: We proposed to update MVP guiding principle 2 to highlight the importance of more comprehensive multispecialty reporting through subgroups as a step in improving comparative performance data. The movement towards standardization of measures reported within MVPs will improve our ability to ensure comparative clinician performance data. We intend to develop policies related to ensuring comparative data and subgroup reporting with stakeholder input and plan to provide further information related to implementation of this guiding principle in the future. We believe that subgroup reporting allows increased comprehensiveness of multispecialty group performance data as more services can be represented when more than one MVP can be reported.

Comment: Several commenters requested clarifications and details of how subgroups would work operationally. Topics listed for clarification include scoring methodology, subgroup election process, and attribution, and thresholds. One commenter suggested that we mitigate the risk of subgroup payment penalties during transition years. One commenter urged CMS to continue clarifying how MVPs will benefit multispecialty physician practices.

Response: We proposed allowing subgroup reporting as a part of our MVP guiding principles and have not developed or proposed subgroup operational processes. As stated previously in this final rule, we intend to work with stakeholders to develop subgroup reporting policies and processes and intend to make subgroup MVP reporting available in future years. Stakeholder input into scoring, subgroup election processes, attribution, and minimal thresholds (if any) will be considered as we move ahead with subgroup reporting policy proposals in the future. MVPs will benefit multispecialty physician practices in that as more MVPs become available, groups will be able to continue to participate in MIPS via subgroups to more fully reflect the breadth of services provided by the various clinician types within the group. We intend that subgroup reporting will assist in improving the meaning and robustness of the performance data used to incentivize high quality and cost-effective care and providing information that patients can use to select clinicians.

Comment: One commenter seemed to suggest that subgroup reporting was an unnecessary step towards more comprehensive performance data by suggesting that electronic health records can capture individual clinician performances that aggregate into group performance, which they believe many practices have reported to CMS these past few years. The commenter further suggested that instead of changing from group reporting to individual reporting, we should consider a mechanism to collect performance details that obtain individual performances while maintaining group reporting option and scoring. One commenter suggested an alternate to subgroup reporting saying it may be more meaningful to have cross-cutting specialty measures for reporting, and provided an example of diabetes chronic condition care, which involves expertise from ophthalmologists, endocrinologists,

primary care providers, cardiologists and nephrologists.

Response: We intend that subgroup reporting would not be restricted to a single data submission type, for example, EHRs, and would like to leverage current and developing technologies, as indicated by MVP guiding principle 5, to reduce reporting burden as MVPs and subgroup reporting is implemented. We encourage stakeholders to share with us new technologies and opportunities to further our goal of comprehensive and comparative performance data while limiting or reducing clinician MVP reporting burden. Regarding the cross-cutting specialty measures suggestion, we note that our MVP development criteria in section IV.A.3.a.(2)(a)(i) of this final rule, includes an appropriateness element related to whether the MVP is reportable by multiple specialties. Our MVP criteria state that to the extent feasible, specialty and sub-specialty specific quality measures are incorporated into the MVP and that broadly applicable (cross-cutting) quality measures may be incorporated if relevant to the clinicians being measured (refer to section IV.A.3.a.(2)(a)(i) of this final rule). While we appreciate the commenter's interest in cross cutting performance measurement, we do not believe it is an alternative to subgroup reporting, which allows multispecialty groups to voluntarily report on MVPs that have more clinical relevance to various specialties and health priorities.

Comment: One commenter, referring to guiding principle 3, requested clarification of whether each MVP developer will be required to incorporate the patient voice. Another commenter recommended that with appropriate guidance from CMS, and integration of growing patient engagement practices, the inclusion of the patient voice should be mandatory.

Response: We proposed modifying guiding principle 3 to read, MVPs should include measures selected using the Meaningful Measures approach and, wherever possible, the patient voice must be included, to encourage performance improvements in high priority areas. We emphasize in the guiding principle that the patient voice should be captured whenever possible and if not possible, the reason should be clear, for example, if for a certain non-patient facing specialty MVP, there are no relevant patient reported measures currently available. As a part of the MVP development process, we believe that it is important to develop MVPs in a manner that takes into consideration the patient's experience, satisfaction, and outcomes and capturing the patient voice will be used as a criterion as we assess candidate MVPs.

Regarding the commenter recommendation about guiding principle 3 language, ''whenever possible, the patient voice must be included'' and their belief that the patient voice should be mandatory, we refer the commenter to our MVP criteria, incorporation of the patient voice, in section IV.A.3.a.(2)(a)(i) of this final rule and our capturing the patient voice in section IV.A.3.a.(2)(a)(ii) of this final rule which make clear our commitment to inclusion of the patient voice both in our MVP criteria and during MVP development. In addition to including patients as a part of the MVP development process, we encourage stakeholders to utilize several approaches to incorporate the patient perspective, such as using focus groups, in-depth interviews with patients, and informal listening sessions, to the extent feasible, for a comprehensive patient perspective. We have finalized in this rule the expectation of patient voice inclusion in MVP measurement and MVP development.

Comment: A few commenters suggested that we add language to the MVP guiding principles to recognize social determinants of health, with one commenter suggesting that the MVP guiding principles explicitly recognize that healthcare outcomes and cost are shaped by, but go beyond, physicians and the care they provide and are substantially attributable to social factors. One commenter again (85 FR 50280) recommended that we supplement guiding principle 3 by stating explicitly measurement of ''high priority areas of morbidity and mortality.''

Response: We aim to implement MVPs that incentivize high value care and encourage clinicians to make care improvements based on performance measurement data. The Assistant Secretary for Planning and Evaluation (ASPE) Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program explored how the social determinants of health impact clinician performance data and value-based programs.[120] This report was publicly released in June 2020 and builds on the analyses included in an earlier report and provides additional insight for addressing risk factors in MIPS and other value-based payment programs. As we continue to review the analyses and findings of the report, we are considering its recommendations, along with any updated data that would become available, for future rulemaking. We plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify longer term policy solutions that achieve the goals of attaining health equity for all beneficiaries and minimizing unintended consequences. As this work progresses, we will assess whether adding any social determinants of health wording to our MVP guiding principles is appropriate. We note that in support of social factor impacts we are finalizing in section IV.A.3.a.(2)(a)(i) of this final rule the proposed MVP criteria related to MVP developer consideration of patients in rural and underserved areas.

We do not believe it is appropriate to add the recommended ''morbidity and mortality'' wording in guiding principle 3 as we do not want to restrict what we mean by ''high priority areas'' to only morbidity and mortality performance improvements (85 FR 50281); we want to encourage performance improvements in a variety of high priority areas.

Comment: A few commenters requested clarification of a definition of ''digital quality measures'' and the associated criteria for MVP measures. One commenter suggested that while digital measures would reduce burden for some, they would increase burden for others and another commenter suggested equity be considered in the use of eCQMs and digital measures for clinicians. One commenter would like to see digital quality measure exceptions for small practices which are not fully electronic. Another commenter suggested clinician choice in selection of dQMs to report. One commenter suggested that as we implement guiding principle 5, we expand the scope to incentivize building an infrastructure of digital systems that track patients longitudinally, inform care decisions, and support their quality improvement efforts. One commenter requested clarification as to whether our examples of dQMs suggested that eCQMs and MIPS CQMs will eventually be collapsed into a single undifferentiated collection type of dQM and that this could lead to a more optimally hybridized environment of quality measure development, collection and reporting. One commenter suggested that MVP digital measures should include all potential validated data sources, particularly patient reported outcomes and remote patient monitoring data, not just administrative data. One commenter suggested that we

[120] ASPE Second Report to Congress. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

need to better define ''digital'' technologies and the associated measure reporting requirements. One commenter, referring to guiding principle 5, encouraged us to more broadly recognize use of electronic data, such as MIPS credit for wearable devices initiatives. One commenter urged CMS to continue investing in further developing standards that support accurate data quality. A few commenters did not support proposed guiding principle 5 citing EHR, IT and cybersecurity burden concerns for small and rural practices. One commenter requested that we consider MVP development criteria that take into account those clinicians who may not be able to satisfy electronic reporting requirements.

Response: We proposed adding new MVP guiding principle 5, MVPs should support the transition to digital quality measures, to communicate our future vision for reducing MVP reporting burden through leveraging digital innovation. Digital Quality Measures (dQMs) originate from sources of health information that are captured and can be transmitted electronically and via interoperable systems. Examples of digital sources include electronic health records (EHR), health information exchanges (HIEs), clinical registries, case management systems, electronic administrative claims systems, electronically submitted assessment data, and wearable devices. Electronic clinical quality measures or eCQMs (data derived from electronic medical records) are a subset of dQMs (85 FR 50281). As we develop MVPs and incorporate dQMs into MVPs we will consider the operational elements, transitional factors and how movement to dQMs impacts clinician burden, office protocols, cross-MVP equity, and small practices in keeping with our intent to reduce burden. We believe including dQMs in MVPs will incentivize the building of clinician infrastructures of digital systems. We intend to continue supporting the development of dQMs and look forward to inclusion of these measures in MVPs in the future.

After consideration of public comments, we are finalizing our proposals as proposed.

(2) MVP Development

(a) Process of Developing MVPs

In the CY 2020 PFS final rule (84 FR 62948), we finalized at § 414.1305 the definition of a ''MIPS Value Pathway'' to mean a subset of measures and activities established through rulemaking. We also clarified our intention to develop MVPs, to the extent feasible, in collaboration with stakeholders (84 FR 62947). Commenters suggested us to work in tandem with clinicians and specialty societies to develop MVPs (84 FR 62948) and have supported the development of MVPs with robust stakeholder input and feedback opportunities. Stakeholders have also clearly emphasized the need for input during the design and implementation of MVPs. We believe it is important to emphasize that the transition to MVPs must occur gradually, without immediate elimination of the current MIPS program, as we continue to work collaboratively with stakeholders regarding MVP development. As MVPs are developed collaboratively and in a manner that involves dialogs with stakeholders, they must be created utilizing a consistent set of parameters and criteria, to ensure that MVPs are constructed and implemented in a uniform manner. In addition, we believe it is important to outline the methods in which collaboration and engagement may occur with stakeholders. Lastly, we intend on formulating a standardized process in which stakeholders can submit formal MVP candidates for CMS' consideration.

(i) MVP Development Criteria

In response to the RFI in the CY 2020 PFS final rule, we have received stakeholder comments that supported the move to MVPs with considerations to departing from the traditional reporting requirements of the existing MIPS program, such as reporting 6 quality measures for the Quality performance category. We also received stakeholder comments through the RFI that supported the use of electronically available measures such as eCQMs and the use of QCDR measures to the extent feasible. Stakeholders also expressed that it is important that the collection type of quality measures be considered as MVPs are designed. As a part of the MVP development process, consideration should be given to the four performance categories in MIPS, and whether the MVP has a clearly defined intent, offers value, and opportunity for improvement. We believe that as a part of MVP development, it is important to clearly identify linkages between the measures and activities within an MVP which will demonstrate the relevancy of measures and activities to the clinicians being captured within the MVP. Furthermore, as MVPs are developed it is important to factor in the appropriateness of the measures and activities being included and the comprehensibility of the MVP to clinicians and patients. Lastly, considerations must be given to existing criteria for measure and activity inclusion or removal, as established for each of the performance categories. For example, as described in the CY 2019 PFS final rule (83 FR 59763) for the quality performance category, quality measures that are identified as extremely topped out (reaching an average performance rate between 98 to 100 percent) will likely be removed from the program. We refer readers to the CY 2020 PFS final rule (84 FR 62949 through 63006) for discussion of previously finalized measure and activity requirements across the Quality, Cost, Improvement Activity, and Promoting Interoperability performance categories. In addition, we also referred readers to section IV.A.3.c. of the CY 2021 PFS proposed rule for updates to the respective performance categories. Therefore, beginning with the 2022 MIPS performance period, we proposed to develop and select MVPs using the following criteria:

- Utilization of Measures and Activities across Performance Categories.

(a) MVPs should include measures and activities from the Quality, Cost, and Improvement Activities performance categories.

(b) MVPs should include the entire set of Promoting Interoperability (PI) measures.

- Intent of Measurement:

(a) What is the intent of the MVP?

(b) Is the intent of the MVP the same at the individual clinician and group level?

(c) Are there opportunities to improve the quality of care and value in the area being measured?

(d) Why is the topic of measurement meaningful to clinicians?

(e) Does the MVP act as a vehicle to incrementally phase clinicians into APMs? How so?

(f) Is the MVP reportable by small and rural practices? Does the MVP consider reporting burden to those small and rural practices?

(g) Which Meaningful Measure Domain(s) does the MVP address?

- Measure and Activity Linkages with the MVP:

(a) How do the measures and activities within the proposed MVP link to one another? (For example, do the measures and activities assess different dimensions of care provided by the clinician?)

(b) Are the measures and activities related or a part of the care cycle or continuum of care offered by the clinicians?

(c) Why are the measures and activities most meaningful to the specialty?

• Appropriateness:

(a) Is the MVP reportable by multiple specialties? If so, has the MVP been developed collaboratively across specialties?

(b) Are the measures clinically appropriate for the clinicians being measured?

(c) Do the measures capture a clinically definable population of clinicians and patients?

(d) Do the measures capture the care settings of the clinicians being measured?

(e) Prior to incorporating a measure in an MVP, is the measure specification evaluated, to ensure that the measure is inclusive of the specialty or sub-specialty?

• Comprehensibility:

(a) Is the MVP comprehensive and understandable by the clinician or group?

(b) Is the MVP comprehensive and understandable by patients?

• Incorporation of the Patient Voice:

(a) Does the MVP take into consideration the patient voice? How?

(b) Does the MVP take into consideration patients in rural and underserved areas?

(c) How are patients involved in the MVP development process?

(d) To the extent feasible, does the MVP include patient-reported outcome measures, patient experience measures, and/or patient satisfaction measures?

• Measures and Improvement Activities Considerations: MIPS Quality Measures.

We were not prescriptive on the number of quality measures that are included in an MVP. In selecting quality measures, we stated that we believe that consideration should be given to the following:

(a) Do the quality measures included in the MVP meet the existing quality measure inclusion criteria? *(For example, does the measure demonstrate a performance gap?)*

(b) Have the quality measure denominators been evaluated to ensure the eligible population is consistent across the measures and activities within the MVP?

(c) Have the quality measure numerators been assessed to ensure the measure is applicable to the MVP topic?

(d) To the extent feasible, does the MVP include outcome measures, or high priority measures in instances where outcome measures are not available or applicable? We encourage stakeholders to utilize our established pre-rulemaking processes, such as the Call for Measures, described in the CY 2020 PFS final rule (84 FR 62953 through 62955) to develop outcome measures relevant to their specialty if outcome measures currently do not exist and for eventual inclusion into an MVP.

(e) To the extent feasible, does the MVP include electronically specified clinical quality measures?

(f) To the extent feasible, does the MVP avoid including quality measures that are topped out?

(g) What collection types are the measures available through?

(h) What role does each quality measure play in driving quality care and improving value within the MVP? Provide a rationale as to why each quality measure was selected.

(i) How do the selected quality measures relate to other measures and activities in the other performance categories?

(j) To the extent feasible, specialty and sub-specialty specific quality measures are incorporated into the MVP. Broadly applicable (cross-cutting) quality measures may be incorporated if relevant to the clinicians being measured.

• Measures and Improvement Activities Considerations: Cost Measures.

(a) What role does the cost measure(s) play in driving quality care and improving value within the MVP? Provide a rationale as to why each cost measure was selected.

(b) How does the selected cost measure(s) relate to other measures and activities in other performance categories?

(c) If there are not relevant cost measures for specific types of care being provided (for example, conditions or procedures), does the MVP include broadly applicable cost measures (that are applicable to the type of clinician)?

(d) What additional cost measures should be prioritized for future development and inclusion in the MVP?

• Measures and Improvement Activities Considerations: Improvement Activities.

(a) What role does the improvement activity play in driving quality care and improving value within the MVP? Provide a rationale as to why each improvement activity was included.

(b) Describe how the improvement activity can be used to improve the quality of performance in clinical practices for those clinicians who would report this MVP.

(c) Does the improvement activity complement and/or supplement the quality action of the measures in the MVP, rather than duplicate it?

(d) To the extent feasible, does the MVP include improvement activities that can be conducted using CEHRT functions? The use of improvement activities that specify the use of certified health IT will help to further align with the CEHRT requirement under the Promoting Interoperability performance category.

(e) If there are not relevant specialty or sub-specialty specific improvement activities, does the MVP includes broadly applicable improvement activities (that is applicable to the clinician type) are used?

• Measures and Improvement Activities Considerations: Promoting Interoperability (PI) Measures.

(a) Must include the full set of PI measures.

The MVP development criteria was developed primarily with consideration with the MVP guiding principles, discussed above. In addition, we considered the spectrum of measures and activities available for MVP development, and the criteria used to include measures and activities within each of the respective performance categories. Through the collaborative process of co-developing MVPs with stakeholders, we have realized how crucial it is to establish a set of MVP development criteria that would standardize what is expected of MVPs and provide our evaluation criteria in a transparent manner. We stated that we believe that the aforementioned criteria will lead to the development of MVPs in a manner that is consistent and reliable. We sought comment on the MVP development criteria.

We received public comments on the MVP development criteria proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters broadly supported the MVP criteria.

Response: We agree and thank the commenters for their support on the MVP criteria. We believe that the establishment of MVP development criteria will allow stakeholders to better understand of our vision for MVPs and ensure that MVPs are constructed in a consistent manner.

Comment: Several commenters broadly supported the MVP criteria. One commenter suggested CMS to continue to prioritize interoperability as a foundational requirement in the new MVP Program. One commenter agreed that MVPs should include criteria related to utilization, intent, and linkage of measures because this would help develop new MVPs. One commenter suggested CMS provide flexibility for innovative MVPs.

Response: We thank the commenters for their support on the MVP criteria,

we believe there is importance to establishing criteria in which MVPs will be developed and implemented for consistency purposes. We also agree that interoperability is an important priority, and should therefore, be included in MVPs as a foundational requirement. We also agree that criteria related to utilization, intent, and linkages would assist in the development of MVPs. Lastly, we continue to encourage stakeholders to be innovative as they partake in MVP development and collaboration with CMS while aligning with the MVP development criteria as described. We do not believe additional flexibility beyond what is described in the MVP development criteria is needed, as we emphasize that MVPs should be developed utilizing a standardized framework.

Comment: Commenters expressed that MVPs should be tailored for participating clinician specialists', such as anesthesiologists, neurosurgeons, rehabilitation medicine, occupational therapists, physical therapists, and speech-language pathologists. A few commenters stated that MVPs should be collaboratively developed by specialties before submission to CMS. One commenter expressed that MVPs could be considered condition-specific (when specialists are part of a larger core team) or specialty-specific (when specialists are treating patients with a wide range of diagnoses). One commenter expressed that specialty organizations would have difficulty contributing measures to MVPs that are not specialty specific.

Response: We agree that MVPs should be developed around specialties that participate in the MIPS program to offer clinicians a more meaningful method of reporting. We also strongly agree and would encourage that MVPs should be collaboratively developed amongst specialties, in instances where an MVP covers an episode of care that involves multiple clinician types, such as surgeons and anesthesiologists. Furthermore, we agree that MVPs could be condition-specific or specialty-specific; it will depend on the clinical topic being measured and envision the specialty organizations would suggest specialty specific measures for MVPs over broadly applicable measures. While broadly applicable measures, such as closing the referral loop, can be considered for inclusion in an MVP, because they cover quality actions that are a part of the care continuum, these are not required to be included should more meaningful and relevant specialty specific measures exist. We believe the measures included in an MVP should be relevant and meaningful to the clinical practice of the specialties being measured. We are open to considering candidate MVPs that are created utilizing the MVP development criteria, for specialties including physical and occupational therapy.

Comment: Several commenters expressed that the proposed MVP criteria should include other elements such as the number of measures and activities required. A few commenters recommended CMS work collaboratively with MVP developers and one commenter specified that CMS's MVP approval process should be transparent with the MVP developers so that specialty societies do not invest resources without assurances of success.

Response: As described in the CY 2021 PFS proposed rule (85 FR 50282), we are not prescriptive on the number of measures or activities included in MVPs. We emphasize that the measure and activities should be relevant and meaningful to the topic being measured through the MVP. We intend to provide educational material including plans to host a public facing webinar to help stakeholders better understand and be prepared to implement the MVP development criteria. In addition, we emphasize it is our intention to work collaboratively by having dialogs with stakeholders to develop MVPs that are meaningful and relevant to their given clinical specialties. Lastly, while we intend to continue to work with stakeholders in an iterative manner that fosters transparency, CMS will ultimately determine if and when an MVP candidate is ready for implementation. We intend to follow our normal processes of notice and comment rulemaking to make stakeholders and the public aware of which MVPs we believe are ready for implementation for the upcoming performance period.

Comment: One commenter recommended CMS clearly define a pathway to phase clinicians into APMs.

Response: We intend that MVPs will assist clinicians and practices as they prepare to take on and manage financial risk, as in Advanced APMs, as they build out their quality infrastructures that align with the MIPS performance categories and gain experience with cost measurement. We believe that experience with MVPs, in which there is aligned measurement of quality (of care and of experience of care) and cost, continuous improvement/innovation within the practice, and efficient management and transfers of information, will help remove barriers to APM participation.

We refer readers to the infographic at *https://qpp.cms.gov/mips/mips-value-pathways*, which provides an overview of our vision for the MIPS path to value future state (see 85 FR 50279). We believe that MVPs, which better align cost and quality measurement and use measures meaningful to clinician practice performance, will help clinicians develop skills and processes that increase their readiness for APM participation. This experience with MVPs may stimulate clinician care improvement processes, a growth of data handling infrastructures, and increase clinician understanding of delivery of high value care. We believe another example of how MVPs may provide a pathway to phase clinicians into APMs may be to consider the inclusion of quality measures in MVPs, which are used in APMs such as the new APM Performance Pathway (APP). The familiarity of reporting those measures, may lead to a smoother glide path for clinicians into APMs.

Furthermore, MVPs should reduce barriers to APM participation by including measures that are part of APMs where feasible, and by linking cost and quality measurement. Experience with MVPs that measure quality of care and patient experience of care, cost, continuous practice improvement, and effective management and transfers of health information will help to reduce barriers to APM participation (84 FR 40732 through 40733 and 84 FR 62947). We anticipate these low burden, meaningful MVPs will move clinicians along the value continuum and facilitate movement into APMs by leveraging APM measures where feasible, and linking cost and quality. We will continue to engage with stakeholders on how MVPs may reduce barriers to APM participation in the future. We are holding a MVP Town Hall meeting on January 7, 2021 that will provide stakeholders with an opportunity to provide feedback on MVP topics, including how MVPs can help reduce barriers to APM participation. (See the November 23, 2020 **Federal Register** (85 FR 74729 through 74730) for additional information on the January 7, 2021 meeting.)

Comment: One commenter requested that CMS define an MVP governance structure that would include a central point of contact and responsibility to prevent the removal of a measure or an improvement activity that would negatively affect stakeholders and specialties.

Response: All MVPs are subject to notice and comment rulemaking with regards to the proposal of new MVPs,

changes to existing MVPs (in the future), and removal of MVPs or components of an MVP (such as a quality measure or improvement activity). CMS is the central point of contact with regards to MVPs. If there are potential changes to an established MVP, we will consider the potential impacts on all stakeholders prior to proposing the changes. Stakeholders will be able to provide comments on the proposed changes through the public comment period for CMS to consider prior to finalizing the MVPs or changes to the MVPs.

Comment: One commenter requested that CMS clarify if it would withhold MVP approval for a specialty specific MVP if patient reported outcome measures for the specialty specific MVP are not available.

Response: While it is our preference to include outcome and patient reported outcome measures in MVPs, we have stated we would do so to the extent feasible, as we understand that there may be limited availability of patient reported outcome measures for all specialties. Therefore, we encourage the use of other measures that consider the patient voice in MVPs, such as patient surveys, patient satisfaction, or patient experience measures in the interim. It is our vision that MVPs will be made up of a majority of outcome measures and will include a patient reported outcome measure that would represent the patient voice. We continue to encourage stakeholders to use their innovative means to develop and submit through our established pre-rulemakings processes patient reported outcome measures that are meaningful to their specialties, and consider the incorporation of tools such as the PROMIS tool into their measure development.

Comment: One commenter requested that CMS clarify how MVPs will incorporate new technology, such as FHIR (Fast Healthcare Interoperability Resource), into data collection.

Response: As mentioned in the previous section of this final rule, within our MVP guiding principles, we indicate that MVPs should support the transition to digital measures to the extent feasible. The inclusion of digital measures within MVPs may facilitate future use of new technologies such as FHIR, in an effort to provide reporting options that reduce reporting burden for clinicians and groups.

Comment: A few commenters opposed including the full set of promoting interoperability (PI) measures in MVPs and recommended CMS emphasize that improvement activities must utilize certified electronic health record technology (CEHRT). One commenter noted that hospitalists or clinicians who do not interact with patients would not be able to collect and report PI data and that MVPs should be designed to reflect this at the outset by allowing groups to attest to using CEHRT. One commenter suggested CMS maintain the existing PI hardship exceptions as a proxy for the PI measurement requirement.

Response: We believe that interoperability is a foundational element of MVPs. In the CY 2020 PFS final rule (84 FR 62948) we stated that we envision an initial uniform set of Promoting Interoperability measures in each MVP and will consider customizing MVP Promoting Interoperability measures in future years. We believe that eligible clinicians could benefit from more targeted approaches that assess the meaningful use of health IT in alignment with clinically relevant MVPs. As we gain additional years of experience with MVPs, we may be able to consider MVP Promoting Interoperability measures in each MVP, but we want to spend some time assessing what criteria should be used in determining which Promoting Interoperability measures fit or do not fit within a given MVP and why. Furthermore, we agree that the establishment and inclusion of improvement activities (IAs) that require the utilization of certified health IT in MVPs would create a stronger linkage between the PI and IA performance categories. Lastly, the existing bases for reweighting the PI performance category under traditional MIPS also will be available through MVPs.

Comment: A few commenters expressed that many small and rural practices cannot afford implementing electronic health records (EHRs), including the information technology and cybersecurity staff required to maintain EHR security and recommended CMS maintain the Promoting Interoperability performance category small practice hardship exception.

Response: We understand that there may be some barriers for small and rural practices in implementing CEHRT, and do intend on maintaining the hardship exception for small practices as we establish the MVP reporting option. In addition, we intend on applying the existing Promoting Interoperability performance category reweighting policies under § 414.1380(c)(2) as we establish MVPs, with any revisions addressed through future notice and comment rulemaking.

Comment: Several commenters suggested overall measure requirements regarding the number of measures and requested measure clarification. A few commenters requested that MVPs include a limited number of measures. One commenter suggested that clinicians report six quality measures and one outcome measure or high-priority measure. One commenter suggested that specialties and sub-specialties with less than six quality measures should be required to report on all cross-cutting measures.

Response: As mentioned in the CY 2021 PFS proposed rule (85 FR 50282), to date, we have not been prescriptive on the number of quality measures that are included in a given MVP. The measures that are being considered for inclusion of the MVP should meet the standards of the MIPS quality measures and QCDR measures inclusion criteria. Measures incorporated into an MVP should be clinically relevant to the topic being measured. Through the gradual transition to MVPs, we intend on allowing for clinicians to report on smaller but more meaningful sets of measures and activities. We appreciate the feedback regarding MVP reporting requirements, and encourage stakeholders to participate in our MVP Town Hall meeting to provide additional feedback with regards to the number of measures clinicians should be required to report in an MVP. As noted previously in this section, we are holding a MVP Town Hall meeting on January 7, 2021 (85 FR 74729 through 74730) that will provide stakeholders with an opportunity to provide feedback on this amongst other MVP topics. We thank the commenters on their suggestions in regards to reporting requirements for specialties and sub-specialties with less than six quality measures, and will take the comment into consideration for future rulemaking.

Comment: One commenter requested clarification on whether every MVP measure and improvement activity should have the same denominator.

Response: To clarify, every measure and improvement activity does not have to have the same denominator. However, we encourage stakeholders to consider the denominator eligible population across the measures being considered for inclusion in the quality and cost component of the MVP. In addition, we also encourage stakeholders to review the measure specifications to validate that the places of service they would like reflected within the MVP, for example, inpatient or outpatient are included. We encourage this review, so that stakeholders are cognizant of incorporating measures that are widely

applicable to the clinicians they intend to measure through the MVP. Furthermore, improvement activities do not utilize numerators and denominators like measures do. Therefore, we encourage stakeholders to utilize improvement activities that are complementary to the quality actions captured by the quality measures and cost measures included within the MVP candidate.

Comment: One commenter stated CMS should ensure there are enough measures to create MVPs applicable for the more than 1 million eligible clinicians that currently participate in the MIPS program, specifically specialists.

Response: In the MIPS program, we have implemented two inventories of measures, which include MIPS quality measures that are submitted through the Call for Measures following the pre-rulemaking process that are eventually proposed and finalized through notice and comment rulemaking. The other inventory of available measures are developed by CMS approved Qualified Clinical Data Registries (QCDRs). We refer readers to the Quality Payment Program (QPP) resource library: *https://qpp.cms.gov/about/resource-library* for details on the available inventories of quality measures and QCDR measures for the 2020 performance period. The measure inventories for the 2021 MIPS performance period will be posted to the prior to the start of the performance period in the QPP resource library. We believe the existing inventories of measures are enough to start creating applicable MVP candidates. Moreover, we continue to encourage measure stewards and QCDRs to innovatively develop measures and keep in mind our desire to transition our inventory of measures to be largely based on outcome measures and develop measures that are outcome, intermediate outcome, or patient reported outcome based.

Comment: Another commenter recommended allowing specialties to rapidly test and replace obsolete measures.

Response: We agree and highly encourage stakeholders, such as specialty groups and measure developers to participate in measure development and submit measures through the Call for Measures as soon as possible to replace retired measures with measures that are more robust and outcomes based. In following the pre-rulemaking guidelines to ensure their measures can be considered, the process also includes measure testing amongst other requirements. We refer readers to the pre-rulemaking website for a comprehensive list of measure development requirements and resources at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Pre-Rulemaking-MUC*.

Comment: Commenters recommended that CMS incorporate patient-reported outcomes measures (PROMs) into MVPs and expressed that these measures not only improve the quality of care but also help patients make more informed decisions. Commenters also recommended that PRO tools such as PROMIS, SDM–Q–9, and CollaboRATE be incorporated into the MVP quality score.

Response: We agree with the commenters that patient reported outcome measures provide value and improve the quality of care, and to the extent feasible, should be included in MVPs. We also agree that PRO tools are valuable, but need to be incorporated into a measure or activity in order to contribute to the MVP quality score per statutory requirements.

Comment: One commenter requested CMS to clarify the number of MVPs per specialty and a few commenters recommended sub-specialty MVPs. For example, one commenter recommended CMS support the development of multiple surgical and procedural MVPs to represent anesthesia practice settings to provide sufficient MVP choices for ECs and groups.

Response: To date we have not been specific as to the maximum number of MVPs a given specialty should have. We are cognizant of the potential need for MVPs that are sub specialized and that the number of MVPs available per specialty may vary. We believe discussions with the specialties will help to determine the best path forward, while keeping in mind our desire to avoid creating large volumes of MVPs per specialty, which may create more complexity and may lead to overwhelmed clinicians unsure of which MVP to report. After consideration of the public comments received, we are finalizing our proposals as proposed.

(ii) Capturing the Patient Voice

As a part of the MVP development process, we believe that it is important to develop MVPs in a manner that takes into consideration the patient's experience, satisfaction, and outcomes. We believe that MVPs should be constructed in a manner that should not only be understood by clinicians, but by patients who may use the ascertained information to make informed decisions regarding their health care providers. Therefore, beginning with the 2022 performance period, we proposed that stakeholders that are developing MVPs to submit to CMS as candidate MVPs should include patients as a part of the MVP development process. We stated that stakeholders should incorporate patients and/or patient representatives through means that may include, but are not limited to technical expert panels or an advisory committee as they work to construct their candidate MVPs prior to reaching out to CMS with a candidate submission. The process of involving patients as a part of the stakeholder's MVP development would be considered a pre-requisite for CMS to consider the candidate MVP for the upcoming performance period. By including patients and/or patient representatives in the MVP development process, we stated we believe that patients will be able to voice how to make the outcomes of measurement meaningful to them. In addition to including patients as a part of the MVP development process, we encouraged stakeholders to utilize several approaches to incorporate the patient perspective, such as using focus groups, in-depth interviews with patients, and informal listening sessions, to the extent feasible, for a comprehensive patient perspective. We sought comments on the proposal.

We received public comments on the capturing the patient voice proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the inclusion of the patient voice in the MVP development process.

Response: We thank the commenters for their support, and agree that there is importance in including the patient voice in the MVP development process. We believe that including patients as a part of the MVP development process will allow for the development of MVPs that provide data that is meaningful to patients as they select providers.

Comment: One commenter opposed the addition of MVP development criteria, citing concern that these will delay MVP development. The commenter suggests that CMS subject each MVP candidate to a robust screening process that includes patient perspective, rather than putting the onus on developers to do so.

Response: We disagree that the establishment of MVP development criteria will delay MVP development. We believe that the creation of MVP development criteria will allow for the implementation of MVPs that are created in a consistent manner that aligns with our vision of MIPS Value Pathways moving clinicians to more meaningful measurement that creates

betters opportunities for quality improvement. Furthermore, we disagree with the commenter's suggestion that CMS alone subject each MVP candidate to a screening process that includes patients. We believe that stakeholders who choose to create a MVP candidate around a clinical topic should consider the patient perspective as a part of the development process rather than waiting until the candidate MVP has completed development to obtain patient feedback. The consideration of the patient perspective in the midst of the development process allows stakeholders to consider the feedback and make changes to their development process that will help to result in a better quality MVP candidate.

Comment: A few commenters recommended that CMS delay implementing the criteria that the MVP is comprehensive and understandable by patients. A few commenters requested a delay until the 2023 performance year so that a technical expert panel could be convened.

Response: We disagree that this criteria should be delayed until the 2023 performance period. We believe all MVP candidates need to be developed with this criteria in mind to ensure that the data collected from MVPs are meaningful for patients to make informed decisions regarding their patient care. Furthermore, it is not a requirement that stakeholders convene technical expert panels, therefore, we disagree that there be a delay until the 2023 performance period. While we have established criteria to develop MVPs, it is to the discretion of the stakeholder to determine how elaborate of a development process they would like to undertake and when their MVP candidate is ready for CMS review and consideration.

Comment: Several commenters recommended approaches for CMS to engage patients. One commenter expressed concern about how CMS will evaluate patient engagement during the MVP development process.

Response: We thank the commenters for their recommendations; however, we note that the requirement is for stakeholders who wish to submit an MVP candidate to CMS. Those stakeholders must engage with patients as a part of their MVP development process prior to submitting the MVP candidate for CMS review and consideration. While we are not prescriptive that patient engagement occur using a single approach, we plan to recommend stakeholders to describe how they engaged patients in the MVP development process through the MVP candidate submission template to help us understand how the patient's perspective was considered in the development process.

Comment: One commenter requested that CMS make exceptions for the inclusion of patient representatives in MVP development in cases where organizations are able to demonstrate that patient reported outcomes cannot be used. Another commenter requested clarity on whether each contributor or specialist to an MVP must include patient testing or interviews. The commenter also requested detail on how CMS will verify the inclusion of the patient voice.

Response: We disagree with the commenter request that we make exceptions for the inclusion of patient representatives in the MVP development process in instances where organizations are unable to utilize patient reported outcome measures. We want to clarify that the requirements around the patient voice are complimentary. We are looking for stakeholders to involve patients or patient representatives as a part of the MVP development process, to ensure that patients are able to understand what the MVP is trying to measure. In addition, to the extent feasible, we suggested that patient reported outcome measures be included in MVPs. While it is our preference to include patient reported outcome measures in MVPs, we understand that there may be limited availability of patient reported outcome measures for all specialties. Therefore, we encourage the use of other measures that consider the patient in MVPs, such as patient surveys, patient satisfaction, patient experience, or patient safety measures. We continue to encourage stakeholders to use their innovative means to develop and submit through our established pre-rulemakings processes patient reported outcome measures that are meaningful to their specialties, and consider the incorporation of tools such as the PROMIS tool into their measure development.

Comment: One commenter recommended that CMS develop patient-facing materials describing MVPs and requested that CMS lead education of patient groups on the goals and quality measurement of the MVP.

Response: We thank the commenter for their recommendation. As a part of our education and outreach efforts we intend on developing educational materials and hosting webinars that are meaningful to all stakeholders, including patients. However, we also believe that stakeholders who choose to partake in MVP development should also educate and involve patients regarding quality care in a given area of clinical care improvement.

Comment: One commenter requested CMS to provide equal focus on patient outcomes as patient experience and satisfaction. Another commenter stated that treating and reversing certain chronic conditions and achieving optimal health outcomes. One commenter recommended that MVPs include the Hospital-Wide 30-day All Cause Unplanned Readmission (HWR) Rate measure.

Response: We agree and continue to emphasize our focus on outcomes, including patient reported outcomes, and our desire to move away from process measures. We also agree that attaining optimal health outcomes by treating, managing, and possibly overcoming chronic conditions should be captured in a future MVP. Furthermore, we agree that there is importance in including population health measures in the foundational layer of all MVPs as described below, and we do intend on finalizing the inclusion of the Hospital-Wide 30-day All Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups measure.

After consideration of the public comments, we are finalizing our proposals as proposed.

(iii) Candidate MVP Co-Development, Solicitation Process, and Evaluation

Through the Request for Information (RFI) on transforming MIPS in the CY 2020 PFS final rule we have learned of stakeholders interests in participating in the MVP development process. In summer 2019, we held numerous focus groups with front-line clinicians, specialty societies, advocacy groups, QCDRs, registries, and health IT vendors to listen to what stakeholders were looking for in regards to program simplification, burden reduction, and the intent of MVPs. In response to the CY 2020 PFS final rule, we received several requests from stakeholders who wanted to discuss their perspectives on MVPs and in some cases, walk us through potential MVP candidates from their specialty. Based on continuous stakeholder interest, we believe that a process must be implemented to ensure that stakeholder engagement and collaboration in the development of MVPs is consistent from an overall perspective.

To consider MVP candidates developed by stakeholders, we believe it is important to implement a streamlined approach to receive and evaluate potential MVPs. Therefore, beginning

with the 2022 performance period, we proposed that stakeholders should formally submit their MVP candidates utilizing a standardized template, which will be published in the QPP resource library for our consideration for future implementation. Stakeholders should submit all information including a description of how their MVP abides by the MVP development criteria as described in the CY 2021 PFS proposed rule (85 FR 50281 through 50283), and provide rationales as to why specific measures and activities were chosen to construct the MVP. We believe the utilization of a standardized template would help stakeholders understand what information is needed to evaluate the feasibility of the candidate MVP.

On an annual basis, we intend on hosting a public facing MVP development webinar, to remind stakeholders of MVP development criteria, the timeline, and process in which to submit a candidate MVP. While we believe that engagement with stakeholders regarding MVP candidates may occur on a rolling basis throughout the year, at CMS' discretion we will determine if an MVP is ready for inclusion in the upcoming performance period. As MVP candidates are received, they will be reviewed, vetted, and evaluated by CMS and our contractors. We intend on utilizing the MVP development criteria (discussed above) to determine if the candidate MVP is feasible. In addition to the MVP development criteria listed above, we will also vet the quality and cost measures from a technical perspective to validate that the coding in the quality measures and cost measure(s) include the clinician type being measured, and whether all potential specialty specific quality measures or cost measures were considered, with the most appropriate included. We may reach out to the stakeholder on an as-needed basis, should questions arise as we review. In addition, once we complete our internal evaluation, we will reach out to select stakeholders whose candidate MVP may be feasible for the upcoming performance period, to schedule a feedback loop meeting to have a dialog regarding our feedback, and next steps that may include recommended modifications to the MVP candidate. Since MVPs must be established through rulemaking, as described at § 414.1305, CMS will not communicate to the stakeholder whether an MVP candidate has been approved, disapproved, or is being considered for a future year, prior to the publication of the proposed rule. We sought comment on the proposed process to solicit MVP candidates.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the use of an MVP candidate template with one believing it is as a way to reduce administrative burden. Another commenter requested that we release the MVP candidate template far in advance of MVP implementation.

Response: We plan to release the MVP candidate template as soon as possible, and potentially in coordination with the publication of this final rule so it can be immediately available for use by stakeholders.

Comment: One commenter voiced their appreciation for our MVP development discussions and feedback to date and supported the idea of a feedback loop on submitted MVPs and greater transparency in the process.

Response: We thank the commenter for their support; we believe establishing a feedback loop with stakeholders will help to strengthen communications regarding MVP candidates that may be iteratively revised based on our review. While we intend to continue to work with stakeholders in an iterative manner that fosters transparency, CMS will ultimately determine if and when an MVP candidate is ready for implementation. We intend to follow our normal processes of notice and comment rulemaking to make stakeholders and the public aware of which MVPs we believe are ready for implementation for the upcoming performance period. If there are potential changes to an established MVP, we will consider the potential impacts on all stakeholders prior to proposing the changes. Stakeholders will be able to provide comments on the proposed changes through the public comment period for CMS to consider prior to finalizing the MVPs or changes to the MVPs.

Comment: A few commenters objected to the idea that CMS would not communicate to the stakeholder developing a candidate MVP whether an MVP candidate has been approved, disapproved, or is being considered for a future year, prior to the publication of the annual QPP proposed rule. A few commenters suggested an interactive dialogue between the stakeholder who has submitted the candidate MVP and CMS would be helpful throughout the development process. One commenter suggested that CMS should provide feedback regardless of whether the MVP will be proposed for implementation and another requested feedback be provided throughout the MVP development process. One commenter believes a clear process and timeline for approving MVPs and new measures should be clearly delineated prior to implementation.

Response: We agree that a dialog between the stakeholder who has developed the candidate MVP and CMS would be meaningful, to ensure that the MVP aligns with program goals and MVP criteria and that CMS provides meaningful feedback on how an MVP may be revised to better align with the aforementioned criteria before being considered for implementation. In some instances, discussions regarding a given MVP candidate may be iterative, and may call for a few meetings to discuss changes. Some MVP candidates may be identified as ready for implementation in the upcoming year, while others may require additional work. That is the reason why we would review MVPs on a rolling basis. In instances where an MVP may not be ready for implementation in the upcoming performance period, it may be ready by the following performance period. The timing in which an MVP may be ready for implementation will be dependent of the MVP's readiness and ability to meet the aforementioned MVP criteria. New measures will need to follow the existing pre-rulemaking processes or QCDR measure requirements to be considered for inclusion in an MVP. While we intend to continue to work with stakeholders in an iterative manner that fosters transparency, CMS will ultimately determine if and when an MVP candidate is ready for implementation. We intend to follow our normal processes of notice and comment rulemaking to make stakeholders and the public aware of which MVPs we believe are ready for implementation for the upcoming performance period.

Comment: A few commenters requested more guidance around expectations, MVP candidate assessment processes and communications. One commenter requested CMS publish MVP development status updates while another commenter requested a CMS website that would provide information on MVPs under development and CMS' initial assessment data.

Response: We intend on hosting a MVP development webinar that will provide additional clarity on expectations, the assessment process and communications between CMS and stakeholders who develop candidate MVPs. We thank stakeholders for their recommendations of how we can make the MVP development process more

transparent, and will take these suggestions under consideration for future implementation, as operationally feasible.

After consideration of the public comments, we are finalizing our proposals as proposed.

(b) Implementing Meaningful Measures in MVPs

(i) Incorporating Population Health Measures Into MVPs

In the CY 2020 PFS proposed rule (84 FR 40742 through 40743), we expressed our interest in incorporating population health measures calculated from administrative claims-based data as a part of the foundational layer within MVPs, in an effort to improve patient outcomes, reduce reporting burden and costs, better align clinician quality improvement efforts, and increase alignment with APMs and other payer performance measurement. Through the RFI, stakeholders expressed concerns with including population health measures due to concerns with reliability, validity, attribution, unintended consequences and/or risk adjustment of claims-based population health measures. We understand stakeholder concerns around the population health measures that were previously considered, and are looking into ways to address and mitigate those concerns. We also received some support from stakeholders who agreed that population health measures will reduce administrative burden with the belief that these measures are not any less relevant to specialists. In MIPS, we currently have one administrative-claims based measure, the All-cause Hospital Readmission measure, which is calculated and scored for groups with 16 or more clinicians that meet a 200-patient case minimum, as described in the CY 2017 Quality Payment Program final rule (81 FR 77300). As described in Appendix 1 of the CY 2021 PFS proposed rule, we proposed to replace the All-cause Hospital Readmission measure with a Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System Program (MIPS) Eligible Clinician Groups because the re-specified measure promotes a system level approach by clinicians, with a focus on high risk conditions such as COPD and heart failure. We referred readers to Appendix 1 of the proposed rule for detailed discussion of the newly proposed measure.

The following is a summary of the comments we received and our responses.

Comment: A few commenters support the use of population health measures in MVPs that are relevant to the population and clinical discipline and focus on preventive measures and early detection.

Response: We thank the commenters for their support, and agree that population health measures should be relevant to the population and the clinical topic being measured. We encourage stakeholders to utilize our pre-rulemaking processes to develop additional clinically relevant population health measures. We also agree that prevention and early detection are two areas where population health measures can be focused on.

Comment: Several commenters voiced their opposition to use of population health administrative claims-based measures in MVPs with some listing concerns about the applicability of MVP population health measures to physician groups or specialists, such as anesthesiologists, pathologists and ophthalmologists. A few commenters suggest that population health measures are not actionable with one commenter listing an example of the hospital-wide readmission measure as not actionable for surgeons. One commenter expressed that MVPs should include measures that are meaningful to group practices and their clinicians rather than administrative claims or population health measures, listing the following concerns: Attribution; retrospective analysis; inability to measure individual physicians; and reliability. A few commenters voiced a concern about performance comparison inequities in applying population health measures across different specialties. One commenter provided an alternative to population health measures that require a large sample that we work with specialty societies to explore ''better'' ways to tie claims data to more robust clinical data collected by registries.

Response: We disagree with commenters who oppose the use of population health administrative claims-based measures in MVPs. Measures such as MIPS hospital wide readmission (HWR) should be used within MVPs. The HWR measure is not a traditional population health measure but is designed to incentivize shared responsibility for clinical outcomes.

This measure is a re-specification of the All-Cause Readmission (ACR) measure currently within the MIPS program, which attributes outcomes solely to the primary care physician that provides the plurality of care during the measurement period, regardless of whether this care was provided before, during or after the inpatient stay. The primary care physician may not be the only clinician with opportunity to impact readmissions. The intent of this measure is to improve upon the attribution of the current ACR measure and incentivize collaboration of care across inpatient and outpatient settings by considering shared attribution to up to three eligible clinician groups that provide care for patients inside and outside of the hospital, and therefore are in position to influence patient risk of readmission.

Our contractor convened a Technical Expert Panel (TEP) to seek detailed input from clinicians and patients to attribute the unplanned 30-day readmission outcome to multiple clinicians with the ability to impact readmission risk through their care and communication. The TEP and clinical consultants, most of whom are clinicians themselves and include representatives from anesthesia and surgery, strongly supported the attribution model. They identified the primary inpatient clinician, discharge clinician, and primary outpatient clinician as important roles in providing appropriate care, practical recommendations, and care transitions and with ability to influence readmission risk.

As such, we disagree with the commenter that the HWR measure is not actionable for these clinicians. Specifically, the primary inpatient clinician is responsible for the medical care provided during the admission, referring patients to inpatient specialists and prescribing medications; the delivery of their care during the hospital admission can influence whether the patient returns with unresolved medical issues or side effects from inappropriate medication or dosage. The discharge clinician is responsible for preparing the patient for discharge, including determining the patient is well enough to leave the hospital, understands their condition and treatments, and has been referred to outpatient specialists or therapy, as needed. Providing clear instructions and arrangements help ensure that the patient adheres to care, medication, and lifestyle changes outside of the hospital (Bowles et al, 2014, Philips et al, 2004, DeCaporale-Ryan et al, 2017, and Verhaegh et al, 2014). The primary outpatient clinician is responsible for the care of the patient outside of the hospital and can prevent readmissions by ensuring accessibility to care and availability for consultations within 30 days after discharge. Through their individual roles and together through coordinated care, these clinicians can reduce the risk of readmission.

NQF panel and committee members have voted on this measure several times, all of which concluded in favor of endorsing the measure. Final endorsement of the measure was deferred to the Spring 2020 Consensus Standards Approval Committee (CSAC) due to efforts to reduce burden for committee members who may need to prioritize COVID–19 in their communities.

Regarding the concern that the HWR measure cannot measure individual physicians, the intent of the HWR measure is to measure performance at the clinician group level where the group can assess and improve the performance across their practice. Regarding reliability, the HWR measure was found to have substantial signal to noise reliability, ranging from 0.82 for surgical to 0.92 for neurology specialty cohorts, when clinician groups were measured on at least 200 patients, the minimum threshold for the current ACR measure. While it is true that clinician groups representing different specialties may have different baseline outcome rates because of different patient condition or procedure cohorts, the use of standardized outcome rates for measurement ensures comparability of measure scores across these different cohorts.

After consideration of public comments, we are finalizing our proposal as proposed.

(ii) Incorporating QCDR Measures Into MVPs

In the CY 2020 PFS final rule, we sought comments from stakeholders as to whether QCDR measures should be considered for integration within MVPs. Stakeholders were generally supportive of including QCDR measures within MVPs, but others expressed concern that including QCDR measures within MVPs would require clinicians to use certain third party intermediaries which may cause additional burden for clinicians who may need to change their current reporting method and undertake additional costs associated with reporting through QCDRs. Under the existing MIPS program and as described at § 414.1330(a)(2), for a MIPS payment year, we can use approved QCDR measures as described under § 414.1400 to assess performance in the quality performance category. We continue to believe that the development of QCDR measures by QCDRs is important as it provides measures that are relevant, applicable, and meaningful to clinicians, and addresses gaps that are not addressed by measures available through the MIPS quality measure inventory. In envisioning MVP development for the 2022 performance period and future years, we believe it is important to consider the opportunity to include QCDR measures within MVPs. Prior to consideration of including the QCDR measure within a candidate MVP, QCDR measures must meet all existing criteria under § 414.1400(b)(3) and the criteria described at § 414.1400(b)(3)(v)(C)(*4*) that QCDR measures should be fully tested at the clinician level prior to the QCDR measure being included in an MVP. We referred readers to section IV.A.3.g.(2)(b)(iv) of the CY 2021 PFS proposed rule for additional discussion of this requirement.

Regarding the timeline to which MVPs and QCDR measures may be established, we have identified differences with the timelines that each of these processes follow. As described in the CY 2020 PFS final rule (84 FR 62948), we finalized the definition of an MVP at § 414.1305 to mean a MIPS Value Pathway is a subset of measures and activities established through rulemaking. Furthermore, as described in the CY 2019 PFS final rule (83 FR 59900) and at § 414.1400(b)(1), entities that wish to self-nominate as a QCDR and submit QCDR measures for CMS consideration must do so within the 60-day self-nomination period that begins on July 1 of the calendar year prior to the applicable performance period and ending on September 1 of the same year. QCDR measures are typically reviewed and approved in the preceding months after the close of the self-nomination period. Therefore, we proposed that beginning with the with the 2022 performance period, only QCDR measures that were approved in the previous year may be considered for inclusion within a candidate MVP. Furthermore, we proposed that the QCDR measures included within a candidate MVP must meet the existing criteria that are currently established at § 414.1400(b)(3). In the traditional MIPS program, we stated that entities that meet the QCDR definition can develop QCDR measures to fulfill the quality performance category reporting requirements. We stated that we believe that QCDR measures can continue to fulfill the reporting requirements of the quality performance category within MVPs. Candidate MVPs should be submitted utilizing the process as described in section IV.A.3.a.(2)(a) of the CY 2021 PFS proposed rule. Candidate MVPs that are approved for inclusion in the upcoming performance period must be proposed and finalized through notice-and-comment rulemaking. Candidate MVPs that include QCDR measures will also need to be proposed and finalized through notice-and-comment rulemaking in order to be available for reporting in the upcoming performance period. Therefore, in instances where MVPs are finalized through notice-and-comment rulemaking with QCDR measures, we proposed that those QCDR measures would be eligible for 2-year QCDR measure approval as described at § 414.1400(b)(3)(vi).

In the CY 2018 PFS final rule (82 FR 53813), we finalized that beginning with the 2018 performance period and for future program years, that QCDRs may seek permission from another QCDR to use an existing QCDR measure that is owned by another QCDR.

The following is a summary of the comments we received and our responses.

Comment: Several commenters supported inclusion of QCDR measures in MVPs.

Response: We thank the commenters for their support; we believe that expanding the availability of QCDR measures that could be included into MVPs will allow for the development of more innovative and meaningful MVPs that are relevant to specialties and subspecialties.

Comment: One commenter suggested that we consider separating dates for QCDR self-nomination and MVP candidate submission due to the amount of developer financial and administrative resources required.

Response: To clarify, as described in the CY 2019 PFS final rule (83 FR 59898) the QCDR self-nomination starts on July 1st to Sept 1st of the year prior to the performance period. As described in the CY 2021 PFS proposed rule (85 FR 50284), beginning with the 2022 performance period, only QCDR measures that were approved in the previous year may be considered for inclusion in a candidate MVP. As stakeholders develop their MVP candidates, and consider the inclusion of their QCDR measures, only those that were approved for the 2022 performance period could be considered for inclusion. We believe the existing differences in the timeline will help to alleviate some of the administrative resources required for both processes. For example, a QCDR will self-nominate a QCDR measure for the 2022 performance period sometime between July 1, 2021 and September 1, 2021. The 2022 performance period QCDR measure approval decisions will be shared with the QCDRs in late Fall of 2021, with finalization of the QCDR measure specifications by the end of 2021. QCDR measures that are approved

for the 2022 performance period, and have been fully tested, may be considered for inclusion in MVPs for the 2023 performance period through the rulemaking process that will occur throughout CY 2022. MVPs that include QCDR measures, which are finalized through the CY 2023 PFS final rule, will be tracked to, and those QCDR measures will be given multi-year approval, so that the QCDR will not have to self-nominate that measure during self-nomination for the 2024 performance period.

Comment: A few commenters supported approval of Qualified Clinical Data Registry (QCDR) measures for 2 years or longer to promote burden reduction and continuity. One commenter supported maintaining MVP QCDR measure approval for 2 years unless the measure steward agrees with a change in approval status. The commenter voiced support for removing a measure if it reflects an outdated clinical deadline or if the QCDR that nominated the measure is no longer in good standing but does not support CMS removing a measure before its second year for it being topped out or duplicative of a more robust measure.

Response: We thank the commenters for their support, but note that a change in a QCDR measure's approval status will be left at the discretion of CMS, and as long as the QCDR measure continues to meet the criteria described at § 414.1400(b)(3)(vi). We disagree that QCDR measures that are identified as topped out or duplicative of a more robust measure should not be removed as it is contradictory to the Meaningful Measure Framework. Measures that are topped out provide limited to no value to quality improvement, and duplicative measures serve no purpose in quality measurement.

Comment: A few commenters did not support our proposal to require QCDR measures be approved for use in MIPS for a year prior to being included in an MVP voicing a concern that this will delay use of meaningful QCDRs measures in MVPs. Another commenter suggested that instead of the proposed 1-year period prior to measure inclusion in MVPs, that QCDR measures be tested entirely before inclusion in an MVP.

Response: We disagree and believe that in order for a QCDR measure to be considered a QCDR measure, it must be approved as such through the Self-Nomination process prior to being proposed through notice and comment rulemaking as a part of an MVP. Measures that do not undergo this process are not considered QCDR measures until they are formally approved as such. Furthermore, to provide clarity, we proposed in the CY 2021 PFS proposed rule (85 FR 50284) that any QCDR measure that is being considered for inclusion in an MVP, must be fully tested before it can be included, as we want to ensure that the measures included in MVPs are a reliable subset of the MIPS measure inventory.

Comment: One commenter suggested, as a way to shorten the timeline, that we consider allowing stakeholders to submit MVPs that include QCDR measures that are simultaneously undergoing approval with final inclusion in an MVP pending their meeting full testing and reliability requirements and receiving final approval.

Response: We disagree, as the differences in the timelines between QCDR measure approvals through the Self-Nomination process and the timeline for notice and comment rulemaking differ, and would not allow for sufficient time to review the results to determine whether a QCDR measure is reliable, feasible, and valid enough for inclusion in an MVP. We are concerned with the unintended consequences of simultaneously including QCDR measures within MVPs before they are approved. If the QCDR measure is not approved through self-nomination, we would not be able to finalize the inclusion of the QCDR measure within the MVP. Time will be needed to determine the implications of the QCDR measure not being finalized in the MVP, and whether there are sufficient number of measures available in the MVP in the event that the QCDR measure cannot be included. Since MVPs will allow for the creation of focused subsets of measures and activities on a given clinical topic, thereby focusing the choices available to clinicians, we believe that all measures included in MVPs should have to meet and pass full measure testing criteria inclusive of reliability, validity, and feasibility. QCDR measures that pass measure testing are considered to be more reliable, we are concerned that incomplete testing will have downstream impacts to clinicians who may not be able to successfully report on measures, or that it may result in skewed results that may impact payment adjustments. Therefore, it would be appropriate to wait until the QCDR measure is officially approved through the self-nomination process before it is considered and finalized for inclusion in an MVP through notice and comment rulemaking.

Comment: One commenter suggested that we use the 2020 performance year QCDR measure approval standards for MVP QCDR measures, and stated that data for reliability and performance rates are often more robust after the QCDR measure has been available for MIPS reporting for at least 1 year.

Response: We disagree. The 2020 performance period QCDR measure approval standards do not currently include QCDR measure testing requirements. Our preference is to include QCDR measures in MVPs only after they have been fully tested and are comparable in standard to the measures within the MIPS quality measure inventory that have undergone vigorous testing.

Comment: One commenter requested further clarification related to how QCDR measures will be selected for MVPs to ensure measures are most relevant, applicable and meaningful to clinicians. The commenter requested that CMS clarify the impact to an MVP if CMS revokes the QCDR measure's second year of approval. The commenter voiced concerns related to the lack of incentives for clinicians to use new QCDR measures that require significant financial and administrative resources to develop and requested support for inclusion of these new QCDR measures.

Response: QCDR measures can be included in MVPs at the discretion of the stakeholder developing the MVP candidate. We refer readers to our previously established policies in the CY 2018 PFS final rule (82 FR 53813), where we finalized that beginning with the 2018 performance period and for future program years, that QCDRs may seek permission from another QCDR to use an existing QCDR measure that is owned by another QCDR. If a QCDR measure approval is revoked for an upcoming performance period, the QCDR measure will be simultaneously proposed for removal from the MVP. As a part of the MVP maintenance process, there may be consideration of including another measure in the QCDR measure's place. To clarify, new QCDR measures can be considered for inclusion in an MVP so long as the measure has met all requirements.

Comment: One commenter voiced concerns regarding burden associated with completing the third party intermediary self-nomination application prior to publication of the QPP final rule and then selecting which MVPs to support after publication of the final rule. To address this concern, the commenter suggested a 1-year delay between selecting the MVPs that QCDRs and qualified registries can support and beginning the reporting for an MVP, and separating the dates for completion of the QCDR self-nomination and the MVP self-nomination.

Response: We disagree that there would be additional burden associated with the process of having approved QCDRs and qualified registries indicate whether they are supporting any of the finalized MVPs once the final rule is published. We believe a 1-year delay would be a disadvantage, because it delays the timing in which a third party intermediary can support an MVP. The timing of when QCDRs would approve their qualified postings typically aligns with the timing of the posting of the final rule; therefore, QCDRs would be able to select the MVPs they wish to support for the upcoming performance period based on the final rule publication, and have those MVPs included in their qualified posting before it is published by January 1st of the performance period.

After consideration of the public comments, we are finalizing our proposals as proposed.

(c) Reporting of MVPs Through Third Party Intermediaries

Through the MIPS program, QCDRs, qualified registries, and Health IT vendors support the reporting of the Quality, Promoting Interoperability, and Improvement Activity performance categories, as proposed and codified at § 414.1400(a)(2). We believe that third party intermediaries who support the aforementioned performance categories are able to support MVPs, since they will be comprised of measures and activities from these performance categories, as well as cost measures that are calculated by CMS (thereby requiring no additional effort by third party intermediaries). We believe allowing third party intermediaries to support MVPs will offer eligible clinicians and groups additional methods to report an MVP. We refer readers to section IV.A.3.g. of this final rule for additional discussion of the proposals.

Since QCDR and qualified registry applicants would be submitting their self-nomination application prior to the publication of the final rule, we will work to establish a process to allow QCDRs and qualified registries to identify and select which MVPs they can support following the publication of the final rule. We sought comments on the proposal.

The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed that third party intermediaries should be allowed to support MVP reporting.

Response: We thank the commenters for their support, and agree that third party intermediaries should be allowed to support the reporting of MVPs. Clinicians and groups may find it beneficial to utilize a third party intermediary to report an MVP for the additional support they may provide.

Comment: One commenter cautioned that the use of third party intermediaries for MVPs could result in financial burden for practices required to purchase additional measure submission services.

Response: We understand that there may be some financial burden associated with utilizing a third party intermediary to report MVPs; however, we note that clinicians and groups are not required to utilize a third party intermediary to report an MVP. Clinicians and groups may use existing reporting options to report on the measures and activities within an MVP without utilizing a third party intermediary.

After consideration of the public comments, we are finalizing our proposals as proposed.

(3) Transition to MVPs

(a) Timeline for MVP implementation

In response to the RFI in the CY 2020 PFS final rule, we have received comments from stakeholders that indicated a gradual implementation of MVPs. Through the MVP development process, we seek to collaborate with stakeholders in the development of MVPs that are meaningful and applicable to clinicians and groups. Therefore, we understand the need for an incremental approach as we transition eligible clinicians and groups to MVP reporting as they are implemented. In light of the PHE of COVID–19, we have decided to delay the implementation of MVPs, and revisit potential MVP implementation through future rulemaking, possibly beginning with the 2022 performance period. Although we believe in the importance of transforming the MIPS program to create greater meaning for clinicians, we understand that there are clinicians who are on the frontlines taking care of COVID–19 patients that should not be burdened with having to learn a new method of reporting for the MIPS program at this time. Overall, our goal is to gradually implement MVPs for all MIPS eligible clinicians and groups overtime, to ensure that MVPs are designed and available in a manner relevant to clinicians. We stated that we intend to continue to work closely with stakeholders to develop MVPs that are relevant to various specialties, and understand that a level of flexibility is needed to allow for meaningful reporting.

The following is a summary of the comments we received and our responses.

Comment: Many commenters supported the proposal to delay MVP Implementation as a result of the PHE for COVID–19, and recommended that CMS introduce MVPs gradually.

Response: We thank commenters for their support, as described in the CY 2021 PFS proposed rule (85 FR 50279), we have delayed our timeline for MVP implementation in light of the PHE for COVID–19. We want to move forward with the transformation of the MIPS program in a manner that does not take away from the nation's response to the COVID–19 pandemic. Furthermore, as described in the CY 2021 PFS proposed rule (85 FR 50284 through 50285), we understand the need for an incremental approach as we transition clinicians and groups to MVP reporting as they are implemented.

Comment: A few commenters recommended that MVPs be delayed beyond 2022 as well, yet did not cite specific reasons why.

Response: While we appreciate the commenters concerns, we believe that further delay is not needed as we have emphasized the need for an incremental approach to transition clinicians and groups to MVP reporting.

After consideration of public comments, we are finalizing our proposals as proposed.

b. APM Performance Pathway

(1) Overview

In the CY 2020 PFS final rule (84 FR 62568), we finalized the MIPS Value Pathway framework as a means of reducing reporting burden, increasing meaningful measurement, and continuing to encourage movement through MIPS away from fee-for-service (FFS) payments and towards APMs. Burden reduction and meaningful measurement are important goals in relation to all eligible clinicians, and we recognize that the best means for achieving these goals may be different for MIPS eligible clinicians that have not yet joined an APM than for those MIPS eligible clinicians who already are participating in APMs, and therefore, have different reporting obligations. This is particularly true for eligible clinicians in Advanced APMs who are subject to MIPS either because they are Partial QPs for a year and elect to participate in MIPS or because they fall below the applicable Partial QP threshold for a performance year.

We proposed at § 414.1367 to establish an APM Performance Pathway (APP) under MIPS beginning in the

2021 MIPS performance year, designed to provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation (85 FR 50285).

(2) Applicability

We proposed that the APP will be in effect beginning January 1, 2021, and would be an optional MIPS reporting and scoring pathway for MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the four snapshot dates (March 31, June 30, August 31, and December 31) during a performance period, beginning in the 2021 MIPS performance period.

(a) Reporting Through the APM Performance Pathway

We proposed that individual MIPS eligible clinicians who are participants in MIPS APMs may report through the APP at the individual level. Groups and APM Entities may report through the APP on behalf of their constituent MIPS eligible clinicians; however, the final score earned by the group through the APP would be applied only to those MIPS eligible clinicians who appear on a MIPS APM's Participation List or Affiliated Practitioner List on one or more snapshot dates. The final score applied to each individual MIPS eligible clinician would be the highest available final score for that clinician (TIN/NPI), or a Virtual Group score, if applicable, as discussed in the CY 2021 PFS proposed rule (85 FR 50315).

As described further in the CY 2021 PFS proposed rule (85 FR 50231), ACOs participating in the Medicare Shared Savings Program would be required to report through the APP for purposes of assessing their quality performance for that program, but MIPS eligible clinicians participating in these ACOs also would have the option of reporting outside the APP, or within it at an individual or group level, for purposes of being scored under MIPS, like all other MIPS APM participants. As the APP would be optional for purposes of MIPS scoring, under the proposal MIPS APM participants would be able to report through the APP or through any other available MIPS reporting mechanism they chose.

We refer readers to the CY 2021 PFS proposed rule (85 FR 50315) for information concerning our proposed changes to the hierarchy that will apply when more than one final score is associated with a TIN/NPI.

We received the following comments on these proposals.

Comment: A few commenters supported the opportunity for individual MIPS eligible clinicians and groups that participate in MIPS APMs to report through the APP or through any other available MIPS reporting mechanism they choose. They believe this approach would enable them to earn a higher score where they perform above the APM Entity average.

Response: We thank commenters for their support of this proposal. We agree that this approach should enable MIPS eligible clinicians and groups that strive to improve their performance to be rewarded with the MIPS score that reflects those efforts. We also believe that this policy approach will create more flexibility for multispecialty practices to report on measures that are the most meaningful to their clinicians.

After considering public comment, we are finalizing this policy as proposed.

(b) MIPS APMs

In the CY 2021 PFS proposed rule (85 FR 50285), we proposed to amend our definition of MIPS APM at § 414.1305 as an APM that meets the criteria in § 414.1367(b). We also proposed to codify the following MIPS APM criteria at the new § 414.1367(b). We proposed to maintain two criteria for MIPS APMs that currently are included at § 414.1370(b)(1) and (3) respectively, namely that: (1) An APM Entity participates in the APM under an agreement with CMS or through a law or regulation; and (2) the APM bases payment on quality measures and cost/utilization. However, under the proposed policy, for purposes of the MIPS performance period we would not depend on the availability of quality measure data reported directly to the APM, and we did not propose to continue requiring that MIPS APMs be in operation, and therefore, collecting quality data for the entirety of the performance period. We also noted that currently, to be a MIPS APM, § 414.1370(b)(2) requires that an APM must be designed such that its APM Entities include at least one MIPS eligible clinician on a Participation List, and does not include APMs that use only Affiliated Practitioner Lists. However, we believe that because we did not propose to require reporting through the APP be done exclusively at the APM Entity level, it is not necessary to limit use of the APP to APM Entities alone. Therefore, we proposed to expand the definition of MIPS APM to include those APMs in which there is only an Affiliated Practitioner List and that otherwise meet the proposed MIPS APM criteria.

We did not receive any comments on these proposals and are finalizing as proposed.

(3) MIPS Performance Category Scoring in the APM Performance Pathway

In general, MIPS reporting and scoring requirements are applicable to all MIPS eligible clinicians, including those reporting through the proposed APP. However, the following reporting and scoring rules would apply only to those MIPS eligible clinicians, groups, or APM entities reporting through the APP.

(a) Quality Performance Category

We proposed that, beginning in the 2021 performance period, MIPS eligible clinicians scored under the APP would be scored on the quality measure set finalized for such MIPS performance period (85 FR 50285 through 50286).

For PY 2021, we proposed to use the measures listed in Table 46 for purposes of quality performance category scoring for the APP.

TABLE 46: APM Performance Pathway Quality Measure Set

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Quality ID:001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID: 236	Controlling High Blood Pressure	eCQM/MIPS CQM	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Measure # TBD	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions

For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we proposed to remove such measure from the quality performance category score for such MIPS eligible clinician, group, or APM Entity.

For MIPS eligible clinicians, groups, or APM Entities reporting through the APP, we proposed not to apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP measure set is determined to be topped out. Because the measure set is fixed, we noted that we do not believe it is appropriate to limit the maximum quality performance category score available to them. Should an APP measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

In the CY 2020 PFS proposed rule, we sought comment on aligning the Shared Savings Program version of the Multiple Chronic Conditions (MCC) measure (that is, the ACO MCC) with the MIPS version of the MCC measure (see 84 FR 40711 and 40712). We noted that the MIPS MCC claims-based measure is similar to the ACO MCC currently used to assess ACO quality under the Shared Savings Program. The MIPS MCC and ACO MCC measures are similar because they both target patients with multiple chronic conditions, but the cohort, outcome, and risk model for the MIPS MCC measure varies from the ACO MCC measure. The cohort for the ACO MCC measure includes eight conditions whereas the MIPS MCC measure includes nine conditions, with the additional condition being diabetes. The ACO MCC measure does not adjust for social risk factors whereas the MIPS MCC measure adjusts for two area-level social risk factors: (1) AHRQ socioeconomic status (SES) index; and (2) specialist density. In 2019, we added a revised ACO MCC measure to the 2019 Measure under Consideration list for the Shared Savings Program for consideration by the Measure Applications Partnership (MAP) Clinician Workgroup. The revised MCC measure specifications aligned with the MIPS MCC measure by: (1) Adding a diabetes cohort; (2) excluding any admissions within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility; and (3) adjusting for the AHRQ SES index and specialist density social risk factors. The only remaining difference between the MIPS and Shared Savings Program versions of the measure would be attribution, which is program-specific. Attribution for Shared Savings Program ACOs uses the Shared Savings Program beneficiary assignment methodology, which emphasizes primary care. During the MAP discussion, it was noted that the original ACO MCC measure has been in use in the Shared Savings Program since 2015, and the MAP expressed no concerns with respect to feasibility and implementation of the revised MCC measure. A measure has high reliability if it produces consistent results from multiple measurements, in other words, it reflects a signal, rather than random error associated with measurement. Reliability values range between zero (all error, little signal) to 1.0 (no error, all signal).[121] The median signal-to-noise reliability for all Shared Savings Program ACOs in 2018 was 0.96 ranging from 0.12 to 1.00 (IQR: 0.94–0.98), indicating an overall excellent reliability of the measure.[122]

The MAP final recommendation for this measure was ''conditional support for rulemaking.'' [123] We intended to take the revised measure through the National Quality Forum (NQF) endorsement process in 2020, but as a result of delays caused by the PHE for COVID–19, we will defer seeking NQF endorsement until 2021. Because the revisions would make the ACO MCC measure more aligned with the MIPS version and given the support received from the MAP, we proposed to include the revised All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions measure in the APP measure set to be reported on by any Medicare ACO.

We received the following comments on the proposal.

Comment: Some commenters requested clarification as to what would

[121] Adams, John L., Ateev Mehrotra, and Elizabeth A. McGlynn, Estimating Reliability and Misclassification in Physician Profiling. Santa Monica, CA: RAND Corporation, 2010. *https://www.rand.org/pubs/technical_reports/TR863.html.*

[122] CMS used the 2018 Shared Savings Program ACO beneficiary assignment data to test the revised MCC measure. Here, reliability refers to measure score reliability of the revised MCC measure.

[123] *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.*

happen if they were unable to report on one or more measures due to submitter type or case size limitations.

Response: Individual MIPS eligible clinicians, groups, and APM Entities reporting through the APP will be scored only on those quality measures on which they are able to report. For example, an APM Entity that is not an ACO will not be scored on the ACO MCC measure; similarly a group that did not meet the minimum beneficiary sample size for the CAHPS for MIPS survey would not be required to report on this measure. In these cases that measure would be removed from the quality performance category score calculation entirely.

Comment: Some commenters expressed concern that the proposed measures do not adequately reflect the scope of practice of all clinicians, particularly specialists, and suggested that we consider expanding the quality measure set to include specialty-specific quality measures, or retaining the use of the quality measures from their APMs, as was done under the APM scoring standard.

Response: We recognize that there are limitations in the ability of the proposed APP quality measure set to fully represent the scope of practice of all specialties and clinicians. However, the goal of the APP quality measure set is not necessarily to reflect the specific quality measure work being done by these clinicians within their respective APMs, but rather to reduce the burden of reporting on quality measures twice: once to MIPS and once to their APMs. We believe by using this broadly applicable population health based measure set, we will enable MIPS APM participants to focus more of their energy and attention on the quality measures being reported through their APMs, while relying on a consistent measure set within the APP from one year to the next. We further refer readers to CY 2020 PFS final rule (84 FR 63007) for a discussion around the operational infeasibility of continuing to use quality measure data reported directly to APMs.

Comment: Some commenters noted confusion about which submission types would be permitted under the APP.

Response: As defined at § 414.1305, submission type refers to the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web Interface. In Table 41 of the CY 2021 PFS proposed rule (85 FR 50286) we proposed a list of quality measures that would be included in the APP. For those measures in this list that are already included in the MIPS quality measure inventory (Quality IDs 001, 134, and 236) the previously established submission types for each measure would continue to be accepted, including by the APM Entity, as applicable, which we proposed to add as a submitter type. We note that the CAHPS for MIPS survey may only be reported by a Third Party Intermediary. For those measures that are not already included in the MIPS quality measure inventory (Quality IDs TBD), the proposed measures are administrative claims-based and do not require data submission

Comment: A few comments supported the proposed APP quality measure set for reducing burden on MIPS eligible clinicians who are also participating in MIPS APMs. Commenters noted that the measures selected represent a broad sampling of practice areas, and should be applicable to nearly any practice group.

Response: We thank the commenters for their support.

Comment: A few commenters objected to the use of two administrative claims measures, relative to the number of non-claims measures. These commenter noted a preference for more performance-based measurement that would be reported by the MIPS eligible clinician, group, or APM Entity.

Response: We understand the concern about the use of more administrative claims measures in the APP quality set, in light of the fact that, historically, these measures produce somewhat lower scores than measures such as those in the CMS Web Interface which are largely topped-out. It is our intent to balance the goals of reducing reporting burden while incentivizing increased quality performance by including in the APP measure set measures that will represent quality performance without creating additional reporting burden. We believe the proposed measure set, and the relative weight of the different submission types, helps to strike that balance.

Comment: Some commenters expressed support for the move to all-payer data for scoring MIPS quality measures for ACOs. These commenters believe that the all-payer data will more accurately reflect the efforts they have made to improve quality performance across their practice.

Response: We agree that by incorporating all-payer data into both the numerator and the denominator, we will be getting a better picture of each MIPS eligible clinician's quality performance across care settings, and incentivizing quality improvement for all patients.

Comment: Commenters recommended that CMS seek NQF and MAP endorsement of any measure to be included in the APP before the measure is included in the APP. Additionally, commenters suggested that CMS seek additional stakeholder input and were concerned that the Measure Applications Partnership did not review these proposed changes.

Response: With regard to the commenters' recommendations that we use measures that are NQF endorsed and have been reviewed by the AMP, we note that where possible CMS uses measures that have been NQF endorsed. In the APP measure set, the three eCQM/CQM measures are NQF endorsed and we plan to take the revised MCC measure that was reviewed by the MAP in December 2019 through the NQF endorsement process in 2021.

Comment: Several commenters have concerns with the Screening for Depression and Follow-up plan measure and recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. One commenter did not support the measure because it was not an outcome measure, and shared concerns that it had previous measurement challenges. Additionally, one commenter noted that depression screening can be difficult to achieve with the limited access that the PHE for COVID–19 has created and suggested that measures be viewed through the lens of the current environment.

Several commenters expressed concerns that this measure determines performance based on a single reading and that there are limitations in accepting patient reported home readings. The commenters also recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. Another commenter recommended that CMS consider including home visits in its measure sets. One commenter supported the Controlling High Blood Pressure measure, noting that successfully treating high blood pressure can save lives.

One commenter was concerned that the Diabetes: Hemoglobin A1c (CbA1c) Poor Control measure is not appropriate for frail, seriously ill, or home limited patient populations. Another commenter supported this measure, citing the fact that uncontrolled diabetes leads to comorbidities.

Response: We appreciate the commenters' feedback on these eCQM/CQM MIPS measures. This measure set was developed using stakeholder

feedback and in conjunction with CMS leadership to help achieve the goals of the APP. Each of the eCQM/CQM quality measures in the APP measure set is MIPS quality measures that has been in use for several MIPS performance years and have a track record of reliability that was taken into consideration when choosing the APP measure set. We believe that this particular set of measures best achieves our goal of reducing reporting burden while providing a quality measure set with measures that are meaningful and widely applicable to various provider types. As with all MIPS quality measures, we encourage continued stakeholder engagement in developing and improving upon measure use and specifications.

Comment: One commenter provided general support for the concept of measuring outcomes for patients with multiple chronic conditions at the group practice level or higher and provided support for the specific methodological changes proposed, including incorporating additional risk factors related to socioeconomic status and social risk factors. Several commenters expressed concerns related to the Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs measure. One commenter did not support using this measure to assess the quality performance of ACOs because they noted the Core Quality Measures Collaborative (CQMC) ACO/Patient-Centered Medical Home (PCMH) core measure set would be less burdensome and would align the measures across public and private payers, making it a better measure set for ACOs. Some commenters stated that this measure does not meet the −.8 reliability threshold because the measure score reliability ranged from 0.12 to 1.00 using data from the 2018 performance year. Therefore, this commenter recommended that CMS increase testing for risk adjustment, increase case minimums, and demonstrate face validity (whether these measures appear to measure what they claim to measure) and that the results are valid when attributed to an ACO. The commenter also recommended that CMS work with stakeholders to improve the measure specifications before this measure is used as part of a limited quality measure set. Another commenter opposed inclusion of this measure in the quality measure set under the APP due to limited information on how the measure performs and because it has not been endorsed by the NQF. The same commenter recommended that CMS increase the minimum sample size to produce a minimum reliability threshold of sufficient magnitude and encouraged CMS to validate the measure through additional testing, such as predictive and construct validity, to ensure that application of the measure to assess the quality performance of ACOs is appropriate and yields scores that are valid and useful.

Another commenter was encouraged to see that the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) index and density of physician specialists were included in the risk adjustment for the measure in the 2018–2019 Measures Application Partnership (MAP) review. This commenter emphasized that CMS should ensure that social risk factors are tested and included in the risk adjustment for the measure and that CMS should also consider including additional variables, such as dual eligibility, frailty, and age, prior to implementing the measure in the APP.

Response: The All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions for ACOs)—the ''ACO MCC'' measure is currently being used to assess ACOs' quality performance under the Shared Savings Program. The proposed MCC measure was created by aligning the current ACO MCC measure with the current MIPS MCC measure by (1) adding a diabetes cohort; (2) excluding any admissions within 10 days of discharge from a hospital, skilled nursing facility, or acute rehabilitation facility; and (3) adjusting for the AHRQ SES index and specialist density social risk factors. The MAP expressed no concerns with respect to implementing this measure and, as discussed in the CY 2021 PFS proposed rule (85 FR 50286), the median signal-to-noise reliability for all ACOs scored on this measure in 2018 was 0.96 ranging from 0.12 to 1.0 (IQR: 0.94–0.98), indicating an overall excellent reliability of the measure. This measure is currently under NQF review.

We believe that this measure will provide a meaningful assessment of ACO quality performance with limited additional reporting burden.

Comment: Many commenters were opposed to sun-setting the CMS Web Interface and its use under the APM scoring standard. Several commenters expressed concern about the timeline for preparing to report APM Entity level data for the 3 eCQM/MIPS CQMs in time for the 2021 performance year. Specifically, ACOs may face difficulty in aggregating the data needed for reporting, particularly in light of the PHE for COVID–19.

Response: We understand that implementing a new reporting system will require administrative time and coordination in order to be prepared not only for reporting APM Entity level data, but for collecting these data as early as January 1, 2021. Particularly in light of the circumstances surrounding the PHE for COVID–19, we believe that it is in the public interest to finalize our proposed quality measure set with a few modifications to include the CMS Web Interface for one year.

After considering public comment, we are finalizing each of the quality measures included in the quality measure set listed in Table 41 of the CY 2021 PFS proposed rule (85 FR 50286).

In addition, we refer readers to section IV.A.3.c.(1)(c) of this final rule, where we are finalizing our proposal to remove the CMS Web Interface with a 1 year delay. As a result, the CMS Web Interface measure set will not be removed until the CY 2022 MIPS performance period. In response to public comments, we are finalizing the addition of the CMS Web Interface measure set to the proposed APP quality measure set for the CY 2021 MIPS performance period for ACOs only. We are limiting the extension of the CMS/Web Interface to those Entity types which, in the past, have used the CMS Web Interface for purposes of MIPS reporting, and may therefore benefit from a transitional year before reporting via a new submission type. Groups and other APM Entity types that have in the past been scored using different submission types do not face the same obstacles, and therefore do not require a transition year.

Each individual MIPS eligible clinician, group, and APM Entity reporting through the APP will be scored on the ACO MCC measure, Hospital-wide Readmission measure, and CAHPS for MIPS survey, as applicable. In addition, individual MIPS eligible clinicians and groups reporting through the APP will be required to report on the three eCQMs/MIPS CQMs included in the APP quality measure set. APM Entities reporting through the APP will be required to report on either the three eCQMs/MIPS CQMs included in the APP quality measure set or on the CMS Web Interface measure set. We refer readers to Appendix 1 for additional measure specification information.

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TABLE 47: Measures included in the Final APM Performance Pathway Measure Set+

Measure #	Measure Title	Collection Type	Submitter Type	Meaningful Measure Area
Quality ID#: 321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient's Experience
Measure # 479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Admissions & Readmissions
Measure # TBD	Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions for ACOs	Administrative Claims	N/A	Admissions & Readmissions
Quality ID#: 001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health
Quality ID#:236	Controlling High Blood Pressure	eCQM/MIPS CQM/CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 318	Falls: Screening for Future Fall Risk	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventable Healthcare Harm
Quality ID#: 110	Preventive Care and Screening: Influenza Immunization	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	CMS Web Interface*	APM Entity/Third Party Intermediary	Prevention and Treatment of Opioid and Substance Use Disorders
Quality ID#: 113	Colorectal Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 112	Breast Cancer Screening	CMS Web Interface*	APM Entity/Third Party Intermediary	Preventive Care
Quality ID#: 438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	CMS Web Interface*	APM Entity/Third Party Intermediary	Mgt. of Chronic Conditions
Quality ID#: 370	Depression Remission at Twelve Months	CMS Web Interface*	APM Entity/Third Party Intermediary	Treatment of Mental Health

+ We note that Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Quality ID# 438); Depression Remission at Twelve Months (Quality ID# 370), and Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID# 134) do not have benchmarks and are therefore not scored; they are, however, required to be reported in order to complete the Web Interface dataset.

* ACOs will have the option to report via Web Interface for the 2021 MIPS Performance year only.

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We are finalizing at § 414.1367(c)(1) the quality measure set for the APP, and are adding the option for ACOs to report on the CMS Web Interface for the 2021 performance year only.

(b) Cost

In the CY 2017 Quality Payment Program final rule (81 FR 77256, 77265), we finalized at § 414.1370(g)(2) to waive the cost performance category under waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center APMs, and at section 1899(f) of the Act for the Medicare Shared Savings Program. We proposed to continue to waive the cost performance category under the same authorities for three reasons. First APM entities in MIPS APMs already are subject to cost performance assessment under their APMs, as the MIPS APM criteria would continue to include the assessment of participants based on cost. Second, MIPS APMs may measure cost performance in different ways than MIPS, for example, by basing cost on total cost of care, which measures a broader scope of cost or resource use than would necessarily be reflected in the narrower claims-based accountability standard under MIPS. Finally, MIPS APMs may attribute beneficiaries differently from MIPS for purposes of measuring cost, leading to an unpredictable degree of overlap between the sets of beneficiaries for whom the MIPS eligible clinicians

would be responsible under their APM and under MIPS. We noted that we believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population under the APM, it is necessary to give the APM Entity the ability to identify a single beneficiary population to prioritize in its cost-saving efforts. This is necessary so that the goals and evaluation associated with the APM are as clear and free of confounding factors as possible. With this flexibility, we noted that MIPS eligible clinicians who are attempting to strategically transform their respective practices would not jeopardize their ability to succeed in either MIPS or under the terms of their APM. Therefore, by participating through the APP, the APM participant may indicate their intent to focus their resources on the beneficiary population and services identified by the terms of the APM rather than the population and services they would have been responsible for under the MIPS cost performance category.

We received the following comments on this proposals.

Comment: Commenters supported the proposal, noting that as APM participants they are already being assessed on cost performance under the terms of participation in their APM.

Response: We thank commenters for their support. We refer readers to section IV.A.3.e. of this final rule, for additional discussion around the reweighting of the cost performance category for APM Entities that choose to report to MIPS outside of the APP.

After considering public comments, we are finalizing this policy as proposed.

(c) Improvement Activities

We proposed to assign a score for the Improvement Activities performance category for each MIPS APM, and that score will be applied to participant MIPS eligible clinicians reporting through the APP. In an effort to further reduce reporting burden for MIPS eligible clinicians in MIPS APMs and to better recognize improvement activities work performed through participation in MIPS APMs, we proposed to assign a baseline score for each MIPS APM based on the improvement activity requirements of the particular MIPS APM. CMS would review the MIPS APM's requirements in relationship to activities specified under the generally applicable MIPS improvement activities performance category and assign for each MIPS APM an improvement activities performance category score that is applicable to all MIPS eligible clinicians reporting through the APP who are participants in the MIPS APM. To develop the improvement activities score for MIPS APMs, we would compare requirements of the APM with the list of Improvement Activities, described in § 414.1355(a), for the applicable year, and score those improvement activities as they would otherwise be scored according to § 414.1380(b)(3). Thus, as proposed, points assigned to an APM participant MIPS eligible clinician participating in MIPS through the APP would be based, at least in part, on the documented terms and requirements of participation in the MIPS APM, such as under a participation agreement or regulation. In the event a MIPS APM participant does not actually perform an activity for which Improvement Activities credit would otherwise be assigned under the proposal, the MIPS APM participant would not receive credit for the associated Improvement Activity.

We noted that we would publish the assigned improvement activities scores for each MIPS APM on the CMS website prior to the beginning of the MIPS performance period. In the event that the assigned score for a MIPS APM does not represent the maximum improvement activities score, we proposed that MIPS eligible clinicians reporting through the APP would have the opportunity to report additional improvement activities that then would be applied towards their scores.

We noted that under section 1848(q)(5)(c)(ii) of the Act, a MIPS eligible clinician in an APM for a performance period automatically earns a minimum score of one half of the highest potential score for the improvement activities category for their participation in an APM for the performance period. Additionally, under section 1848(q)(5)(c)(i) of the Act, MIPS eligible clinicians participating in a patient-centered medical home model or comparable specialty practice, as determined by the Secretary for a performance period, automatically earn the highest potential score for the improvement activities category. These baseline scores would be automatically applied for all MIPS eligible clinicians who participate in an APM in accordance with § 414.1380(b)(3)(i) and (ii), respectively.

We sought comment on the proposal.

Comment: One commenter expressed confusion about the improvement activities reporting requirements for MIPS eligible clinicians reporting through the APP. Specifically, how participants of a MIPS APM would know when they are required to report additional improvement activities for MIPS scoring.

Response: In past years, and in the 2021 performance year, we have identified all MIPS APMs as having met the improvement activity threshold score requirement to receive a score of 100 percent for that performance category. In the event that in the future an APM does not meet this threshold, we would allow participants in that APM to report additional quality measures in order to earn a score of up to 100 percent for that performance category.

Similarly, should we learn that a MIPS eligible clinician or group has reported through the APP, but we discovered that their APM Entity has failed to complete the required improvement activities and any CAP developed as a result of this discovery, participants in that APM Entity may be subject to an audit wherein they would have the opportunity to produce evidence that they have completed sufficient improvement activities to maintain their performance category score of up to 100 percent. If it is determined that participants in such APM Entity did not complete enough improvement activities to earn a score of 100 percent, their performance category score will be recalculated. We note that the statute assigns a minimum improvement activities performance category score of 50 percent to all APM participants.

After considering public comments, we are finalizing the policy as proposed.

(d) Promoting Interoperability

We proposed that the Promoting Interoperability performance category score would be reported and calculated in the same manner described at § 414.1375. We sought comment on the proposal.

Comment: One commenter suggested that we enable ACOs to report the PI performance category.

Response: As in past years, it is not currently operationally feasible for CMS to accept PI performance category reporting at the APM Entity level in cases where an APM Entity is comprised of more than one TIN. However, we continue to reassess this issue annually, and we welcome stakeholder input on how we might implement changes of this sort in future program years.

After considering public comment, we are finalizing the policy as proposed.

(4) APP Performance Category Weights

We proposed to continue to waive the requirement to weight each MIPS performance category as described in

section 1848(q)(5)(E) of the Act using the waiver authority in sections 1115A(d)(1) and 1899(f) of the Act for CMS Innovation Center APMs and the Medicare Shared Savings Program, respectively. For reasons described in the CY 2021 PFS proposed rule (85 FR 50287), we stated that we believe it is necessary to waive the cost performance category for MIPS eligible clinicians reporting to MIPS through the APP. As a result, we stated that it also would be necessary to waive the requirement to weight each MIPS performance category as described in section 1848(q)(5)(E) of the Act and to redistribute the cost performance category weight to the remaining performance categories to be scored for APM participants reporting through the APP.

We proposed to reweight the performance categories for APM participants reporting through the APP to:

- *Quality:* 50 percent
- *Cost:* 0 percent
- *Promoting Interoperability:* 30 percent
- *Improvement Activities:* 20 percent

We noted that we believe these weights are appropriate as they generally align with the relative performance category weights under MIPS and MVPs in circumstances where the cost performance category has been reweighted to zero percent of the final score, and the cost performance category weight has been distributed proportionately among the remaining performance categories.

We proposed to codify these proposals at § 414.1367(d)(1). We did not receive any comments on these proposals, and we are finalizing them as proposed.

(a) Reweighting a Performance Category

We recognize that there are certain circumstances when a MIPS eligible clinician, group, or APM Entity may be unable to complete reporting to MIPS due to, for example, extreme and uncontrollable circumstances, hardship, or the unavailability or inapplicability of measures due to practice size or other data limitations. Therefore, under the authority provided in section 1848(q)(5)(F) of the Act, it may become necessary to reweight one or more performance categories.

In a case where the Promoting Interoperability performance category is reweighted to zero percent, we proposed to reweight the quality performance category to 75 percent and the Improvement Activities performance category to 25 percent.

In a situation where the quality performance category is reweighted to zero percent, we proposed to reweight the Promoting interoperability performance category to 75 percent and the improvement activities performance category to 25 percent.

We noted that we believe that the distributions appropriately value performance categories that require reporting on measures and measuring improvement, without disproportionately emphasizing one performance category over another. Furthermore, the performance category weights will contribute to a unified performance category reweighting policy throughout MIPS in the event of an Extreme and uncontrollable circumstance that requires the reweighting of cost and any other MIPS performance category.

We proposed to codify this policy at § 414.1367(d)(2). We did not receive any comments on this proposal, and therefore, we are finalizing as proposed.

(5) Scoring for APM Participants Reporting Through the APP

We proposed that final scoring for APM participants reporting to MIPS through the APP would follow the same methodology as established for MIPS generally at § 414.1380. Specifically, we noted that we would continue to score each performance category and multiply each performance category score by the applicable performance category weight, and then calculate the sum of each weighted performance category score and apply any applicable adjustments.

We proposed to codify this policy at § 414.1367(e). We did not receive any comments on this proposal, and therefore, we are finalizing as proposed.

(6) Performance Feedback for APM Participants Reporting Through the APP

We proposed to make performance feedback available to MIPS eligible clinicians reporting through the APP according to the methods applicable to all MIPS eligible clinicians, as described in the 2017 QPP final rule (81 FR 77347). We did not receive any comments on this proposal, and therefore, we are finalizing as proposed.

c. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

We refer readers to §§ 414.1330 through 414.1340 and the CY 2018 Quality Payment Program final rule (82 FR 53626 through 53641) for our previously established policies regarding the quality performance category.

In the CY 2021 PFS proposed rule (85 FR 50288), we proposed to:

- Weight the quality performance category at 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year, at § 414.1330(b)(4) and (5), respectively.
- Sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2021 performance period.
- Make changes to the MIPS quality measure set as described in Appendix 1 of the CY 2021 PFS proposed rule (85 FR 50413 through 50665), including addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.
- Establish separate performance periods specific to administrative claims measures at § 414.1320(d)(1).
- Make changes to the CAHPS for MIPS Survey to address the increased use of telehealth care.
- Expand telehealth codes used in beneficiary assignment for the CAHPS for MIPS Survey beginning with the performance year 2021 survey.

(b) Weight in the Final Score

Section 1848(q)(5)(E)(i)(I) of the Act, provides that 30 percent of the final score shall be based on performance for the quality performance category, in which the percentage points attributed to the final score for the quality and cost performance categories will both be equivalent at 30 percent, totaling 60 percent of the final score. The percentage points attributed to both the quality and cost performance categories are in tandem. For each year within the first 5 years of the MIPS program, the quality performance category performance percentage can be increased to more than 30 percent of the final score. The percentage increase of the quality performance category is equivalent to the decrease of the cost performance category.

As discussed in the CY 2021 PFS proposed rule (85 FR 50293 through 50294), we proposed to weight the cost performance category at 20 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. Accordingly, we proposed to establish the weight of the quality performance category for the 2023 and 2024 MIPS payment years. At § 414.1330(b)(4), the percentage points attributed to performance in the quality performance category would comprise 40 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and at § 414.1330(b)(5), the

percentage points attributed to performance in the quality performance category would comprise 30 percent of a MIPS eligible clinician's final score for the 2024 MIPS payment year and future years.

We noted our belief that being transparent in how both the quality and cost performance category weights would be modified over the next 2 years of the program will allow stakeholders to better plan and anticipate how the performance category scores would be calculated in future for MIPS eligible clinicians, groups, and virtual groups as we incrementally adjust the final score weights for the quality and cost performance categories.

We solicited public comment on the proposals to incrementally reduce the weight of the quality performance category as we incrementally increase the weight of the cost performance category, specifically our proposal to adjust the percentage points attributed to the final score in the quality performance category to be comprised of 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and future years. The following is a summary of public comments received regarding the proposals.

Comment: A few commenters supported our proposal to incrementally reduce the weight of the quality performance category while increasing the weight of the cost performance category in order to achieve the weights established by Congress under the Act.

Response: We appreciate the support from commenters.

Comment: Many commenters did not support our proposal to incrementally reduce the weight of the quality performance category in order to increase the weight of the cost performance category during the PHE for COVID–19 because clinicians are burdened in new ways and trying to navigate through various challenges brought on by the PHE. The commenters recommended that CMS maintain the weight of the quality performance category at 45 percent until the PHE for COVID–19 has ended in order for clinicians to focus on serving patients safely. A few commenters recommended that CMS maintain the weight of 45 percent for the quality performance category for the 2023 MIPS payment year in order for the commenters' concerns regarding the cost measures to be addressed. In particular, the commenters noted that there are not many cost measures to select, particularly for specialties, which has significant implications for not accurately measuring cost performance. One commenter requested that CMS work with Congress on an extension for the timeframe to increase the weight for the cost performance category.

Response: Section 1848(q)(5)(E)(i) of the Act provides that by the sixth year of the program, 30 percent of the final score shall be based on performance for the quality performance category and 30 percent of the final score shall be based on the cost performance category. Prior to the sixth year, section 1848(q)(5)(E)(II)(bb) of the Act states that the cost performance category may be weighted at not less than 10 percent and not more than 30 percent of the total score. If less than 30 percent, the percentage by which it is less than 30 percent is to be shifted to the quality performance category. Given that the percentage points attributed to both the quality and cost performance categories are in tandem, and we are required to achieve equal weighting at 30 percent for each of the two performance categories by payment year 2024, we believe that it is important to meet the statutory requirement while balancing the impact of simultaneously reducing the weight of the quality performance category and increasing the weight of the cost performance category. We are providing a gradual transition over a 2-year period subject to the limitations imposed by the statute. In section IV.A.3.c.(2)(a) of this final rule, we finalized our proposal to increase the weight of the cost performance category to 20 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. Thus, the weight of the quality performance category will be reduced to 40 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent years.

Regarding concerns that the weight of the quality performance category should not be reduced until there are additional cost measures applicable to specialties in order to adequately measure cost performance for specialties, we note that there are two broad-based cost measures (Medicare Spending Per Beneficiary Clinician and Total Per Capita Cost) that generally apply to all clinician types, including specialties. There are a total of 20 cost measures, including 18 episode-based cost measures. In the event that there are not any applicable cost measures to measure performance, the cost performance category would be re-weighted to zero. Also, we previously established facility-based measurement. Facility-based measurement provides certain clinicians and groups that primarily work within an inpatient setting with the opportunity to receive MIPS quality and cost performance category scores based on their assigned facility's hospital value-based purchasing program score in lieu of receiving scores based on quality and cost measures. We do not believe that maintaining the weight of the quality performance category at 45 percent until there are additional cost measures is necessary to assess cost performance. We will consider the inclusion of additional cost measures in future rulemaking, as available and appropriate. Regarding the comment requesting that CMS work with the Congress to extend the timeframe for increasing the weight of the cost performance category, we will take the comment into consideration.

After consideration of the public comments, we are finalizing our proposal, which is as follows: At § 414.1330(b)(4), the percentage points attributed to performance in the quality performance category will comprise 40 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and at § 414.1330(b)(5), the percentage points attributed to performance in the quality performance category will comprise 30 percent of a MIPS eligible clinician's final score for the 2024 MIPS payment year and each subsequent year.

(c) Groups and Virtual Groups Reporting via the CMS Web Interface

At § 414.1335(a)(2), the CMS Web Interface measures is a collection type in which groups and virtual groups with 25 or more eligible clinicians are able to report data on a set of pre-determined quality measures. For the 2020 performance periods, the total number of CMS Web Interface measures required to complete reporting on is 10 CMS Web Interface measures (83 FR 59713 through 79715 and 59756). Each CMS Web Interface measure must have complete reporting (no partial reporting) on all 10 measures while quality measures in other collection types require the reporting of fewer measures. The reporting requirements for the CMS Web Interface measures are more stringent than other collection types for the quality performance category, which include reporting on a larger set of measures and a higher data completeness rate. At § 414.1335(a)(1)(i), it is established that groups and virtual groups reporting quality measures using non-CMS Web Interface measures collection types (such as Qualified Registries, Qualified Clinical Data Registries (QCDRs), electronic health records (EHRs), and Medicare Part B claims) are required to report on a minimum of 6 quality

measures, including at least one outcome measure. The data completeness criteria for reporting quality measures for Qualified Registry measures, QCDR measures, EHR measures, and Medicare Part B claims measures has a lower threshold compared to the CMS Web Interface measures. The data completeness criteria for the CMS Web Interface measures requires groups and virtual groups to report on the first 248 consecutively ranked beneficiaries in the sample for each measure (and if the sample of eligible assigned beneficiaries is less than 248, then the group or virtual group must report on 100 percent of assigned beneficiaries), and at least one measure for which there is Medicare patient data (at §§ 414.1335(a)(2) and 414.1340(c)). For the 2020 performance period, the data completeness criteria threshold for Qualified Registry measures, QCDR measures, EHR measures, and Medicare Part B claims measures is 70 percent of the MIPS eligible clinician, group, or virtual group's patients (and applicable Medicare Part B patients for Medicare Part B claims measures) that meet the measure's denominator criteria (at §§ 414.1340(a)(3) and 414.1340(b)(3)). Thus, groups and virtual groups submitting quality data through the CMS Web Interface measures report on a significantly larger number of patients compared to other collection types and such patients are identified in a sample by us (at § 414.1340(c)).

In sections III.G.1.b. and III.G.1.c. of the CY 2021 PFS proposed rule (85 FR 50231 and 50234 through 50235), we discussed the proposal to revise the quality reporting requirements for the Medicare Shared Savings Program to align with the APP framework and make corresponding revisions to the quality performance standard that ACOs must meet in order to be eligible to share in savings under the program. In conjunction with the proposed modifications to the Medicare Shared Savings Program quality reporting requirements, which included a proposal to transition to an APP for ACOs starting with the 2021 performance period, we conducted an assessment of the utilization of the CMS Web Interface measures as a collection type for groups and virtual groups participating in MIPS. As noted above, we recognize that the CMS Web Interface reporting requirements, which include reporting on a larger set of measures and a higher data completeness rate, are more stringent than other collection types available under MIPS.

In assessing the utilization of the CMS Web Interface by groups and virtual groups, there has been a substantial decrease in participation each year since the inception of MIPS in the 2017 performance year. From the 2017 to 2019 performance years, the number of groups eligible to report quality measures via the CMS Web Interface (groups registered to utilize the CMS Web Interface) decreased by approximately 45 percent. Similarly, the number of groups utilizing the CMS Web Interface as a collection type has decreased by approximately 40 percent from the 2017 to 2019 performance years. It is not clear as to why groups and virtual groups are not seeking to participate in MIPS by submitting quality data for CMS Web Interface Measures. There could be various reasons explaining the decrease in CMS Web Interface participation such as MIPS offering several collection types that can be utilized by any individual MIPS eligible clinician, group, or virtual group to meet program requirements; the CMS Web Interface measure reporting requirements may be burdensome compared to other collection types/submission types; the measure set is limited to primary care; groups and virtual groups may have a preference to select their own measures to have performance assessed instead of a pre-determined measure set; or as a result of the CMS Web Interface measures being topped out, it may deter groups and virtual groups from participating because they would not fiscally benefit to be compared and assessed when there is little or no data variation in performance across ACOs, groups, and virtual groups.

Given the above factors, we considered the following two options in our assessment: Continue the utilization of the CMS Web Interface measures solely for groups and virtual groups while ACOs transition to APP participation; or sunset the utilization for the CMS Web Interface measures as a collection type for groups and virtual groups. Groups and virtual groups account for less than 20 percent of organizations utilizing the CMS Web Interface measures while ACOs participating in the Medicare Shared Savings Program or Next Generation ACO Model account for more than 80 percent. With an expected 80 percent reduction if our proposed revisions to the quality performance standard under the Shared Savings Program are finalized and a continued decrease in groups and virtual groups seeking to report quality data on CMS Web Interface measures, we explained that it is not fiscally viable, feasible, or sustainable for MIPS to continue to make available the CMS Web Interface measures as a collection type/submission type. A reduction in the number of organizations submitting quality data on CMS Web Interface measures does not equate to the reduction in direct costs associated with operating and maintaining the CMS Web Interface measures. To operate and maintain the CMS Web Interface measures solely for groups and virtual groups, there would be an increase in cost and needed resources under MIPS associated with the items such as the establishment and maintenance of CMS Web Interface benchmarks, assignment and sampling, technical support, and education and outreach; thus, there would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface measures as a collection type/submission type.

In assessing the second option to sunset the CMS Web Interface measures as a collection type starting with the 2021 performance year, we would be aligning with the proposal under the Medicare Shared Savings Program to no longer utilize the CMS Web Interface as a means for assessing and scoring the quality performance of ACOs. For purposes of MIPS, groups and virtual groups would transition to meeting requirements under the quality performance category using other collect and submission types. We recognized that the sunset of the CMS Web Interface for groups and virtual groups may be burdensome to current groups and virtual groups submitting quality data on CMS Web Interface measures. Such groups and virtual groups would need to select a different collection type/submission type and redesign their systems to be able to interact with the new collection type/submission type. The timeframe for groups and virtual groups to select a new collection type/submission type and redesign their systems may be perceived as burdensome.

We noted that groups and virtual groups would be able to select a different collection type/submission type, including at least six quality measures that are similar to previously established CMS Web Interface measures and reflect their specialty, and prepare for the 2021 reporting period in advance of the reporting period starting in January of 2022. While there may be an initial increase in burden for current groups and virtual groups utilizing the

CMS Web Interface measures having to transition to the utilization of a different collection type/submission type, we recognized that we would also be reducing reporting requirements by no longer requiring groups and virtual groups to have to completely report on all pre-determined 10 CMS Web Interface measures; groups and virtual groups would be able to select their own measures to report, would be reporting data on at least six measures, and data completeness threshold would be 70 percent for each measure, which is a reduction in program requirements compared to completed reporting required for all CMS Web Interface measures. We noted our belief that groups and virtual groups would be able to transition to the utilization of an available alternative collection type for the 2021 performance period. The type of data collected by groups and virtual groups for the 2020 performance period would be able to be captured by one of the available collection types such as an eCQM or MIPS CQM for the 2021 performance period. The 10 CMS Web Interface measures that are required for reporting under the 2020 performance period have an eCQM and MIPS CQM equivalent measure. For the 2021 performance period, there are 10 eCQMs and 9 CQMs that are equivalent to the 10 CMS Web Interface measures. Also, we noted our belief that groups and virtual groups would be able to identify at least 6 equivalent eCQMs or MIPS CQMs (or a combination) that capture the same type of data collected for the measures used in the CMS Web Interface. Also, such transition for groups and virtual groups could potentially be more beneficial. For example, if a measure from a different collection type (for example, MIPS CQMs) meets data completeness but may not meet case minimum, the measure would receive a score of 3; whereas, under the CMS Web Interface, any measure that did not meet reporting requirements would receive a score of 0.

The sunset of the CMS Web Interface measures would reduce burden on groups and virtual groups while aligning program requirements and scoring policies for MIPS and the Medicare Shared Savings Program, and removing CMS Web Interface measures that do not provide a meaningful means of assessing performance across groups, virtual groups, and ACOs. With the CMS Web Interface measures being topped out as noted above, we strive to remove measures that are topped out and establish a set of robust and meaningful measure sets that are available under the other collection types. We noted our belief that the benefits groups and virtual groups would reap from transitioning to the utilization of other collection types starting with the 2021 performance year outweigh the initial disruption that would be experienced when the CMS Web Interface measures would be sunset. Based on our assessment, we proposed at § 414.1325(c)(1) and (2) to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 performance period. Specifically, at § 414.1305, we proposed to modify the definition of the terms collection type and submission type to remove the CMS Web Interface measures as an available option starting with the 2023 MIPS payment year. We proposed to modify the definition of collection type to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the 2019 through 2022 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS Survey; and administrative claims measures. We proposed to revise the definition of ''submission type'' to mean the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct; log in and upload; log in and attest; Medicare Part B claims; and for the 2019 through 2022 MIPS payment years, the CMS Web Interface.

We solicited public comment on the proposal to sunset the CMS Web Interface as a collection and submission type under MIPS starting with the 2021 performance period. The following is a summary of public comments received regarding the proposal.

Comment: Several commenters generally supported the proposal to sunset the CMS Web Interface as a collection and submission type (with a few commenters expressing support of the proposal based on the condition of having a transition period of at least 1 year) and noted that the removal of the CMS Web Interface would reduce the quantity of quality measures reported, allow groups and virtual groups to select specialty measures, and encourage the use of electronically reported measures rather than the manual abstraction of data using a CMS-created Excel template for uploading quality data.

Response: We appreciate the support from commenters and note that we are finalizing our proposal to remove the CMS Web Interface as a collection and submission type with a 1-year delay. Also, we note that the CMS Web Interface not only has the function of providing for a manual abstraction of data using a CMS-created Excel template for uploading quality data, but allows for the use of an application programming interface (API), which encourages the use of enhanced EHR technology.

Comment: Most commenters did not support the proposal to sunset the CMS Web Interface as a collection and submission type starting with the 2021 performance period, indicating that CMS did not provide adequate notice of the CMS Web Interface being under consideration for elimination and noting that the lack of adequate notice would create a burden for users to be able to successfully transition to the use of a different collection and submission type, which would require a significant amount of time and fiscal resources to build a new health IT infrastructure and workflows, and train staff on the new system. A few commenters indicated that organizations elect to utilize the CMS Web Interface as a cost-effective option for TINs using multiple, disparate EHR systems and the removal of the CMS Web Interface would make it particularly burdensome for such organization to change collection and submission types. One commenter indicated that not all organizations have the resources to transition to a different collection and submission type and doing so would be difficult for small community practices to implement. Most commenters recommended that CMS delay the sunset of CMS Web Interface by one or more years, particularly as clinicians are responding to the PHE for COVID–19 and CMS continues to define the MVP framework, which may necessitate program participants to change collection and submission types again in a few years.

Response: We recognize that the general sentiment of most commenters was not in opposition to the proposal to remove the CMS Web Interface as a collection type and submission, but rather the proposed timeframe for removal, which would be burdensome due to insufficient time to build and integrate new health IT infrastructures and systems, implement workflows, and train staff on new health IT systems while mitigating and responding to the PHE for COVID–19 that has further strained limited fiscal resources. To reduce the burden of transitioning to a new collection and submission type, we are extending the availability of the CMS Web Interface as a collection and submission type for one additional performance period. Thus, we are

modifying our proposal to sunset the CMS Web Interface starting with the 2022 performance period.

Comment: Some commenters indicated that the removal of the CMS Web Interface as a collection and submission type may limit the ability of clinicians to achieve the maximum possible score under the quality performance category. One commenter expressed concern that as APMs migrate to other collection types, the performance rates for benchmarks of other collection types would increase and the performance of non-APM participants may be disadvantaged when compared to the increased benchmarks.

Response: We disagree that the removal of the CMS Web Interface as a collection type would inhibit APM Entities, groups, or virtual groups that formerly utilized the CMS Web Interface from being able to achieve the maximum possible score allotted under the quality performance category or pose a potential disadvantage for non-APM participants that had not previously reported quality data via the CMS Web Interface as APMs that migrate from utilizing the CMS Web Interface to other collection types. It should be noted that the way in which APM Entities (ACOs participating in the Medicare Shared Savings Program or Next Generation ACO Model), groups, and virtual groups are scored relative to the benchmarks established for the CMS Web Interface measures differ from the way in which MIPS eligible clinicians, groups, virtual groups, and APM Entities are scored relative to the benchmarks established for all other quality measures. The deciles for the CMS Web Interface benchmarks are flat (meaning that each decile is stagnant and equally distributed increments equating 100 percent; for example, if a CMS Web Interface user had a performance score of 92 percent, the points achieved would be 9 points) while the deciles for other quality measure benchmarks are based on the distribution of performance (meaning that each decile reflects a specific range of performance distribution in incremental percentages equating to 100; for example, the decile representing the 10 percent of highest performance could have a range of performance from 98 percent to 100 percent, so in order to achieve the maximum points, a MIPS eligible clinician, group, or virtual group would need to have a performance within such range). Performance rates pertaining to the CMS Web Interface measures are not comparable to performance rates pertaining to other quality measures for other collection types and do not provide an indication of how performance would be distributed across the performance curve outside of the CMS Web Interface. In order to achieve the maximum possible score for the quality performance category, a MIPS eligible clinician, group, virtual group, or APM Entity would need to have better performance compared to other clinicians along the distribution curve of performance for a particular measure.

Comment: One commenter suggested that CMS provide CMS Web Interface users with an option to file a hardship exception for transitioning to a new EHR as a collection type, which would reweight the quality and promoting interoperability performance categories to zero to ensure that such clinicians would not be penalized while transitioning to new collection types.

Response: We disagree with the commenter's suggestion that a hardship exception be established for groups or virtual groups utilizing the CMS Web Interface as such users transition to a different collection type. The hardship exemption is a policy established pertaining to specific circumstances such as using decertified EHR technology, insufficient internet connectivity, extreme and uncontrollable circumstances, and the lack of control over CEHRT. We do not believe that the transition to utilizing a different collection type would warrant the establishment of a new hardship exception. The CMS Web Interface will remain as a collection type for the 2021 performance period to provide sufficient time for CMS Web Interface users to prepare to utilize a different collection type starting with the 2022 performance period as the CMS Web Interface will sunset starting with the 2022 performance period.

Comment: One commenter recommended CMS to provide tools to assist with the transition from the CMS Web Interface to other collection types by providing a simple tool for aggregating QRDAIII files from multiple EHR systems into a single QRDAIII or JSON format file for MIPS submission. The commenter acknowledged that CMS has provided open source software for such purpose, but requested that CMS embed the file aggregation process in the MIPS quality submission workflow in order to allow an authorized submitter to choose an upload and submission method for the quality performance category that automatically aggregates multiple QRDAIII files.

Response: We note that groups and virtual groups are required to aggregate data across the group or virtual group in order to meet reporting requirements established at §§ 414.1310(e)(3) and 414.1315(d)(3). We are unable to provide the embedded aggregation tool the commenter is requesting, but will take this into consideration for future enhancements.

After consideration of the public comments, we are finalizing our proposal to remove the CMS Web Interface as a collection and submission type with a 1-year delay. In order to address the potential burden that groups and virtual groups would experience by the removal of the CMS Web Interface as a collection and submission type during the PHE for COVID–19, we believe it is critical to reduce the burden of groups and virtual groups at this juncture and postpone the sunset of the CMS Web Interface to the 2022 performance period. Thus, we are finalizing at § 414.1325(c)(1) and (2) to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 performance period. Specifically, at § 414.1305, we are finalizing our proposal with modification to define the terms collection type and submission type to remove the CMS Web Interface measures as an available option starting with the 2024 MIPS payment year. We are finalizing our proposal with modification to revise the definition of collection type to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the 2019 through 2023 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS Survey; and administrative claims measures. We are finalizing our proposal with modification to revise the definition of ''submission type'' to mean the mechanism by which the submitter type submits data to CMS, including, but not limited to: Direct; log in and upload; log in and attest; Medicare Part B claims; and for the 2019 through 2023 MIPS payment years, the CMS Web Interface.

(d) Selection of MIPS Quality Measures

Previously finalized MIPS quality measures can be found in the CY 2020 PFS final rule (84 FR 63205 through 63513); CY 2019 PFS final rule (83 FR 60097 through 60285); CY 2018 Quality Payment Program final rule (82 FR 53966 through 54174); and in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77816). Proposed changes to the MIPS quality

measure set as described in Appendix 1 of the CY 2021 PFS proposed rule (85 FR 50412 through 50663) include the following: Addition of new measures; updates to specialty sets; removal of existing measures, and substantive changes to existing measures. For the 2021 performance period, we proposed a measure set of 206 MIPS quality measures.

The new MIPS quality measures proposed for inclusion in MIPS for the 2021 performance period and future years were found in Table Group A of Appendix 1 of the proposed rule (85 FR 50413 through 50414). For the 2021 performance year, we proposed 2 new administrative claims outcome measures. In addition to the establishment of new individual MIPS quality measures, we also develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice. The proposed modifications to existing specialty sets and new specialty sets were outlined in Table Group B of Appendix 1 of the proposed rule (85 FR 50415 through 50580). Specialty sets may include: New measures; previously finalized measures with modifications; previously finalized measures with no modifications; the removal of certain previously finalized quality measures; or the addition of existing MIPS quality measures. Note that the specialty and subspecialty sets are not inclusive of every specialty or subspecialty.

On January 6, 2020,[124] we announced that we would be accepting recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for year 5 of MIPS under the Quality Payment Program. These recommendations were based on the MIPS quality measures finalized in the CY 2019 PFS final rule, the 2019 Measures Under Consideration list, and provides recommendations to add or remove the current MIPS quality measures from existing specialty sets, or provides recommendations for the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations with which we agreed were proposed in the CY 2021 PFS proposed rule.

[124] Listserv messaging was distributed through the Quality Payment Program listserv on January 6, 2020, titled: ''CMS is Soliciting Stakeholder Recommendations for Potential Consideration of New Specialty Measure and/or Revisions to the Existing Specialty Measure Sets for the 2021 Program Year of Merit-based Incentive Payment System (MIPS).''

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets and new specialty sets as outlined in Tables Group A and Group B of Appendix 1 of the CY 2021 PFS proposed rule, we refer readers to Table Group C of Appendix 1 of the CY 2021 PFS proposed rule for a list of quality measures and rationales for removal (85 FR 50580 through 50585). For the 2021 performance period, we proposed to remove 14 MIPS quality measures: 2 MIPS quality measures that are extremely topped out; 1 MIPS quality measure that is duplicative to another current quality measure; 1 MIPS quality measure that is duplicative to one of the new proposed MIPS quality measures; 2 MIPS quality measures that do not align with the Meaningful Measures Initiative; 5 MIPS quality measures that are no longer stewarded or maintained; 1 MIPS quality measure that does not meet current clinical guidelines; and 2 MIPS quality measures that are under the topped out lifecycle. We noted that we have continuously communicated to stakeholders our desire to reduce the number of process measures within the MIPS quality measure set. Also, we noted our belief that the proposal to remove the quality measures outlined in Table Group C would lead to a more parsimonious inventory of meaningful, robust measures in the program, and that our approach to remove measures should occur through an iterative process that will include an annual review of the quality measures to determine whether they meet our removal criteria.

Lastly, MIPS quality measures with proposed substantive changes can be found in Table Group D of Appendix 1 of the CY 2021 PFS proposed rule. We proposed substantive changes to 112 MIPS quality measures. On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. Section 1848(q)(2)(D)(i)(II)(cc) of the Act requires all substantive measure changes to be proposed and identified through notice-and-comment rulemaking. In the CY 2017 Quality Payment Program final rule (81 FR 77137), we determined that substantive changes to measures (that is, measure specifications, measure title, and domain modifications) would be identified during the rulemaking process while maintenance changes that do not substantively change the intent of the measure (that is, updated diagnosis and procedure codes, definitions, and changes to patient population exclusions) would not be included in the rulemaking process.

We note that changes to measure Q134, Prevention Care and Screening: Screening for Depression and Follow-Up Plan (eCQM Specifications and CMS Web Interface Measure Specifications collection types), specifically the removal of SNOMED codes, were published in the eCQI Resource Center and the Value Set Authority Center (in May of 2018 for the eCQM Specifications) and on the CMS website (in December of 2018 for the CMS Web Interface Measure Specifications). While the current cycle of measure updates to MIPS quality measures is separate from the eCQM annual update process, we inadvertently recognized such update allowed MIPS eligible clinicians to meet performance of a follow-up plan by rescreening the patient who has a positive depression screen with an additional standardized depression screening tool. The change to the measure was continued for CY 2020. As a result, such changes were not identified during the CY 2019 PFS or CY 2020 PFS rulemaking cycles. The changes to measure Q134 (eCQM Specifications and CMS Web Interface Measure Specifications collection types) impact performance periods starting with 2019. For the 2019 and 2020 performance periods, measure Q134 applicable to the eCQM Specifications and CMS Web Interface Measures Specifications will be suppressed from scoring. To adequately capture the substantive changes to measure Q134 (eCQM Specifications and CMS Web Interface Measure Specifications collection types) through rulemaking for the 2021 performance period, we are identifying the substantive changes for this MIPS quality measure as outlined in Table Group D of Appendix 1 of the CY 2021 PFS proposed rule (85 FR 50586 through 50663).

We refer readers to Table Groups A through D of Appendix 1 of this final rule for a summary of public comments received regarding the proposed changes to the MIPS quality measure set for the 2021 performance period and our final decisions.

(e) MIPS Performance Period

(i) Establishing Separate Performance Periods for Administrative Claims Measures Under the Quality Performance Category Beginning With the 2023 MIPS Payment Year

In the CY 2019 PFS final rule (83 FR 59745), we established at § 414.1320(d)(1) that beginning with the 2022 MIPS payment year, the

performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year. We noted that we established a 1-year performance period for measures in the quality performance category because a 1-year performance period would provide statistically larger sample sizes and more accurate and actionable information. As discussed in Table Group A of Appendix 1 of the CY 2021 PFS proposed rule, we proposed to add a new administrative claims measure of risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty. As discussed, this measure was developed and tested using a performance period that was longer than a full calendar year in order to provide larger sample sizes, and more accurate and actionable information. Beginning with the 2021 performance year, this measure would have a 3-year performance period (consecutive 36-month timeframe) that would start on October 1 of the calendar year 3 years prior to the applicable performance year and conclude on September 30 of the calendar year of the applicable performance year, and proceeding with a 3-month numerator assessment period (capturing complication outcomes) followed by a 2-month claims run-out period. For example, the 3-year (36 consecutive months) performance period for this measure would span from October 1, 2018 to September 30, 2021 with a 90-day numerator assessment period followed by a 60-day claims run-out period.

To account for this measure and other future administrative claims measures that may have a performance period differing from 1 full calendar year, we proposed to modify the definition of the performance period for the quality and cost performance categories at § 414.1320(d)(1) to be as follows: Beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1). We noted that while we have established a single performance period for measures and activities within each performance category in the MIPS program, we have established measure-specific performance periods in other programs, such as in the hospital value-based purchasing program, which includes measures of various performance periods (84 FR 42394 through 42395). We continue to believe that establishing a single performance period for measures requiring the submission of data optimizes operational efficiency for MIPS eligible clinicians, groups, and virtual groups that submit data on such measures. However, administrative claims measures (proposal to add 2 new administrative claims measures found in Table Group A of Appendix 1 of the CY 2021 PFS proposed rule: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate, and Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)); and the proposal to remove the All-Cause Readmission measure found in Table Group C of Appendix 1 (was the only administrative claims-based measure) do not require the submission of data and are calculated by CMS based on administrative data. Thus, we noted our belief that a different performance period should be considered on a measure-by-measure level for administrative claims measures.

We solicited public comment on the proposal to modify the definition of performance period for the quality and cost performance categories that would establish a separate performance period for administrative claims measures under the quality performance category. The following is a summary of the public comments received regarding the proposal.

Comment: One commenter supported the incorporation of a 3-year timeframe for the RSCR following elective primary THA and/or TKA measure because the measure evaluates individuals and groups over a longer timeframe for increased reliability and aligns with the HWR measure. The commenter recommended that CMS allow for a longer performance period for other MIPS measures, where appropriate.

Response: We appreciate the support from the commenter.

Comment: Several commenters expressed concern about the proposal to establish a separate performance period for administrative claims measures under the quality performance category and recommended that the performance period for administrative claims measures under the quality performance category retain a 1-year performance period. The commenters understood the issue surrounding the basis for larger sample sizes, and more accurate and actionable information needed for reliable measurement, but indicated that a 3-year performance period is too long to provide timely, meaningful feedback for MIPS eligible clinicians. The commenters expressed concern that the performance is not representative of the changes in data over 3 consecutive years. One commenter indicated that many small and independent practices would not be able to retroactively report quality measures that require a 3-year performance window. One commenter stated that differing performance periods under the same performance category would cause confusion for clinicians.

Response: We believe that it is important for measures to be developed based on larger sample sizes, and more accurate and actionable information in order to reliably measure quality performance. We disagree with commenters that a 3-year performance period for administrative claims measures under the quality performance category would inhibit timely and meaningful feedback for MIPS eligible clinicians, groups, and virtual groups; MIPS eligible clinicians, groups, and virtual groups will continue to receive annual, confidential performance feedback reports that reflect prior performance. MIPS eligible clinicians, groups, and virtual groups can compare their performance provided in performance feedback to better understand their performance relative to their peers, identify care coordination and quality of care opportunities, and streamline resource use for their attributed patients. The performance period for administrative claims measures would span a 3-year period, in which 2 years of the 3-year period would overlap with the prior measurement period and 1 year would represent new data. While this approach may not capture small improvements in the quality of care, it ensures statistical reliability and therefore, a valid measure result. For example, the proposed new administrative claims measure of risk-standardized complication rate following elective primary total hip arthroplasty and/or total knee arthroplasty would have a 3-year (36 consecutive months) performance period, including elective primary total hip/knee arthroplasty procedures performed between October 1, 2018 to September 30, 2021.

We do not believe that establishing different performance periods specific to administrative claims measures under the quality performance category would cause confusion within the quality performance category while all other quality measures have a full calendar year as a performance period given that differing performance periods only

pertain to administrative claims measures and the submission of data is not required for such measures due to CMS conducting the calculations based on administrative claims data. The introduction of measure-specific performance periods is a concept established in other CMS programs, such as in the hospital value-based purchasing program, which includes measures of various performance periods (84 FR 42393 through 42395). We continue to believe that establishing a single performance period for measures requiring the submission of data optimizes operational efficiency for MIPS eligible clinicians, groups, and virtual groups that submit data on such measures.

After consideration of the public comments, we are finalizing our proposal to define the performance period for the quality and cost performance categories at § 414.1320(d)(1) as follows: Beginning with the 2023 MIPS payment year, the performance period for the quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1).

(f) Quality Data Submission Criteria

(i) Performance Criteria for Quality Measures for Groups Electing To Report Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Survey

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53629 through 53632) for previous finalized policies for the CAHPS for MIPS Survey, specifically regarding the Summary Survey Measures (SSMs).

To address the PHE for COVID–19 and the increased use of telehealth care, we proposed the following changes to our policies related to the CAHPS for MIPS Survey:

- We proposed to integrate one telehealth item into the CAHPS for MIPS Survey. Specifically, we proposed to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services (for example, phone or video visit) to the PY 2021 CAHPS for MIPS Survey.
- We also proposed revisions to the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings. This may help to ensure that patients who respond to the survey are reflecting on experiences of the care they received via telehealth in their responses. We noted that we are considering such changes for the PY 2021 CAHPS for MIPS Survey administration.
- To clarify the instructions in the CAHPS for MIPS Survey, we proposed revisions to the instructions in the ''Your Care From Specialists in the Last 6 Months'' section of the CAHPS for MIPS Survey to clarify the inclusion of the provider named in Question 1 of the survey. We noted that we are considering such changes for the PY 2021 CAHPS for MIPS Survey administration.

We refer readers to section VII of this rule the Collection of Information Requirements for additional information.

We received public comments on the performance criteria for quality measures for groups electing to report CAHPS for MIPS Survey proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported adding a survey-based measure in the CAHPS for MIPS Survey that reflects the increased use of telehealth services, and helps clinicians understand utilization patterns, consumer satisfaction and outcomes of telehealth. One commenter indicated support for a survey question related to the use of telehealth services only, but not a question or measure to evaluate a clinician's performance during the telehealth visit.

Response: We clarify that the item on use of telehealth would be a single question that collects self-reported information from CAHPS for MIPS Survey respondents on the modalities of care they received over the prior 6 months (in-person, by phone, or video visit). We clarify here that this survey item would be for informational purposes only (similar to the existing CAHPS for MIPS Survey item that assesses internet use at home), and would not be used for quality scoring or payment purposes.

Comment: One commenter did not support the inclusion of a new measure assessing telehealth services until there is clarification on the intent of the questions, descriptions of what information will be collected, robust testing of the usefulness of the new measure and impact on response rates and performance, and NQF endorsement of the new CAHPS for MIPS survey question. One commenter wanted clarification on whether the purpose of adding a telehealth measure is to assess digital literacy of patients or to allow patients to assess the degree to which services provided remotely were appropriate and met their needs.

Response: We note that in 85 FR 50292, we proposed to integrate a single item into the CAHPS for MIPS Survey to collect respondents' self-reported data on use of telehealth services (for example, by phone or video visit) during the prior 6 months. We clarify here that this survey item would be for informational purposes only (similar to the existing CAHPS for MIPS Survey item that assesses internet use at home). That is, this item would not be used for quality scoring or payment purposes. Rather, the purpose of this question would be to provide CMS and participating groups with useful information about utilization of telehealth by their assigned patients, specifically, self-reported data on mode of telehealth delivery (phone vs. video). The item will also capture whether any in-person visits occurred and will allow CMS and participating groups to examine the reports and ratings of care for patients receiving telehealth visits and will allow CMS to examine resulting CAHPS scores for groups whose patients used telehealth. It may promote comparison of the experiences of patients using telehealth with those who have not used telehealth, which could inform quality improvement efforts for individual groups and allow CMS to monitor the experiences of assigned patients (both those utilizing telehealth and those who do not). The proposed item has not been field tested. As with existing CAHPS for MIPS Survey items, the proposed item has been tested in one-on-one interviews with patients to assess whether patients correctly understand the terms and phrases used in the question and are able to recall experiences relevant to the question. Testing was conducted in English and Spanish. CAHPS for MIPS Survey items are not a candidate for NQF review. We do not anticipate the addition of a single telehealth question will affect the survey response rate. Given the rapidly evolving use of telehealth services as a result of the COVID–19 pandemic, we believe the addition of an item to capture the use of telehealth should be added to the performance year 2021 CAHPS for MIPS Survey.

Comment: A few commenters supported the proposed revisions to the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings.

Response: We appreciate the commenters for their support.

After consideration of public comments, we are finalizing our proposal to integrate one telehealth item and update the cover page to reference to care received in telehealth settings

starting in the PY 2021 CAHPS for MIPS Survey administration. Additionally, while no public comments were received, as a result of the qualitative testing we are not making any changes regarding the instructions in the ''Your Care From Specialists in the Last 6 Months'' section of the CAHPS for MIPS Survey in Question 1 of the survey.

(ii) CAHPS for MIPS Patient Assignment

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, these specified Medicare telehealth services are reported using the same codes used for the ''face-to-face'' services, but are furnished using audio/video, real-time, interactive communications technology instead of in person. As such, the majority of the codes for primary care services included in the additional telehealth services added in the March 31st COVID–19 IFC for purposes of the PHE for COVID–19 are already included in the definition of primary care services for purposes of the MIPS assignment methodology for the CAHPS for MIPS Survey (82 FR 77168 through 77169; and 82 FR 53646 through 53647). At § 414.1305, we proposed to codify the definition of primary care services for purposes of MIPS assignment methodology for the CAHPS for MIPS Survey as follows:

- CPT codes:

++ 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for E/M services furnished in a patient's home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and

++ Beginning with the 2023 MIPS payment year, 99421, 99422, and 99423 (codes for online digital E/M services (e-visit)); 99441, 99442, and 99443 (codes for telephone E/M services); and 96160 and 96161 (codes for Administration of Health Risk Assessment).

- HCPCS codes:

++ G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

++ Beginning with the 2023 MIPS payment year, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

In the March 31st COVID–19 IFC, we also established flexibilities for certain services that are furnished virtually using communication technologies, but that are not considered Medicare telehealth services such as virtual check-ins and e-visits (separate payments for such services had previously been established in the CY 2019 PFS final rule). We also established separate payment for telephone E/M services codes during the PHE. The communications technology-based services (CTBS) and the telephone E/M services are not currently included in the MIPS assignment methodology for the CAHPS for MIPS survey.

We believe it is critical to include codes for CTBS and telephone E/M services, as identified and discussed later in this section, in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment. Such inclusion ensures that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for COVID–19 and allowing vulnerable beneficiaries and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. By including services provided virtually, either through telehealth or other uses of communications technology, we would ensure that this care is appropriately reflected in our consideration of the plurality of care used to assign beneficiaries to groups and virtual groups.

We have added new services to the separately billable CTBS under the Physician Fee Schedule over the past several years and a result of the PHE, we expect that the utilization of communications technology-based services will substantially increase during the PHE for COVID–19 and thereafter. We believe that clinicians are increasingly using such services as a key component of their ongoing primary care. In an effort to address the increased use of telehealth during the PHE and use of telehealth, and to maintain alignment with the Shared Savings Program, we proposed to integrate the same telehealth CPT and HCPCS codes that are used for purposes of assigning beneficiaries to Shared Savings Program ACOs into the set of primary care service codes that are used for patient assignment to MIPS groups. We proposed to revise the definition of primary care services used in the MIPS assignment methodology for the 2021 CAHPS for MIPS Survey, and for any subsequent performance year, to include the following additions: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital E/M services (e-visits)); 99441, 99442, and 99443 (codes for telephone E/M services); and 96160 and 96161 (codes for administration of health risk assessment); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in). It should be noted that the proposed inclusion of such codes in the MIPS assignment methodology for the CAHPS for MIPS Survey would align with the definition of primary care services used for purposes of beneficiary assignment under the Medicare Shared Savings Program, which was amended in the May 8th COVID–19 IFC to ensure that these codes for e-visits, telephone E/M services, remote evaluation of patient video/images, and virtual check-ins would be included in determining beneficiary assignment for the 2020 performance year and any subsequent performance year that starts during the PHE for COVID–19 (85 FR 27583). We referred readers to the May 8th COVID–19 IFC (85 FR 27582 through 27586) for a detailed description of the codes that were added to the definition of primary care services under the Medicare Shared Savings Program. We also referred readers to the 2018 PFS final rule (82 FR 53007 through 53011) for a detailed description of the primary care services codes for Administration of Health Risk Assessment.

The services represented by the codes listed above are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. We noted that as a result, we believe these services are an important component of primary care and it is appropriate to include these codes in the definition of primary care services used for assignment for the CAHPS for MIPS Survey. The only codes that are newly billable during the PHE for COVID–19 pertain to the telephone E/M services. It should be noted that these services as well as the remote evaluation of patient video/images and virtual check-in codes, and the online digital E/M service (e-visit) codes are not separately billable by a clinician if they are related to a visit within the past 7 days or lead

to a visit within the following 24 hours or next available appointment.

We believe that clinicians are increasingly using CTBS as a key component of their ongoing primary care. We noted that we expect that the utilization of such services will substantially increase not only during the PHE for COVID–19, but also thereafter. Accordingly, we proposed to include virtual primary care visits and telehealth visits to determine patient assignment to groups for purposes of the CAHPS for MIPS Survey for PY 2021 and subsequent performance years.

We did not receive public comments on this proposal, and therefore, we are finalizing it as proposed.

(g) Quality Performance Category: Expansion of Telehealth Codes Used in Beneficiary Assignment for the CMS Web Interface and CAHPS for MIPS Survey

(i) Background

In conjunction with this final rule and the ongoing impact of the PHE for COVID–19, we published the ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' IFC in the September 2, 2020 **Federal Register**, (hereinafter referred to as the September 2nd COVID–19 IFC), in which we adopted on an interim final basis a policy to include codes for CTBS and telephone E/M services in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment.

As discussed in the IFC, on March 17, 2020, we announced (*https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet*) the expansion of payment for telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 such that Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence, starting March 6, 2020. In the context of the PHE for COVID–19, we recognize that physicians and other health care professionals are faced with new challenges regarding potential exposure risks, including for Medicare beneficiaries, for health care providers, and for members of the community at large. For example, the CDC has recommended health care professionals to make every effort to interview persons under investigation for infection by telephone, text messaging system, or video conference instead of in-person. In the March 31st COVID–19 IFC, to facilitate the use of telecommunications technology as a safe substitute for in-person services, we added on an interim basis many services to the list of eligible Medicare telehealth services, eliminating frequency limitations and other requirements associated with particular services furnished via telehealth, and clarifying several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks (85 FR 19232).

Section 1834(m) of the Act specifies the payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, these specified Medicare telehealth services are reported using the same codes used for the ''face-to-face'' services, but are furnished using audio/video, real-time, interactive communications technology instead of in person. As such, the majority of the codes for primary care services included in the additional telehealth services added in the March 31st COVID–19 IFC for purposes of the PHE for COVID–19 are already included in the definition of primary care services for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey (81 FR 77168 through 77169; and 82 FR 53646 through 53647).

In the March 31st COVID–19 IFC, we also established flexibilities and separate payment for certain services that are furnished virtually using communication technologies, but that are not considered Medicare telehealth services such as virtual check-ins, e-visits. Additionally, we established separate payment for telephone E/M services codes during the PHE. The CTBS and the telephone E/M services are not currently included in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey.

We believe it is critical to include codes for CTBS and telephone E/M services, as identified and discussed later in this section, in the definition of primary care services to ensure these services are included in our determination of where beneficiaries receive the plurality of their primary care for purposes of beneficiary assignment. Such inclusion ensures that the assignment methodology appropriately reflects the expanded use of technology that is helping people who need routine care during the PHE for COVID–19 and allowing vulnerable beneficiaries and beneficiaries with mild symptoms to remain in their homes, while maintaining access to the care they need. By including services provided virtually, either through telehealth, or other uses of communications technology, we ensure that this care is appropriately reflected in our consideration of the plurality of care used to assign beneficiaries to groups and virtual groups.

(ii) Use of Codes for Virtual Check-ins, Remote Evaluations E-Visits, and Telephone E/M Services in MIPS Beneficiary Assignment for the CMS Web Interface and CAHPS for MIPS Survey

We added new services to the separately billable CTBS under the PFS over the past several years and a result of the PHE for COVID–19, we expect that the utilization of CTBS will substantially increase during the PHE for the COVID–19 pandemic and thereafter. We believe that clinicians are increasingly using such services as a key component of their ongoing primary care. In the September 2nd COVID–19 IFC (85 FR 54820), we codified the definition of primary care services used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey. The included codes consisted of previously finalized codes that were already considered primary care services and additional codes that we will be treating as primary care services for the duration of the PHE for COVID–19. The previously finalized codes were as follows: (1) CPT codes: 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31) (81 FR 77168); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for E/M services furnished in a patients' home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for

chronic care management); and 99495 and 99496 (codes for transitional care management services); and (2) HCPCS codes: G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits). The additional codes we added through the September 2nd COVID–19 IFC are as follows: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in). It should be noted that the inclusion of such codes for the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey aligns with the revision that was made to the definition of primary care services used for purposes of beneficiary assignment under the Medicare Shared Savings Program to include the same codes in determining beneficiary assignment for performance year 2020 and any subsequent performance year that starts during the PHE for COVID–19 (85 FR 27583 through 27586).

The services listed above are an important component of primary care and as a result, we believe it is appropriate to include these codes in the definition of primary care services used for assignment for the CMS Web Interface and CAHPS for MIPS Survey because the services represented by these codes are being used in place of similar E/M services, the codes for which are already included in the list of codes used for assignment. It should be noted that the remote evaluation of patient video/images and virtual check-in codes, and the online digital E/M service (e-visit) codes are not separately billable by a clinician if they are related to a visit within the past 7 days or lead to a visit within the following 24 hours or next available appointment. The only codes that are newly billable during the PHE for COVID–19 pertain to the telephone E/M services.

We included the codes in the definition of primary care services for the 2020 performance year and any subsequent performance year that starts during the PHE for COVID–19. We recognized that the application of this policy for the 2020 MIPS performance period is retroactive. Section 1871(e)(1)(A)(ii) of the Act provides for retroactive application of a substantive change to an existing policy when the Secretary determines that failure to apply the policy change retroactively would be contrary to the public interest. Without the inclusion of these codes for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey for the 2020 performance year during the PHE for COVID–19, we would not be able to adequately account for the ways in which beneficiaries are receiving primary care services during the PHE for COVID–19 and as a result, the process to derive assignment and sampling of beneficiaries for the CMS Web Interface and CAHPS for MIPS Survey would not be able to comprehensively capture how primary care services are being furnished to beneficiaries, which may cause many groups and virtual groups to have insufficient sample sizes to be able to administer the 2020 CAHPS for MIPS Survey or report data for the quality performance category using the CMS Web Interface measures. In regard to the CMS Web Interface, such groups and virtual groups may not have sufficient time to select an alternate collection type and prepare their systems to report on measures from a different collection type before the submission period begins for the 2020 performance period and as a result, they would not be able to meet the quality performance category reporting requirements, which could negatively impact their MIPS final score and MIPS payment adjustment. We believe it is important to include the above codes in our assignment methodology because we determine assignment based upon where beneficiaries receive the plurality of their primary care services and whether beneficiaries have designated a MIPS eligible clinician as their primary clinician, responsible for their overall care, and hold groups and virtual groups accountable for the resulting assigned beneficiary population. Including such codes in the definition of primary care services used in MIPS beneficiary assignment during the PHE for COVID–19 will result in a more accurate identification of where beneficiaries have received the plurality of their primary care services.

We received the following comments on the codified definition of primary care services used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey.

Comment: Several commenters supported the proposal to expand the use of telehealth codes to the definition of primary care services that is used in the beneficiary assignment for purposes of MIPS for the CMS Web Interface and CAHPS for MIPS Survey. The commenters indicated that the inclusion of CTBS and telephone E/M services in the primary care definition appropriately reflects the reality of the care being provided during the PHE for COVID–19 and allows patients with mild symptoms to remain in their homes while maintaining access to care. Some commenters stated that the expansion of CTBS and telephone E/M services codes may incentivize clinical data registry reporting. A few commenters recommended that CMS continue this policy on a permanent basis.

Response: We appreciate the support from commenters. In regard to the comment about the applicability of including the added CTBS and telephone E/M services codes for purposes of the assignment methodology on a permanent basis, we note that for purposes of the CMS Web Interface, the addition of such codes would be included for the 2020 performance year and any subsequent performance year that starts during the PHE for COVID–19. The CMS Web Interface will be removed as a collection and submission type starting with the 2022 performance period. For purposes of the CAHPS for MIPS Survey, in section IV.A.3.c.(1)(f)(ii) of this final rule, we note that the inclusion of the added CBTS and telephone E/M services codes in the assignment methodology would be applicable for PY 2021 and subsequent performance years.

Comment: One commenter requested that CMS consider the inclusion of audio-only services.

Response: We will take into consideration the inclusion of other additional service codes pertaining to telehealth services for future rulemaking.

After consideration of the public comments, we are finalizing the provisions of the September 2nd COVID–19 IFC without any modifications. We are finalizing the codified definition of primary care services used in the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS Survey for the 2020 performance year due to the PHE for COVID–19 as defined in § 400.200, to include the following additions: (1) CPT codes: 99201 through 99215 (codes for office or other outpatient visit for the E/M of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31) (81 FR 77168); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for E/M services furnished in a patients' home for claims identified by POS modifier

12); 99421, 99422, and 99423 (codes for online digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and (2) HCPCS codes: G0402 (code for the Welcome to Medicare visit); G0438 and G0439 (codes for the annual wellness visits); G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

(2) Cost Performance Category

We refer readers to the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 and CY 2020 PFS final rules (81 FR 77162 through 77177, 82 FR 53641 through 53648, 83 FR 59765 through 59776, and 84 FR 62959 through 62968, respectively) for a description of the statutory basis and existing policies pertaining to the cost performance category.

In the CY 2021 PFS proposed rule (85 FR 50293), we proposed to weight the cost performance category at 20 percent for MIPS payment year 2023 and 30 percent for MIPS payment year 2024 and all subsequent MIPS payment years.

(a) Weight in the Final Score

Under section 1848(q)(5)(E)(i)(II)(aa) of the Act, in general, 30 percent of the MIPS final score shall be based on the cost performance category. However, section 1848(q)(5)(E)(i)(II)(bb) of the Act gives the Secretary discretion with respect to the weight of the cost performance category for the first 5 years of MIPS. Specifically, under that section, for the first year for which the MIPS applies to payments (the 2019 MIPS payment year), not more than 10 percent of the MIPS final score shall be based on the cost performance category; and for each of the second, third, fourth, and fifth years for which the MIPS applies to payments (the 2020, 2021, 2022, and 2023 MIPS payment years, respectively), not less than 10 percent and not more than 30 percent of the MIPS final score shall be based on the cost performance category. Additionally, section 1848(q)(5)(E)(i)(II)(bb) of the Act states that it shall not be construed as preventing the Secretary from adopting a 30 percent weight for the second, third, fourth, or fifth year if the Secretary determines, based on information posted under section 1848(r)(2)(I) of the Act, that sufficient cost measures are ready for adoption for use under the cost performance category for the relevant performance period. The weights adopted in prior rulemaking for the cost performance category are codified under § 414.1350(d).

In the CY 2020 PFS proposed rule (84 FR 40752), we proposed to incrementally increase the weight of the cost performance category from the existing weight of 15 percent for the 2021 MIPS payment year to 30 percent beginning with the 2024 MIPS payment year as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act. We proposed to incrementally increase the weight of the cost performance category by 5 standard increments each year through the 2024 MIPS payment year, reflecting a weight of 20 percent for the 2022 MIPS payment year, 25 percent for the 2023 MIPS payment year, and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year (84 FR 40752 through 40753).

As cost measures are still being developed, we recognized that clinicians may not have the same level of familiarity or understanding of cost measures as they do with the comparable quality measures. To implement a gradual and predictable approach of increasing the weight of the cost performance category each year would provide clinicians with adequate time to prepare for a 30 percent weight and enable clinicians to gain experience with the cost measures while they represent a smaller portion of the MIPS final score. We recognized that there may be greater understanding of the measures in the cost performance category as clinicians obtain more experience with the measures (84 FR 62959).

After considering the comments we received, we did not finalize our proposals, and instead established at § 414.1350(d)(3) that the weight of the cost performance category will remain at 15 percent of the MIPS final score for MIPS payment years 2021 and 2022 (84 FR 62961). We stated that we expected to propose a weight for the cost performance category for the 2023 MIPS payment year in the CY 2021 PFS proposed rule.

In developing the proposals in the CY 2021 PFS proposed rule, we considered a range of numerical options for the weight of the cost performance category for the 2023 MIPS payment year, with the intention of reaching a weight of 30 percent no later than the 2024 MIPS payment year as required by the statute. The first option we considered was to maintain the cost performance category weight at the status quo for an additional year, in which it would remain at 15 percent for the 2023 MIPS payment year and then increase to 30 percent beginning with the 2024 MIPS payment year, which would be a 100 percent increase (an increase of 15 percentage points) in the weight from 2023 to 2024. We considered such option as a result of the PHE for COVID–19 in order to not increase the weight of the cost performance category during an unprecedented time. However, by maintaining the weight at 15 percent for the 2023 MIPS payment year, the weight would increase two-fold to 30 percent beginning with the 2024 MIPS payment year, which we believe would pose a significant burden to stakeholders and would eliminate any transition of an incremental increase in the cost performance category weight. We believe that the first option would be more burdensome than beneficial to clinicians as they continue to gain more experience with the cost measures and confront the PHE for COVID–19.

The second option we considered was to increase the weight from 15 percent for MIPS payment years 2021 and 2022 to 20 percent for the 2023 MIPS payment year in order to provide a minimal transition that would enable clinicians to continue to become familiar with the cost measures and be prepared for the final increase in the weight of the cost performance category from 20 percent to 30 percent beginning with the 2024 MIPS payment year. We believe that such approach would allow us to reach the statutorily required weight of 30 percent by the 2024 MIPS payment year while providing clinicians with an eased incremental transition starting with the 2023 MIPS payment year and accounting for the consequential impact of the increased clinical costs associated with the PHE for COVID–19. For the 2023 MIPS payment year, we sought to identify a smaller increase in weight while enabling clinicians to gain more experience and familiarity with the cost measures amidst the mitigation of the PHE for COVID–19.

After considering these options, we proposed to establish at § 414.1350(d)(4) the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and at § 414.1350(d)(5) the weight of the cost performance category to be 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year.

We solicited public comment on the proposal, the other options we considered, and any additional options for the weight of the cost performance category that commenters believe we should consider, such as a 22.5 percent weight for the 2023 MIPS payment year and a 30 percent weight beginning with the 2024 MIPS payment year (a 7.5 percent increase for each year). In

general, we noted that we prefer to consider whole numbers for performance category weights, but were interested in obtaining feedback from commenters on the weighing of the cost performance category to have an increase of 7.5 percent for 2 consecutive years for the 2023 and 2024 MIPS payment years.

The following is a summary of the public comments received regarding the proposal to establish the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and 30 percent of the MIPS final score for the 2024 MIPS payment year and each subsequent MIPS payment year and other options for weighting the cost performance category.

Comment: Several commenters supported the proposal to reduce the weight of the quality performance category while simultaneously increasing the weight of the cost performance category. Some commenters supported a gradual and incremental weight increase of the cost performance category from 20 percent for the 2023 MIPS payment year to 30 percent for the 2024 MIPS payment year as a means to balance short-term scoring changes with long-term statutory requirements, which would enable MIPS eligible clinicians, groups, and virtual groups to continue to become familiar with cost measures and be prepared for the final weight increase to 30 percent for the 2024 MIPS payment year. One commenter indicated that such increases to the weight of the cost performance category have been anticipated and is statutorily mandated. Another commenter indicated that the changes to the weight of the cost performance category would heighten the importance of efficiency and cost control for clinicians remaining in FFS and encourage more clinicians to consider migrating to APMs. Another commenter stated that the gradual and incremental increase in weighting for the cost performance category would help compensate for the impact of increased clinical costs associated with the PHE for COVID–19.

Response: We appreciate the support from commenters and agree that providing a 2-year timeframe for the cost performance category to gradually increase would allow us to meet the statutory requirement for weighing the cost performance category at 30 percent by the 2024 MIPS payment year. We also agree that this approach of gradually and incrementally increasing the weight of cost enables MIPS eligible clinicians, groups, and virtual groups to continue to become familiar with the cost measures during the PHE for COVID–19.

Comment: In regard to other options for weighing the cost performance category, one commenter indicated that a 7.5 percent increase in weight each year over a 2-year period (22.5 percent for the 2023 MIPS payment year and 30 percent for 2024 MIPS payment year) may be the most equal option, but that a 5-percentage point weight increase from 15 percent to 20 percent for the 2023 MIPS payment year and a 10-percentage point weight increase from 20 percent to 30 percent for the 2024 MIPS payment year would not be any more of a burden. Another commenter recommended that the weight of the cost performance category be weighted in whole numbers.

Response: We recognize that any increase in weight for the cost performance category could potentially pose varying levels of burden; however, we sought to decrease burden by establishing a gradual and incremental transition over a 2-year period while allowing clinicians to gain more experience with the cost measures and confront the challenges brought forth by the PHE for COVID–19. We believe that increasing the weight of the cost performance category from 15 percent to 20 percent for the 2023 MIPS payment year in order to provide a minimal transition would enable clinicians to continue to become familiar with the cost measures and be prepared for the final increase in the weight of the cost performance category from 20 percent to 30 percent beginning with the 2024 MIPS payment year, which allows clinicians to become familiar with cost measures and accounts for the consequential impact of the increased clinical costs associated with the PHE for COVID–19. In regard to the comment pertaining to the weight of the cost performance category to be in whole numbers, we agree with the commenter that weighting the cost performance category in whole numbers may reduce added confusion and complexity within our scoring system.

Comment: A few commenters suggested that as the weight of the cost category increases, CMS should help clinicians understand their performance throughout the performance period by creating an application programming interface (API) or another mechanism to provide MIPS eligible clinicians, groups, and virtual groups with real-time information about their cost score in order for them to understand their performance during the performance year and identify areas for improvement.

Response: We appreciate the recommendation from the commenters. We strive to provide performance feedback reports on the MIPS performance categories as soon as we are able to technically and feasibly do so. In order to further assist MIPS eligible clinicians, groups, and virtual groups in understanding their performance under the cost performance category, we provide additional feedback on cost measures that is at the patient level. With the submission and analysis of all data, including the assessment and calculation of cost data occurring after the conclusion of the applicable performance year, it would be impossible to provide real-time scores and feedback reports when the cost performance category has a performance period of a full calendar year, in which performance is based on 12 months of data. We believe that MIPS eligible clinicians, groups, and virtual groups are able to benefit and effectively utilize the performance feedback reports that are typically available around July 1 after the close of the submission period for an applicable performance period. Information provided in the feedback reports are applicable and can be used by MIPS eligible clinicians, groups, and virtual groups to identify areas for improvement for the cost performance category.

Comment: Many commenters did not support the proposal to reduce the weight of the quality performance category to increase the weight of the cost performance category during the PHE for COVID–19 given clinicians are burdened in new ways and trying to navigate through various challenges brought on by the PHE. Several commenters indicated that the PHE for COVID–19 has caused major disruptions in practice, prompting the need to adjust to unusual and unpredictable patient volumes, and indicated that the PHE would impact performance data and therefore, the ability of CMS to accurately assess quality and cost. One commenter indicated that practices in COVID–19 hotspots that are testing for and treating patients with the virus, and fighting the pandemic would be unfairly penalized. Several commenters urged CMS to defer changes to the weight of the cost performance category and maintain the weight at 15 percent of the final MIPS score for the 2023 MIPS payment year while a few commenters recommended that the cost performance category be reweighted to zero percent for the 2023 MIPS payment year to provide clinicians with more time to care for patients through the pandemic, as well as familiarize themselves with

their resource use, including telehealth visits.

Other commenters expressed concern regarding the appropriateness of the cost measures, specifically indicating that there are not many cost measures available to assess cost performance, particularly for specialties. These commenters indicated that a limited number of cost measures would have significant implications for not accurately measuring cost performance and requested that we add new cost episodic-based measures for specialties. One commenter expressed concern that the outcome measures for many specialties are still in the testing phase and indicated that there continues to be confusion surrounding their use and reliability. These commenters did not support any increases to the weight of the cost performance category until more cost measures are available and concerns regarding the validity and accuracy of existing cost measures are addressed (for example, attributing costs at the group level (not attributing the same costs to both individual clinicians and groups), adjusting for risk of social determinants of health, publishing detailed testing results, and holding all measures to strict standards for reliability, statistical significance, actionability, and impact on health outcomes).

Response: Under section 1848(q)(5)(E)(i)(I) and (II) of the Act, for each of the first 5 years of MIPS, the weight of the quality performance category in the final score is determined based on the weight of the cost performance category. The statute requires that by the sixth year of MIPS, the quality performance category and the cost performance category each will make up 30 percent of the final score. Given that the percentage points attributed to the quality and cost performance categories are in tandem, we believe that it is important to meet the statutory requirements while balancing the impact of simultaneously reducing the weight of the quality performance category and increasing the weight of the cost performance category. We believe that increasing the weight of the cost performance category to 20 percent for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year provides a transition that eases the impact of experiencing an increase in the weight of the cost performance category by enabling a gradual and incremental transition over a 2-year period while clinicians confront the challenges brought forth by the PHE for COVID–19 and become familiar with cost measures and feedback reports.

In regard to concerns regarding an insufficient number of cost measures for specialties, and the appropriateness, actionability, validity, and accuracy of available cost measures, we recognize that measures focusing on specific clinical areas and specialties allow for clinicians to receive more actionable and meaningful feedback. To date, we have developed and implemented 18 episode-based cost measures, which are intended to capture the nuances of costs associated with procedures and conditions spanning different types of specialties and clinical areas. We revised the total per capita cost measure to focus on specialties that provide primary care and the Medicare spending per beneficiary clinician measure to focus on costs associated with an inpatient hospitalization. We anticipate that future measures may apply to a greater range of specialties and clinical areas, including areas suggested by stakeholders. We believe that we are able to continue to accurately assess performance for the cost performance category with the available cost measures; in the event that we cannot calculate a score for a given cost measure (for example, if we cannot calculate a benchmark for the measure, or a clinician does not meet the minimum case volume), the measure will not be scored and thus will not affect a clinician's overall cost performance category score. It should be noted that we are not able to address concerns with the existing cost measures during this rulemaking cycle for 2021 performance year given that any new cost measure or modifications to the existing cost measures for the 2021 performance period would have had to be proposed in the CY 2021 PFS proposed rule. The next opportunity for us to introduce new cost measures or modify existing measures would be for the 2022 performance year rulemaking cycle. We do not believe that maintaining the weight of the cost performance category at 15 percent until there are additional cost measures or modifications made to cost measures would be appropriate as we are statutorily required to increase the weight of the cost performance category to 30 percent by the 2024 MIPS payment year and want to ease the impact of experiencing the increase in the weight of the cost performance category by providing a gradual and incremental transition over a 2-year period. We believe it would be significantly more burdensome for MIPS eligible clinicians, groups, and virtual groups to experience a two-fold increase from 15 percent to 30 percent beginning with the 2024 MIPS payment year.

In regard to the concerns about inaccurately assessing cost performance amidst the PHE for COVID–19 and unfairly penalizing practices in COVID–19 hotspots that are testing for and treating patients with the virus, and fighting the pandemic, we note that service assignment allows the episode-based cost measures to capture only the cost of services that are clinically related to the triggering event for the episode (for example, a knee replacement procedure or a hospitalization for stroke). This means that costs resulting from high volumes of COVID–19 treatment services are less likely to be captured in the episode-based costs measures. In addition, all cost measures, including total per capita cost measure and Medicare spending per beneficiary clinician measure are adjusted for clinical risk to account for different levels of care beneficiaries may require due to comorbidities, disability, age, and other risk factors. The risk adjustment model includes variables for clinical factors based on the patient's recent medical history that are outside the influence of the attributed condition to ensure that clinicians who treat higher risk populations, are not penalized. Also, cost measures use standardized claims payments to account for differences in Medicare payments for the same services across health care providers, removing the effect of regional differences in health care provider costs measured by the hospital wage indexes and geographic price cost indexes (GPCIs) or other payment adjustments such as those for teaching hospitals. The payment standardization process also removes the 20 percent increase in the IPPS relative weight under the CARES Act for individuals diagnosed with COVID–19. Furthermore, we have policies in place to account for scenarios when we cannot calculate a score for a given cost measure that does not meet our reliability and benchmark requirements. We believe that the measures in place will allow us to continue to accurately assess cost performance.

In regard to the comment expressing concern about outcome measures for specialties, we note that we have not adopted any such measures in the cost performance category, as these are quality measures. The episode-based cost measures pertaining to specialties that we have adopted are procedural and acute inpatient medical condition measures. These measures focus on the clinicians performing particular procedures or managing particular acute

inpatient medical conditions. These clinicians may often come from one specialty, but not necessarily.

After consideration of the public comments, we are finalizing our proposal to establish at § 414.1350(d)(4) the weight of the cost performance category to be 20 percent of the MIPS final score for the 2023 MIPS payment year and at § 414.1350(d)(5) the weight of the cost performance category to be 30 percent of the MIPS final score for the 2024 MIPS payment year and each subsequent MIPS payment year. We believe that such approach allows us to reach the statutorily required weight of 30 percent by the 2024 MIPS payment year while reducing the impact of experiencing an increase in the weight of the cost performance category too much in any one year, and providing clinicians with an eased gradual and incremental transition starting with the 2023 MIPS payment year.

(b) Addition of New Codes for Telehealth Services to Previously Established Measures for the Cost Performance Category Beginning With the 2021 Performance Period

For the 2021 performance period and future performance periods, we proposed to add costs associated with certain telehealth services to the previously established cost measures. For each cost measure, the telehealth services we proposed to add are directly relevant to the intent of the measure. We referred readers to Table 47 in the CY 2020 PFS final rule (84 FR 62979) for a summary list of the cost measures that have been established for the 2021 performance period and future performance periods, as well as the related discussions in the CY 2019 PFS final rule (83 FR 59767 through 83 FR 59774) and the CY 2020 PFS final rule (84 FR 62962 through 62979). Many services included on the Medicare telehealth service list are billed as telehealth services through the use of a modifier appended to the same code that is used when the service is furnished in person. These codes are already included in the cost measures; however, the additional codes we proposed to add are not currently included for a few reasons. First, some of the codes we proposed to add to the cost measures were newly included on the Medicare telehealth services list through the March 31st COVID–19 IFC (85 FR 19230) and subsequent subregulatory process established in the May 8th COVID–19 IFC (85 FR 27550). Second, some of the codes we proposed to add were not previously considered for inclusion because they were not billed widely enough to be found in empirical claims-based data. This is because our approach for determining clinically related services to include in cost measures, which we established in the CY 2019 PFS final rule (83 PFS 59767 through 59771), relies on empirical data to examine existing practice patterns, in addition to clinical expertise. Having observed an increase in the use of these codes, including those that existed before the PHE for COVID–19, we proposed to add them to adapt the measures to this change in practice patterns. The codes we proposed to add to the cost measures represent service categories already captured in the measures (for example, E/M, follow up consultation following hospital discharge); thus, we do not consider their addition to alter the intent of the measures or capture a new category of costs. Updated measure specifications with the added telehealth codes are available on the CMS website at *http://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*.

We solicited public comment on the proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported our proposal to add costs associated with certain telehealth services to the previously established cost measures beginning with the 2021 performance period. Other commenters requested that CMS release updated measure specifications that include the additional telehealth services as soon as possible.

Response: We appreciate the support of our proposal to add costs associated with certain telehealth services to the cost measures. We posted the measure codes list files, which include the telehealth codes that we proposed to add for each cost measure, at the link specified in the proposed rule (*http://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*) (85 FR 50294) for the duration of the public comment period.

Comment: One commenter suggested that CMS explore options for separately identifying telehealth services on episode cost performance feedback reports provided to clinicians to help guide clinicians' assessment of optimal telehealth use from the cost perspective.

Response: We thank the commenter for their suggestion. We will explore the possibility of including information on telehealth use when producing future performance feedback reports.

Comment: A few commenters suggested that CMS conduct and publicly share testing on the inclusion of telehealth services in the existing cost measures so that clinicians can become more familiar with how these services will affect the measures and to allow CMS to implement any necessary changes based on input from physician specialty societies regarding the impact of the addition of these services. One commenter indicated that the codes CMS proposed to add within the cost measures represent service categories already captured in the measures and requested that CMS clarify whether they plan to alter the intent of the cost measures. Another commenter requested more information on how telehealth services would be identified, whether the inclusion of these services could penalize physicians practicing in areas with COVID–19 outbreaks, and whether there will be downstream effects from adding codes that are only temporarily covered by Medicare during the PHE.

Response: The addition of the proposed telehealth services and corresponding codes to the measures beginning with the 2021 performance period will ensure that the cost measures adapt to the changes in care provision and service utilization caused by the PHE. As we explained in the proposed rule (85 FR 50294), we do not consider the addition of the proposed codes for telehealth services to be a substantive change as they do not represent a new category of costs or change the intent of the measure and so we do not believe it is necessary to conduct specific testing on their inclusion for public feedback. Our intent is only to update the list of codes in the service categories already captured in the measures. For this reason, we do not anticipate that these services will have an impact on the measures' ability to accurately capture cost of care or clinician performance on measures in a way that is different from other similarly appropriate services that are currently included in the measures.

Furthermore, not all telehealth services billed by a clinician will be automatically included in all of the cost measures. Specific telehealth services will be included in a given measure if they are clinically relevant (for example, contain a relevant diagnosis code) to the trigger event of the measure (for example, a knee arthroplasty). For this reason, clinicians in areas with COVID–19 outbreaks would not be adversely affected by the addition of these services to the cost measures; only telehealth services they bill in relation to the care provided for the trigger event would be included in the cost measure. The service assignment logic and the specific telehealth codes that we

proposed to include for each cost measure are available in the measure codes list files on the CMS website (*http://www.cms.gov/Medicare/Quality-Payment-Program/Quality-Payment-Program/Give-Feedback*).

Upon the expiration of the PHE, Medicare will no longer include on the Medicare telehealth list the services that were added on an interim basis during the PHE for COVID–19, which we expect will result in the reduction of telehealth utilization in place of the corresponding in-person services already included in the cost measures. As the cost measures include the costs of services found empirically in the Medicare claims data, only services actually billed by clinicians, whether furnished in-person or via telehealth, would be included in service assignment for the measure. For this reason, we do not anticipate any downstream effects of adding to the cost measures codes that may be temporarily billed as telehealth services. As we anticipate that telehealth will continue to occupy an important role in care delivery, we do not plan to remove the proposed telehealth codes from the cost measures unless they are no longer applicable or payable by Medicare. We will continue to monitor the telehealth services for potential updates, if necessary, as part of ongoing measure maintenance for the cost measures.

Comment: One commenter indicated that the rationale for including telehealth costs within the cost performance category measures was understood, but urged CMS to consider developing hardship exemptions from such telehealth cost attribution and/or providing bonus points for cost measures that include telehealth services to help adjust for the upfront investments that solo practitioners and small practices would need to put forth to upstand and scale telehealth platforms during the PHE for COVID–19.

Response: We appreciate the commenter's feedback. The proposed telehealth codes would be added to the cost measures to capture costs of services clinicians have continued to provide via telehealth and not in person during the PHE and that are related to the trigger event for a given measure. There is no separate telehealth cost attribution for which these codes would be used. Performance under the cost measures will be assessed according to existing MIPS scoring policies and any new policies we are finalizing in this rule. With regard to hardship exemptions, we provide the option for clinicians to submit applications requesting reweighting for one or more MIPS performance categories based on extreme and uncontrollable circumstance.

After consideration of the public comments, we are finalizing our proposal to add costs associated with certain telehealth services and their corresponding codes to the previously established cost measures as proposed, beginning with the 2021 performance period.

(3) Improvement Activities Performance Category

(a) Background

For previous discussions on the background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 PFS final rule (83 FR 59776 through 59777), and the CY 2020 PFS final rule (84 FR 62980 through 62990). We also refer readers to § 414.1305 for the definition of improvement activities and attestation, § 414.1320 for the performance period, § 414.1325 for the data submission requirements, § 414.1355 for the improvement activity performance category generally, § 414.1360 for data submission criteria, and § 414.1380(b)(3) for improvement activities performance category scoring.

In the CY 2021 PFS proposed rule (85 FR 50294), beginning with the CY 2021 performance period and future years, we proposed: (1) Changes to the Annual Call for Activities: An exception to the nomination period timeframe during a PHE; and a new criterion for nominating new improvement activities; (2) a process for HHS-nominated improvement activities; and (3) to modify two existing improvement activities. In addition, in the March 31st COVID–19 IFC (85 FR 19276 through 19277), we adopted, on an interim final basis, a policy to add one new improvement activity to the Inventory for the CY 2020 performance period in response to the PHE titled ''COVID–19 Clinical Trials.'' The activity required that a clinician must attest to participation in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection and report their findings through a clinical data repository or clinical data registry. Following the publication of March 31st COVID–19 IFC, we received several inquiries from stakeholders requesting further information on whether a clinician working with COVID–19 patients who provides their data to a clinical data registry, without participating in a clinical trial, may get credit for this activity. In our efforts to provide clarification we realized that we needed to codify changes in the regulation for this improvement activity to apply in the manner that was intended. Therefore, in the September 2nd COVID–19 IFC (85 FR 54848 through 52851), we issued an IFC in which we adopted a modification, on an interim final basis, to the COVID–19 improvement activity that for CY 2020 continuing into CY 2021, the improvement activity IA_ERP_3 titled ''COVID–19 Clinical Data Reporting with or without Clinical Trial'' would include: (1) Clinicians participating in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection who report their findings through a clinical data registry for the duration of their study; or (2) clinicians participating in the care of a patient diagnosed with COVID–19 who simultaneously submit their clinical patient data to a clinical data registry for research.

(b) Improvement Activities Inventory

(i) Annual Call for Activities

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination

form available at *www.qpp.cms.gov* during the Annual Call for Activities.

(A) Timeframe for the Annual Call for Activities

(aa) Currently Adopted Timeframe

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the transition year of MIPS, we implemented the initial improvement activities Inventory and took several steps to ensure it was inclusive of activities in line with statutory and program requirements. For Year 2, we provided an informal process for submitting new improvement activities or modifications for potential inclusion in the comprehensive improvement activities Inventory for the Quality Payment Program Year 2 and future years through subregulatory guidance (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Annual-Call-for-Measures-and-Activities-for-MIPS_Overview-Factsheet.pdf*). In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), for Year 3 and future years, we finalized a formal Annual Call for Activities process for adding possible new activities or providing modifications to the current activities in the improvement activities Inventory, including information required to submit a nomination form similar to the one we utilized for Year 2 (82 FR 53656 through 53659). It is important to note that in order to submit a request for a new activity or a modification to an existing improvement activity the stakeholder must submit a nomination form available at *www.qpp.cms.gov* during the Annual Call for Activities.

In the CY 2019 PFS final rule (83 FR 59781 through 59782), we finalized to change the performance year for which nominations of prospective new and modified improvement activities would apply, such that beginning with the CY 2019 performance period and for future years, improvement activities nominations received in a particular year will be vetted and considered for the next year's rulemaking cycle for possible implementation in a future year. In addition, we finalized to change the submission timeframe for the Annual Call for Activities from February 1st through March 1st to February 1st through June 30th, providing approximately 4 additional months for stakeholders to submit nominations beginning with the CY 2019 performance period.

(bb) Exception During Public Health Emergencies

The unprecedented PHE [125] for COVID–19 has brought to our attention the necessity of having the flexibility to consider nominations of new improvement activities to the Inventory outside the established Annual Call for Activities nomination period. We believe having the flexibility to consider nominations during a PHE is important because of the nature of a PHE; we want the ability to consider relevant improvement activities while the emergency is ongoing. We refer readers to the CY 2019 PFS final rule (83 FR 59779) for a complete definition of PHE and its application to inclusion criteria for new improvement activities.

As a result, beginning with the CY 2021 performance period, we proposed to make an exception to the established timeframe, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through June 30th each year, we would accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). We noted that we continue to believe it is important for stakeholders to be able to comment on improvement activities. Therefore, any improvement activity considered for inclusion in the Inventory would be finalized through a future rulemaking. We invited public comments on the proposal.

We received public comments on the proposal to make an exception to the established Annual Call for Activities timeframe, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported adding flexibility to consider nominations of new improvement activities outside the established Annual Call for Activities nomination period during a PHE, noting that it will allow new improvement activities to reflect real-world events, spur innovation, and allow for timely responses to a PHE.

Response: We appreciate the support for establishing the flexibility to consider nominations of new improvement activities outside the established Annual Call for Activities nomination period during a PHE. We believe that this flexibility will allow us to be responsive to the needs of clinicians during PHEs.

Comment: A few commenters supported adding this flexibility, but recommended that data validation and other guidance for how to receive credit be provided when activities were introduced, that new additions allow for a 90-day performance period with a ''ramp-up'' period, and that feedback be provided on why certain submitted improvement activities were not accepted.

Response: We appreciate the additional comments related to data validation, a ''ramp-up'' period, and feedback for submitted activities that are not accepted. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). We noted that we continue to believe it is important for stakeholders to be able to comment on improvement activities. Therefore, any improvement activity considered for inclusion in the Inventory would be finalized through a future rulemaking. For improvement activities related to a PHE, we plan to issue subregulatory guidance as soon as feasible following adoption of the new improvement activity. Improvement activities added during a PHE will be subject to the same 90-day performance period requirement as all improvement activities and will be available for reporting as stated in the regulation that the new activity is finalized. There will not be an added ''ramp-up'' or trial period as the goal of this added flexibility is to encourage clinicians to begin addressing the PHE as soon as possible and get credit for early efforts.

Comment: We received a few comments stating that the improvement activity submission and acceptance process through the Annual Call for Activities is unclear. Commenters stated that they are uncertain what types of improvement activities we are looking for, and the reasons improvement activities are not accepted are not explicitly provided. A few commenters recommended that we should better incorporate the suggestions of physicians and specialty societies and allow more time for providers to adjust

[125] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.*

to changes to improvement activities before they take effect.

Response: We understand the need for feedback on why certain submitted improvement activities were not accepted during the Call for Activities and will do our best to provide clear responses when not accepting suggested activities in the future. In the CY 2018 Quality Payment Program final rule (85 FR 53656 through 53660), we provide details regarding adding new activities through the Annual Call for Activities, the criteria for nominating new improvement activities, and the submission timeline for nominating new improvement activities. In addition, each year we provide subregulatory guidance that contains comprehensive information regarding the Annual Call for Activities. We refer readers to these documents on the Quality Payment Program website in the resource library at *https://qpp.cms.gov/about/resource-library*. After consideration of the public comments, we are finalizing this policy as proposed.

(B) Criteria for Nominating New Improvement Activities

In the CY 2019 PFS final rule (83 FR 59778 through 59779), we adopted one new criterion and removed a criterion from the improvement activities nomination criteria. We also clarified our considerations in selecting improvement activities.

(aa) Currently Adopted Criteria

In the CY 2017 Quality Payment Program final rule (81 FR 77190 through 77195), we discussed guidelines for the selection of improvement activities. In the CY 2018 Quality Payment Program final rule, we formalized the Annual Call for Activities process for Year 3 and future years and added additional criteria; stakeholders should apply one or more of the below criteria when submitting nominations for improvement activities (82 FR 53660). In addition, in the CY 2019 PFS final rule (83 FR 59779) we finalized to add a ''public health emergency as determined by the Secretary'' to the criterion below.

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary; or
- CMS is able to validate the activity.

(bb) New Criteria

In addition to the aforementioned considerations, when considering improvement activities for possible inclusion in MIPS, we proposed that beginning with the 2021 Call for Activities, MIPS improvement activities submitted should be linked to existing and related quality and cost measures, as applicable and feasible. Stakeholders that select this criteria would be required to provide a rationale describing how they believe their improvement activity correlates to other performance category measures as a part of the Call for Activities. We noted that we believe that when possible, it is important to establish a strong linkage between quality, cost, and improvement activities.

Therefore, we proposed to adopt an additional criterion entitled ''Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible'' to the criteria for nominating new improvement activities beginning with the CY 2021 performance period and future years. We noted that if the proposal to add one criterion is adopted as proposed, stakeholders should apply one or more of the below criteria when submitting nominations for improvement activities beginning with the CY 2021 performance period and future years:

- Relevance to an existing improvement activities subcategory (or a proposed new subcategory);
- Importance of an activity toward achieving improved beneficiary health outcomes;
- Importance of an activity that could lead to improvement in practice to reduce health care disparities;
- Aligned with patient-centered medical homes;
- Focus on meaningful actions from the person and family's point of view;
- Support the patient's family or personal caregiver;
- Representative of activities that multiple individual MIPS eligible clinicians or groups could perform (for example, primary care, specialty care);
- Feasible to implement, recognizing importance in minimizing burden, especially for small practices, practices in rural areas, or in areas designated as geographic HPSAs by HRSA;
- Evidence supports that an activity has a high probability of contributing to improved beneficiary health outcomes;
- Include a public health emergency as determined by the Secretary;
- Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible; or
- CMS is able to validate the activity.

We received public comments on the proposal to adopt an additional criterion entitled ''Include activities which can be linked to existing and related MIPS quality and cost measures, as applicable and feasible'' to the criteria for nominating new improvement activities. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal for improvement activities to be linked to existing and related MIPS quality and cost measures, noting that it could offer more visibility for cost measures, synchronize cost and quality measures, and help reduce reporting burden.

Response: We appreciate commenters' support for this policy. We believe these policies will also facilitate cohesive MVPs in the future.

Comment: A few commenters supported linking improvement activities to MIPS quality and cost measures but recommended deferring the requirement until the MIPS MVPs have been implemented and assessed. Commenters also recommended linking new improvement activities to existing MIPS QCDR measures, adding more improvement activities that are focused on specific specialties and clinician types and can be more easily linked to quality and cost measures, and allowing new improvement activities to be added even when they cannot be linked to existing quality and cost measures.

Response: We appreciate the support for linking improvement activities to MIPS quality and cost measures. To clarify, linking nominated improvement activities to existing and related MIPS quality and cost measures is not a stand-alone requirement. In the proposed rule, we proposed that beginning with the 2021 Call for Activities, MIPS improvement activities submitted should be linked to existing and related MIPS quality and cost measures, as

applicable and feasible. Stakeholders should apply one or more of the listed criteria when submitting nominations for improvement activities. The quality and cost performance categories are two of the four performance categories required by statute in MIPS. We believe that the improvement activities should be linked to existing and related quality and cost measures rooted in statute. We applied a similar criterion for the quality measures as finalized in the CY 2020 PFS final rule (84 FR 62954) such that beginning with the 2020 Call for Measures process, MIPS quality measure stewards will be required to link their MIPS quality measures to existing and related cost measures and improvement activities, as applicable and feasible. MIPS quality measure stewards will be required to provide a rationale as to how they believe their measure correlates to other performance category measures and activities as a part of the Call for Measures process. In addition, we have finalized in the CY 2020 PFS final rule (84 FR 63063 through 63065) that QCDRs will be required to link their QCDR measures to existing and related cost measures and improvement activities, as applicable and feasible.

Comment: Several commenters supported making changes to how MIPS improvement activities are developed and added to the Improvement Activity Inventory, including selecting improvement activities that promote modern connected technologies, incent clinicians who participate in COVID–19 efforts, encourage clinicians who serve as preceptors for students, promote integration of registered dietitians on population management care teams, incent bone health, and expand the list of health equity-related improvement activities.

Response: We encourage stakeholders to submit nominations for activities through the Call for Activities period where nominations may include promoting modern connected technologies, incenting clinicians who participate in COVID–19 efforts, encouraging clinicians who serve as preceptors for students, promoting integration of registered dietitians on care teams, incenting bone health, and increasing the number of health equity-related improvement activities. Regarding the latter, we currently have an improvement activity in the Inventory, IA_AHE_6, titled ''Provide Education Opportunities for New Clinicians'' that is weighted high for participation as a preceptor for clinicians in-training that encourage clinical rotation in community practices in small underserved, or rural areas. If the commenter believes an additional improvement activity for preceptors should be included in the Inventory, we encourage them to submit a nomination through the Call for Activities. In addition, in the September 2nd COVID–19 IFC (85 FR 54848 through 52851), we adopted, on an interim final basis, a policy to add an additional improvement activity to the Inventory for CY 2020 and CY 2021. We also refer readers to Appendix 2 of the CY 2021 PFS proposed rule (85 FR 50664 through 50665) for further details and Appendix 2 of this final rule for responses to comments received and finalization of the COVID–19 improvement activity, IA_ERP_3, titled ''COVID–19 Clinical Data Reporting with or without Clinical Trial.'' Furthermore, in section IV.A.3.c.(3)(b)(i) of this final rule, we are finalizing an exception to the established Annual Call for Activities timeframe, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. In section IV.A.3.c.(3)(b)(ii) of this final rule, we are also finalizing a process for HHS-nominated improvement activities. Combined, we believe these two new policies will help streamline efforts to create MIPS policies in a timely manner in response to PHEs.

After consideration of the public comments, we are finalizing this policy as proposed.

(ii) HHS-Nominated Improvement Activities

(A) Background

As stated in the CY 2021 PFS proposed rule (85 FR 50295), this unprecedented PHE for COVID–19 has brought to our attention the necessity of having the flexibility to consider nominations of new improvement activities to the Inventory outside the Annual Call for Activities nomination period and process.'' We noted that we believe that we should have the flexibility to nominate activities from within HHS. We noted that the federal government is uniquely positioned to quickly address administration goals versus the public sector in pertinent areas that may have national impact to improve the health care system. For example, CMS has established the CMS Strategic Initiatives which provides 16 distinct focus areas including Patients over Paperwork. The CMS Strategic Initiatives focus areas aim to empower patients and unleash innovation while transforming the health care system. We also noted that we believe that goals such as the CMS Strategic Initiatives deliver better value and results for patients through competition and innovation. To accomplish goals included in agency-wide plans, such as the CMS Strategic Initiatives, there are instances when it is necessary to accept HHS-nominated improvement activities outside of the Call to advance these type of goals in an expedited manner. We referred readers to *https://www.cms.gov/About-CMS/Story-Page/our-16-strategic-initiatives* for more information about CMS strategic initiatives and to *https://www.cms.gov/About-CMS/story-page/patients-over-paperwork* for more information about Patients over Paperwork.

(B) HHS-Nominated Improvement Activities Process

Beginning with the CY 2021 performance period and future years, we proposed that we would consider HHS-nominated improvement activities all year long in order to address HHS initiatives in an expedited manner. These HHS-nominated improvement activities would be subject to the same criteria for nominating new improvement activities as discussed in the CY 2021 PFS proposed rule (85 FR 50295 through 50296) titled ''Criteria for Nominating New Improvement Activities.'' In addition, the HHS-nominated activity would need to apply the criteria of: ''aligned with at least one of the HHS goals, when feasible and appropriate'' to the nominated activity. Further, the HHS-nominated improvement activity would be assessed for the most appropriate subcategory; we refer readers to § 414.1355(c).

We noted that we continue to believe it is important for stakeholders to be able to comment on these HHS-nominated improvement activities. Thus, we would propose any HHS-nominated improvement activities through rulemaking. In such proposal, we would specifically request comment on whether stakeholders agree the activities improve clinical practice or care delivery.

We received public comments on the proposal that we would consider HHS-nominated improvement activities all year long to address HHS initiatives in an expedited manner. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposal to allow for HHS-nominated improvement activities all year long.

Response: We appreciated the support for allowing HHS-nominated improvement activities all year long. This will allow us to be responsive to HHS initiatives.

After consideration of the public comments, we are finalizing this policy as proposed.

(iii) Changes to the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303), and Tables A, B, and C in the Appendix 2 of the CY 2020 PFS final rule (84 FR 63514 through 63538) for our previously finalized improvement activities Inventory. We also refer readers to the Quality Payment Program website under Explore Measures and Activities at *https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2020* for a complete list of the most current list of improvement activities. In the CY 2021 PFS proposed rule, we did not propose to remove any previously adopted improvement activities. We also proposed to modify two existing improvement activities for the CY 2021 performance period and future years. In this final rule, we are finalizing the modification of two existing improvement activities, removal of one obsolete improvement activity, and adoption of the COVID–19 improvement activity added via IFC. We refer readers to the below and Appendix 2 of this final rule for more details.

(A) Removal of IA_CC_5

Subsequent to publication of the proposed rule, we became aware that one underlying program, which forms the basis for one improvement activity, has expired. The improvement activity is: IA_CC_5, titled ''Partner in Patients Hospital Engagement Network.'' The Partner in Patients Hospital Engagement Network activity description requires membership and participation in a CMS Partnership for Patients Hospital Engagement Network which ended March 31, 2020, and may be found at *https://innovation.cms.gov/innovation-models/partnership-for-patients*. Because the Partnership for Patients Hospital Engagement Network has ended and performance of this activity will no longer be possible starting with the CY 2021 performance year, this improvement activity is obsolete; therefore, we are finalizing removal of this improvement activity beginning with the CY 2021 performance year/2023 MIPS payment year to avoid any potential confusion. We refer readers to Appendix 2 of this final rule for more details.

(B) Finalization of COVID–19 Improvement Activity Added via IFC

The COVID–19 pandemic was deemed a PHEby the Secretary of the Department of HHS. In response, in the March 31st COVID–19 IFC (85 FR 19276 through 19277), we added one new improvement activity to the Improvement Activities Inventory for the CY 2020 performance period in response to the PHE titled ''COVID–19 Clinical Trials.'' As described in the March 31st COVID–19 IFC, this improvement activity promotes clinician participation in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection. We stated that to receive credit for this improvement activity, a clinician must attest to participation in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection and report their findings through a clinical data repository or clinical data registry (85 FR 19276). In that IFC, we also stated that we believe that participation in this activity would likely result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID–19 and drive care improvements (85 FR 19277). We stated that we believe that encouraging clinicians to utilize an open source clinical data repository or clinical data registry for data reporting will bring the results of their research to the forefront of healthcare far quicker than if it goes through the cycle of peer review and publishing (85 FR 19277). In addition, we stated that we believe that centralized data could improve clinical practice and care delivery (85 FR 19277). As stated in the September 2nd COVID–19 IFC (85 FR 54848 through 52851), following the publication of the March 31st COVID–19 IFC, we received several inquiries through meetings, email correspondence, and Quality Payment Program help desk requesting further information on whether a clinician working with COVID–19 patients who provides their data to a clinical data registry, without participating in a clinical trial, may get credit for this activity. The Quality Payment Program help desk tracks, documents, and resolves inquiries submitted by MIPS eligible clinicians and groups. Stakeholders may submit inquiries to the help desk via 1–866–288–8292 (Monday–Friday 8 a.m.–8 p.m. ET) or email *QPP@cms.hhs.gov*. Some stakeholders believed that clinicians providing care to patients with COVID–19 outside of a clinical trial that report those data through a clinical data registry should receive credit for this activity. It came to our attention that clinical data registries not only collect data as part of clinical trials, but also collect data from clinicians not participating in clinical trials. The improvement activity as written was causing confusion for clinicians and groups attempting to meet the needs of patients and address gaps in research. Since IA_ERP_3 titled ''COVID–19 Clinical Trials'' was established, this improvement activity has been the subject of approximately 30 percent of the inquiries to the Quality Payment Program help desk, demonstrating the desire for clinicians to improve clinical care and overall outcomes for patients diagnosed with COVID–19 by conducting this improvement activity, but also indicating the need for further clarity in its activity description.

As a result, we expanded the improvement activity to include clinicians participating in the care of a patient diagnosed with COVID–19 who simultaneously submit their clinical patient data to a clinical data registry for research. Thus, in order to receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) Participate in a COVID–19 clinical trial utilizing a drug or biological product to treat a patient with a COVID–19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID–19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID–19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. We also modified the improvement activity title to reflect this change.

For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) The receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes.

Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publicly available specific information on what data the registry gathers, technical

requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.

As stated in the March 31st COVID–19 IFC, we continue to believe that participation in this activity is likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients. We believe that all clinical data gathered in the treatment of patients diagnosed with COVID–19 may be helpful in finding a solution to end this pandemic. We believe encouraging clinicians collectively to utilize a clinical data registry for data reporting could facilitate sharing of data for use in additional clinical studies with larger sample sizes. These additional and larger clinical studies are likely to identify efficacy of certain treatments, which in turn could result in wider improvements in health outcomes, including reduced severity and mortality due to COVID–19 across the nation. This could benefit patients nationwide as well as improve clinical practice and care delivery for the patients of the clinician attesting to this improvement activity. We would like to encourage all clinicians to provide data through an open source clinical data repository or clinical data registry, meaning that the results of research are made public, including via publications and scientific data sources, which enables reuse, increases transparency, and facilitates reproducibility of research results. Furthermore, a clinical data registry may allow such data to be publicly available which may be used for research.

As stated above, we previously added the improvement activity to the Inventory for the CY 2020 performance period only in response to the PHE for COVID–19. In the IFC, we extended the newly modified COVID–19 Clinical Data Reporting with or without Clinical Trial improvement activity through the CY 2021 performance period due to the increased rate of COVID–19 infection we were experiencing nationwide. We anticipated the need for COVID–19 clinical trials and data collection/sharing through registries to continue through CY 2021 at which time we would reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed. We wanted eligible clinicians to be able to attest to this improvement activity if it is still pertinent. We believed that participation in this improvement activity was likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID–19.

In this final rule, we are providing summary of public comments and our responses as well as finalizing the addition of this COVID–19 improvement activity and its subsequent modification and continuation. We refer readers to Appendix 2 of this final rule for more details.

(4) Promoting Interoperability

(a) Background

Section 1848(q)(2)(A) of the Act includes the meaningful use of certified electronic health record technology (CEHRT) as a performance category under the MIPS. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of the MIPS shall be used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians will be evaluated under all four of the MIPS performance categories, including the Promoting Interoperability performance category.

(b) Promoting Interoperability Performance Category Performance Period

As finalized in the CY 2020 PFS final rule at § 414.1320(f)(1) (84 FR 62992), for purposes of the 2023 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Thus, for the 2023 MIPS payment year, the performance period for the Promoting Interoperability performance category is a minimum of a continuous 90-day period within CY 2021, up to and including the full CY 2021 (January 1, 2021 through December 31, 2021).

For the 2024 MIPS payment year and each subsequent MIPS payment year, we proposed to add § 414.1320(g)(1), which would establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. As discussed in the CY 2021 PFS proposed rule (85 FR 50297), the proposal aligns with what we proposed (and subsequently finalized) for the EHR reporting period in CY 2022 for the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) (85 FR 58966 through 58967). We stated that we believe this would be an appropriate performance period because it would offer stability and consistency for eligible clinicians reporting for the Promoting Interoperability performance category.

We requested comments on the proposal and the following is a summary of the comments we received and our responses.

Comment: Many commenters appreciated the continuation of the flexibility of being able to choose a 90-day performance period, which allows more eligible clinicians to successfully participate in the Promoting Interoperability performance category. A few commenters believe that 90 days is a sufficient amount of time to capture the necessary information required for the Promoting Interoperability performance category and allows the opportunity to update or implement new and innovative technology through the course of the CY without fear of negatively impacting performance data. Several commenters supported our proposal because it aligns with the EHR reporting period for eligible hospitals and CAHs adopted for the Medicare Promoting Interoperability Program.

Response: We agree that keeping the performance period to a minimum of 90 consecutive days affords MIPS eligible clinicians the flexibility they may need to develop and update their evolving EHRs. We believe aligning the length of the Promoting Interoperability Performance category performance period with the EHR reporting period for the Medicare Promoting Interoperability Program for eligible hospitals and CAHs will reduce health IT burden across EHR systems in the clinician and hospital settings.

Comment: Several commenters suggested that we make the Promoting Interoperability Performance category performance period any continuous 90-day period for the remainder of the Quality Payment Program. One stated that by providing continued program stability, CMS allows clinicians and groups to focus more on caring for patients and improving interoperability and less on prescriptive reporting requirements.

Response: We agree and proposed that the performance period for the 2024 MIPS payment year and each subsequent MIPS payment year would be a minimum of a continuous 90-day period within the calendar year.

After consideration of the comments we received, we are finalizing the proposal for the 2024 MIPS payment year and each subsequent MIPS payment year to establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. We codified this policy at § 414.1320(g)(1).

(c) Promoting Interoperability Performance Category Measures for MIPS Eligible Clinicians

(i) Changes to the Query of Prescription Drug Monitoring Program (PDMP) Measure Under the Electronic Prescribing Objective

As discussed in the CY 2021 PFS proposed rule (85 FR 50297 through 50298), stakeholders have continued to express concern that it is still too premature to require the Query of PDMP measure because PDMPs are still maturing in their development, use and integration with EHRs. We proposed to make the Query of PDMP measure under the Electronic Prescribing objective optional and eligible for 10 bonus points in CY 2021. This would represent an increase in the amount of the bonus points for the Query of PDMP measure from 5 points to 10 points to reflect the importance of this measure and to further incentivize clinicians to perform queries of PDMPs.

We solicited comments on these proposals.

The following is a summary of the comments we received and our responses.

Comment: Many commenters stated that CMS should maintain the Query of the Prescription Drug Monitoring Program (PDMP) measure as optional. One commenter stated that many clinicians will not be able to fulfill this measure because not all clinicians prescribe controlled substances.

Response: We appreciate commenters for their support for maintaining the Query of PDMP measure as optional for the performance period in CY 2021 and allowing time for further progress around EHR–PDMP integration efforts minimizing the burden on MIPS eligible clinicians. We believe this will provide an opportunity for capable implementers to report on and earn bonus points for fulfilling the optional measure. Additionally, eligible clinicians who choose not to report on the Query of PDMP measure or are unable to report on this optional measure may still earn a full score for the Promoting Interoperability performance category.

Comment: Commenters indicated that clinicians have made great strides in their adoption of PDMPs despite a continuing lack of interoperability across many systems; therefore, they supported the measure remaining optional. Some commenters stated that it should not be required because it is challenging to electronically report due to the additional documentation and verification requirements with an external system, which creates unnecessary burden for clinicians. Another commenter expressed concern that until the information found within PDMPs is easily and seamlessly integrated into health IT systems that this type of EHR functional-use measure will be burdensome and require multiple actions outside of the clinical workflow. One commenter noted concerns that separate sign-in to a non-integrated PDMP requires hand entry of demographic data elements to search for a specific patient, which may increase the probability of erroneously matching a patient to another individual's health information, which in turn raises patient safety concerns. For those reasons, the commenters support CMS' proposal to maintain the Query of PDMP measure as optional for the performance period in CY 2021.

Response: We agree with the commenters' concerns and the importance of working towards improved EHR–PDMP integration. Keeping the Query of PDMP measure as optional for CY 2021 would allow states and other stakeholders an additional year to make further progress on developing functionality to support better integration of PDMPs within clinical workflows.

Comment: One commenter stated that the use of PDMPs is a proven means to increase accountability in opioid prescribing practices by providing information directly to the clinician that facilitates the coordination of multiple medications. Also, it has been proven to help prevent adverse drug interactions. The commenter concurred that PDMPs increase patient safety by assisting prescribers in the identification of patients who have multiple prescriptions for controlled substances or may be misusing or overusing them. Expanding the use of PDMPs is a component of a broader strategy to prevent opioid abuse and ensure the safe, legal, and responsible prescribing of opioids for those who need them. The commenter also agreed that improving prescribing practices by use of PDMPs should reduce hospitalizations, emergency room visits, and the social challenges associated with the opioid epidemic. They believe that this not only demonstrates the importance of the measure, but also signals it will likely become a required Promoting Interoperability performance category measure in the future.

Response: We agree that PDMPs are an important tool to support clinicians' efforts to coordinate multiple medications, and increase patient safety by ensuring safe, legal and responsible prescribing. With the many benefits of clinicians querying PDMPs, we are finalizing the policy as proposed for the 2021 performance period. We plan on reevaluating this measure in future years to determine whether integration efforts have enabled improvements in PDMP querying.

Comment: A commenter stated that while they understand that CMS wants to limit burden regarding the implementation and integration of PDMP queries, the commenter is concerned about the potentially negative effect on patient outcomes occurring due to insufficient querying of PDMPs amid the current opioid epidemic. Thus, the commenter suggested CMS move this measure from optional to required as soon as possible.

Response: We understand the importance of implementation and integration of PDMP queries and effects on patient outcomes for the opioid crisis and during the PHE. We also recognize that various state programs are still maturing toward the development of robust EHR–PDMP integration. We will continue to collaborate with our partners in ONC on how to advance standards surrounding PDMP functionality and integration. Keeping the Query of PDMP measure as optional for the performance period in 2021 would allow states and other stakeholders an additional year to make further progress on developing functionality to support better integration of PDMP use within clinical

workflows, which is necessary before we will propose to require this measure.

Comment: Many commenters appreciated and supported increasing the bonus from 5 to 10 points for this measure to reflect the importance of this measure and to further incentivize clinicians to perform queries of PDMPs. A commenter agreed with the proposed increase because it emphasizes the importance of the measure as it relates to improved patient safety and incentivizes clinicians to expand the use of PDMPs. Another commenter stated that the increase of the bonus points for the Query of PDMP measure from 5 to 10 points, not only demonstrates the importance of the measure, but also signals it will likely become a required Promoting Interoperability measure in the future.

Response: We appreciate the overwhelming support and agree that our proposed approach emphasizes the importance of the measure as it relates to improved patient safety and incentivizes clinicians to expand the use of PDMPs.

Comment: One commenter did not support increasing the value of this measure from 5 points to 10 points. Instead, they suggested that CMS keep the bonus at the current 5 points, because they believe most vendors who plan on implementing functionality for this measure have done it, and that groups are currently attesting for it.

Response: We disagree and believe that increasing the points from 5 to 10 points emphasizes the importance of conducting PDMP queries and the importance of this activity for patient outcomes during the PHE and for the opioid crisis. Solo and small practices may have more difficulties incorporating PDMP into practice than larger groups; therefore, we want to incentivize all clinicians to adopt this measure.

After consideration of the comments received, we are finalizing the proposal to maintain the Electronic Prescribing objective's Query of PDMP measure as optional for the performance period in CY 2021. We are also finalizing the proposal to increase the amount of the bonus points for the Query of PDMP measure from 5 points to 10 points for performance periods in CY 2021.

2. Health Information Exchange Objective

a. Support Electronic Referral Loops by Receiving and Incorporating Health Information Measure

In the CY 2019 PFS final rule (83 FR 59807 through 59812), we established a new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure by combining the Request/Accept Summary of Care measure and the Clinical Information Reconciliation measure. To better reflect specific actions required by the measure's numerator and denominator, we proposed to replace the word ''incorporating'' with the word ''reconciling'' in the name of the measure (85 FR 50299). The new name would read: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.

We requested comments on the proposal and the following is a summary of the comments we received and our responses.

Comment: Several commenters agreed that the use of the word ''incorporating'' was confusing to clinicians and supported our proposal. Some stated that the new name better reflects the workflow associated with the measure.

Response: We appreciate the commenters support and agree that modifying the name to Support Electronic Referral Loops by Receiving and Reconciling Health Information measure reduces confusion for clinicians and is a more accurate representation of the measures.

Comment: Several commenters opposed the nomenclature change because it is confusing for clinicians when measure names are changed.

Response: We received significant stakeholder feedback that the proposed name change would more clearly reflect the existing policy. The measure is not requiring clinicians to input redundant information, but rather to review and reconcile what is received with what is already in the patient record.

Comment: A commenter supported the change to the name, but noted that ''reconciling'' may be impossible with certain patient data, so ''attempting to reconcile'' would be preferable.

Response: While we understand the commenter concern, the measure only requires reconciling the available data. Thus, we believe the new name accurately reflects the measure.

Comment: A commenter suggested CMS to maintain this name in future years, as this is the third change in 5 years.

Response: We believe that we are adopting a name that is reflective of the intent of the measure, which should result in no need to revise it in the near future.

After consideration of the comments received, we are finalizing the proposed change to the name of the measure as proposed. The new name is: Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.

b. Engagement in Bi-Directional Exchange Through Health Information Exchange (HIE)

As discussed in the CY 2021 PFS proposed rule (85 FR 50299 through 50302), we proposed an alternative measure for bi-directional exchange through an HIE under the Health Information Exchange objective.

We proposed to add the following new measure under the HIE objective beginning with the performance period in 2021: Health Information Exchange (HIE) Bi-Directional Exchange measure. We proposed to add this new HIE Bi-Directional Exchange measure to the HIE objective as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. We proposed that clinicians either may report the two existing measures and associated exclusions OR may choose to report the new measure. We proposed that the HIE Bi-Directional Exchange measure would be worth 40 points. We also proposed the HIE Bi-Directional Exchange measure would be reported by attestation and would require a yes/no response. We proposed that clinicians would attest to the following:

++ I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the EHR during the performance period.

++ The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and does not engage in exclusionary behavior when determining exchange partners.

++ I use the functions of CEHRT for this measure, which may include technology certified to criteria at 45 CFR 170.315(b)(1), (b)(2), (g)(8), or (g)(10).

We requested comments on our proposals and the following is a summary of the comments we received and our responses.

Comment: The overwhelming majority of commenters supported the addition of the HIE Bi-Directional Exchange measure. Several stated that incentivizing participation in HIEs that support bi-directional exchange would contribute to a longitudinal care record for the patient and facilitate enhanced care coordination across settings. Several commenters supported the increased use and integration of HIEs

into the clinical workflow and applauded CMS for taking steps to incentivize bi-directional exchange with these systems. One commenter supported the measure because it removes the barrier of not having access to another clinician's ''Direct address'' to send transition of care information manually. The commenter stated that this is not only a step in the right direction both to promote increased HIE adoption and use, but also to move away from the existing Send/Receive Transitions of Care measures, which can be convoluted and onerous to optimize within EHR documentation and reporting workflows.

Response: We appreciate all the support for this new measure as we agree that there are many benefits to HIE participation.

Comment: Some commenters appreciated that the attestation statements require information exchange for all patients and all patient records without exclusion, or allowances for partial credit to ensure all patients will benefit from bi-directional exchange.

Response: We appreciate commenters' support and agree that an important feature of this measure is that it emphasizes enabling bi-directional exchange for all of an eligible clinician's patients.

Comment: A commenter worries the proposed new HIE Bi-Directional Exchange measure is unworkable in real-world practice settings and is likely to be cumbersome. The commenter stated that the proposed attestations assume clinicians know what HIEs their hospital uses, and its particular usage. The commenter noted that this generally is not the case and puts the clinician in a position of having to defer to others with this knowledge—an unnecessary and onerous task that increases burden.

Response: We understand that not all eligible clinicians are currently aware of the HIE arrangements utilized by the hospitals and other institutions in which they practice. However, we believe that in many cases eligible clinicians' institutions may be submitting data for MIPS on behalf of clinicians and will be able to assist clinicians with further information about the HIEs in which they participate. Furthermore, we encourage the HIEs whose services qualify to support clinicians in meeting this measure to reach out to participants in order to make them aware of how they can satisfy the measure.

Comment: Another commenter stated that the inclusion of this measure is premature because there are numerous ways that HIEs connect to EHRs. The commenter recommended that CMS partner with ONC to develop certification criteria as there is great variability among HIE connection requirements currently.

Response: We recognize that there is significant variation in the technology arrangements used by HIEs currently. Accordingly, in the third proposed attestation statement, we sought to allow for use of different CEHRT functions, which may support robust HIE connections. Moreover, we believe that HIEs are likely to continue to leverage different technology capabilities to connect to EHRs in accordance with local variations in technology implementation. While we believe it is important to move forward now with incentivizing eligible clinicians to establish robust connections with HIEs, we will continue to work with ONC to explore how the ONC Health IT certification program can further support integration between HIEs and EHRs.

As we stated in the proposed rule, we believe there are numerous certified health IT capabilities which can support bi-directional exchange with a qualifying HIE. For instance, participants may interact with an HIE by using technology certified to the criterion at § 170.315(b)(1) to transmit patient summary care records in the form of a C–CDA to the HIE, or using the technology certified to the criterion at § 170.315(b)(2) to receive and reconcile information received from the HIE into an EHR. Participants could also utilize API technology certified to either the criterion at §§ 170.315(g)(8) or (10) as finalized in the 21st Century Cures Act final rule (85 FR 25742), to enable an HIE to obtain data from a participant's EHR. We note that certified health IT modules meeting certification criteria beyond those mentioned in the proposed rule may also support exchange of information with an HIE for transitions of care, including: Certification criteria at § 170.315(g)(7), ''Design and performance—Application access—patient selection,'' and (g)(9), ''Design and performance—Application access—all data request,'' which support information exchange via API; the certification criterion at § 170.315(e)(1) ''View, download, and transmit to 3rd party'' which supports patient access to their information; and the certification criterion at § 170.315(g)(6) ''Consolidated CDA creation performance'' which supports creation of a summary of care record.

However, we believe that we can provide more clarity in the third attestation statement regarding our intent to allow flexibility for clinicians to use different functions of CEHRT as appropriate to enable bi-directional exchange with an HIE that meets the requirements of the measure. While there are many certified technology capabilities which may support connections with HIEs, as described above, we wish to emphasize that clinicians are only required to use the certified functionality appropriate to their connection with an HIE necessary to support the measure actions. Accordingly, we are finalizing modifications to the third attestation statement, to read: ''I use the functions of CEHRT to support bi-directional exchange with an HIE.'' We believe that this revised statement will provide more clarity to stakeholders regarding the requirements of the measure.

Comment: Several commenters requested that this measure be added to the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. CMS should maintain program alignment by including the HIE Bi-Directional Exchange measure starting in the 2022 reporting year, only after the measure is finalized for inclusion in the program for eligible hospitals and CAHs.

Response: We appreciate the commenters' suggestion to include the HIE Bi-Directional Exchange measure in the Medicare Promoting Interoperability Program for eligible hospitals and CAHs. We may consider adding this measure in future rulemaking. We believe that the benefits that could be reaped by implementing the measure for the 2021 performance period for MIPS eligible clinicians do not warrant a delay of a year for alignment. We disagree that CMS should maintain program alignment with the Promoting Interoperability Program and delay implementing this measure by starting in the 2022 performance period. Due to the PHE and the importance of HIE's enabling enhanced use of telehealth and telemedicine for obtaining and aggregating patient information it is important to implement for the 2021 performance period.

Comment: A commenter stated that the measure fails to account for the significant expense to clinicians who wish to report this new measure. HIEs are expensive, often requiring monthly or yearly subscription fees. Many operational hurdles exist for bi-directional exchange for ''every patient encounter, transition or referral, and record stored or maintained in the EHR'' (section IV.A.3.c.(4)(c)(ii)). These hurdles include but are not limited to: The cost of HIE agreements and implementation, the ability of an HIE to implement interfaces capable of meeting

the standards of the measure, and the difficulty of logistics for healthcare organizations that exist across the jurisdictions of multiple HIE agencies. A commenter recommended that the measure requirements be relaxed for the first year in order to implement the processes through the EHRs and to educate clinicians on utilization and workflows. A suggestion would be to treat this like the measures of the Public Health and Clinical Data Exchange objective thus allowing ''credit'' for being in the process of implementation and/or testing to be compliant with the new measure.

Response: We recognize that there may be additional costs related to establishing a connection with an HIE. Accordingly, we proposed to make this measure optional, and understand that many eligible clinicians may wish to use the capabilities of their CEHRT which represent investments which eligible clinicians have already made. However, we understand that many eligible clinicians are also seeking to take advantage of robust HIE connections which can enable information exchange in an advanced fashion, and we are seeking to incentivize these investments as part of the Promoting Interoperability performance category.

As this measure is optional and attestation-based, we also do not believe it is necessary to provide a ''phase-in'' period for this measure, or to provide credit for eligible clinicians that are in the process of establishing these connections. These clinicians may continue to report on the existing numerator-denominator measures for the HIE objective and switch to reporting on the optional HIE Bi-Directional exchange measure at a future date when they are prepared to do so.

Comment: Several commenters stated that the attestation statements for this measure appropriately reflect the expectations for information exchange capabilities. The commenters believed that the attestation statements are sufficiently broad and allow for the different ways health care providers connect with HIEs.

Response: We appreciate the commenters support.

Comment: A commenter encourages CMS to expand the measure to include ''*HIEs, exchange frameworks, or other organizations focused on bi-directional health information exchange*'' since participation in a single HIE might not meet the measure's requirement to support HIE for ''every patient encounter, transition or referral.''

Response: We appreciate the commenters' concerns. The term ''HIE'' is intended to broadly refer to arrangements that facilitate the exchange of health information, and may include arrangements commonly denoted as exchange ''frameworks,'' ''networks,'' or using other terms. To qualify for the measure, an HIE or other exchange network may qualify to support clinicians in meeting the measure provided it qualifies under the attestation statements including providing the capabilities specified under attestation statement 1 to allow a clinician to enable bi-directional exchange for all of an eligible clinician's patient records and meeting the standard specified under attestation statement 2 related to facilitating non-exclusionary exchange.

Comment: A commenter suggested the first attestation statement be modified by replacing ''enable'' with ''attempt''. Another commenter stated that the second part of the first attestation is confusing: ''and record stored or maintained in the EHR during the performance period.'' EHRs interact with HIEs in different ways and clarification is requested.

Response: We appreciate the commenters' concerns. As we are offering a significant amount of points for this measure, we believe that ''enable'' more accurately reflects the high level of performance and the specific action we are expecting clinicians to take. Also, we understand that there is wide variation in HIE arrangements which may result in different modes of information exchange. The description of services in the first attestation statement would only require enabling of bi-directional functionality for the specified patient population and information. Eligible clinicians would not be required to adhere to specific guidance regarding what data is stored locally by the eligible clinicians EHR and what data is stored within the HIE, if any.

Comment: A commenter suggested that until there is more widespread connectivity and available information in the HIE space that CMS should remove the second attestation statement. Another commenter requested that to minimize burden, CMS remove the second attestation statement.

Response: We disagree that we should remove the second attestation statement, and believe that removing the attestation statement would not be consistent with the exchange behavior we are seeking to encourage through this measure, which is focused on the use of an HIE to exchange with any other clinician who may be involved in the care of any of an eligible clinician's patients. The second attestation statement is intended to ensure that an HIE which supports a clinician in attesting to this measure has the capacity to enable widespread exchange across a given health care market. We also believe that prioritizing those HIEs capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and which do not engage in exclusionary behavior when determining exchange partners, will encourage HIE networks to adopt wider connectivity.

Comment: A commenter stated that the requirement that ''bi-directional engagement occurs for all patients and all records'' is naïve. Newborn babies, for example, do not have information in an HIE, and it is a waste of resources for the system to send a query regarding them.

Response: The first attestation statement as proposed would require clinicians to attest that they have enabled bi-directional exchange for every patient record in their EHR. Enabling bi-directional exchange does not mean that an eligible clinician would be required to conduct information transactions that are not clinically necessary. Rather, it means that an eligible clinician has established the capabilities necessary to complete exchanges of information for their patients at the appropriate time.

Comment: One commenter was encouraged by CMS' proposal and supported CMS relying on yes/no measure attestations for this category as much as possible, which would minimize clinician reporting burden and aligns with how clinicians attest to the improvement activity performance category.

Response: We agree that this measure will provide an optional path for qualifying clinicians to earn credit under the HIE objective while reducing administrative burden associated with reporting on the current measures.

Comment: The definition of an HIE is broad and could apply to many existing entities across the country. A commenter requested that CMS provide some examples of HIEs that they consider to meet the definition of the measure. They added that it would be helpful if CMS could provide examples of the types of evidence that an organization might preserve and provide in case of an audit due to the broad nature of the attestation measure, and multiple sub-statements in which an organization must attest.

Response: We decline to provide a list of HIEs that meet the attributes specified

in the measure. We believe there are a wide number of organizations providing HIE services around the country which could effectively support clinicians who wish to attest to the measure, and we do not want to appear to endorse particular HIEs over others. We also recognize that the HIE space is rapidly changing, and additional organizations may emerge or evolve to meet the attributes described in the attestation statements following the publication of this final rule. In regards to audit documentation, eligible clinicians who choose to attest to this optional measure could support their attestation statements using a variety of materials, including: Agreements with the organization providing them with health information exchange services; materials from the organization that provides their HIE services describing their services in a manner consistent with the attestation statements; or systems documentation from their EHR vendor describing their connection to the HIE.

Comment: Several commenters suggested that CMS implement this new 'bi-directional engagement' replacement option immediately. However, the commenters stated that the threshold should not be every patient encounter. Instead, to make the measure reasonable, the threshold should be set at 50 percent of all eligible encounters. Another commenter suggested that CMS impose a lower threshold for performance. A commenter stated that, as this measure is new and robust connections with HIEs are still rare, they contend that this is an unreasonable requirement and recommend for the CY 2021 reporting year that it be modified to be ''a minimum of 10 percent of patient encounters and for a minimum of 10 percent of patient records transmitted during the performance period.'' Another commenter recommended that CMS consider partial credit for eligible clinicians and new sites being on-boarded to an HIE during the performance period.

Response: We appreciate the commenter's support. However, we disagree with the recommendation to set a threshold for the measure. The goal of this measure is to incentivize connections with HIEs that enable bi-directional functionality for all of the patient records in an eligible clinician's EHR. For clinicians with a robust connection available to an HIE, we do not believe that it would make sense to only enable this functionality for a subset of patients. Therefore, we decline to apply a threshold percentage to this measure. We understand that all eligible clinicians may not have a connection with an HIE that is capable of enabling bi-directional exchange for all of the patient records in an eligible clinician's EHR. However, in recognizing that this functionality is not available for all eligible clinicians, we have proposed that this measure would be optional. We also decline to provide partial credit for this measure as partial performance would not meet the goals of the measure. Our goal in proposing this measure is to incentivize the high standard of performance on health information exchange which can be achieved by establishing robust, bi-directional exchange capabilities facilitated by an HIE. We do not believe that allowing eligible clinicians to satisfy the measure based on a partial threshold would be consistent with incentivizing a high performance standard for the exchange of health information.

Comment: A commenter applauded CMS' desire to incentivize eligible clinicians to participate in HIEs while establishing a high performance standard for sharing information with other clinicians. Like many other practices, the commenter struggles with the ''Sending Health Information'' measure because many receiving health care providers and facilities have not implemented the technology necessary to receive and acknowledge the summary of care.

Response: We appreciate the commenter for their support.

Comment: Commenters suggested that CMS ensure that clinicians continue to have multiple options to meet the Health Information Exchange objective, as not all clinicians will have access to an HIE. The other issue facing practices is the cost of connecting with their local exchanges. High connectivity fees imposed by the HIE and/or the practice's EHR vendor can act as a significant deterrent to connectivity.

Response: We are only finalizing this measure as optional at this time, and recognize that many clinicians may prefer to continue to report using the existing HIE objective measures. We also agree and understand that there are costs associated with utilizing the capabilities of an HIE, and that all clinicians may not choose to assume these costs in addition to existing EHR investments.

Comment: A commenter recommended that CMS limit its HIE Bi-Directional measure conditions to that of exchange between unaffiliated health care provider entities regardless of whether they are using the same EHR product or participating in the same EHR-run HIE. Another commenter stated that more should be done to promote bi-directional exchange between unaffiliated entities and between disparate EHRs.

Response: While we believe that HIE arrangements which only permit exchange between the clinicians using the same EHR product may be useful for increasing interoperability among specific groups of clinicians, our goal with this measure is to incentivize exchange arrangements that allow for advanced interoperability across users of different vendor products. We agree that it is important to continue to encourage HIE arrangements that are capable of supporting exchange between different EHR systems. We note that there are a number of promising initiatives currently seeking to address this issue, and believe that incorporation of the HIE Bi-Directional Exchange measure will contribute to furthering these initiatives and making such services more widely available.

Comment: A commenter stated that while they support incentivizing interoperability of EHRs and the bi-directional flow of health information, the commenter did not believe it is appropriate or timely to introduce this new measure. Clinicians and EHR vendors, in particular, need additional time to comply with 21st Century Cures and subsequent rulemaking requirements regarding interoperability before this measure is added.

Response: We recognize that eligible clinicians participating in the Promoting Interoperability performance category are also impacted by the recently finalized provisions in the 21st Century Cures Act final rule. Our goal in finalizing this measure is to provide eligible clinicians with additional options to earn credit under the Promoting Interoperability performance category. We believe that the flexibility associated with this attestation-based measure can contribute to reducing administrative burden for eligible clinicians.

Comment: A commenter required clarification from CMS of whether an attestation response of ''yes'' could mean that the eligible clinician is prepared to implement the measure but their vendor is not yet capable of supporting the measure. Analogous to the public health measure with a similar attestation, the commenter suggested confirmation that an eligible clinician can attest ''yes'' to the proposed new measure when the clinician is ready and able to participate in the bi-directional exchange but for a limitation of the vendor.

Response: No. To earn the 40 points, the clinician must be connected to an HIE. If their vendor does not support

that connection, they do not fulfill the measure and would earn zero points.

Comment: A commenter stated that given that greater use of HIEs for bi-directional exchange will immediately contribute to enhanced care coordination across settings, this measure should not be optional for 2021, it should be required. Additionally, the commenter recommended that CMS continue to include this as a required measure in the MVPs.

Response: We appreciate commenters' support for this measure. However, at this time we do not believe it is appropriate to require clinicians to report this measure. For instance, we understand that some clinicians may not yet have access to an HIE that is capable of the functions reflected in the attestation statements. As the Promoting Interoperability performance category measures are considered foundational under the MVP framework, all Promoting Interoperability performance category measures would be available to those clinicians choosing to participate in MVPs.

Comment: A commenter requested CMS clarify the HIE being measured through the Promoting Interoperability performance category relates to *any* exchange of health information between HIE entities, meaning the measure does not restrict the exchange to only information sent and received from state HIEs or local health authority HIEs. Another commenter inquired as to whether national HIE networks would qualify.

Response: Nothing in the proposed requirements for this measure would limit qualifying HIE services to those entities managed by states or local health authorities. Moreover, we note that networks providing HIE services which are national in scope could also support eligible clinicians' successful attestation, provided they satisfy the finalized attestation statements.

Comment: A commenter questioned if there are requirements that dictate which HIE clinicians are expected to connect to. The commenter also noted that CMS should clarify whether clinicians are expected to connect to more than one (one in each state) HIE if they practice near a state border. The commenter also requested clarification surrounding a clinician's ability to fulfill this measure if there are no HIEs available for them to connect to.

Response: We did not propose any requirements for HIEs beyond those specified in the attestation statements for eligible clinicians, specifically, that the HIE permits a clinician to enable bi-directional exchange for all of the patient records within their EHR, and that the HIE meets the attributes described around exchanging information across unaffiliated health care providers and disparate EHR systems. We recognize that an organization providing HIE services could meet the conditions in the attestation statements while not facilitating a connection to every clinician or maintaining information on every patient in a given health care market, for instance, in cases where a health care market crosses a state line and the HIEs in each state do not yet share records. However, an eligible clinician may successfully attest to the measure statements as long as they are connected to at least one HIE in a manner consistent with the statements. We also understand that there may be some eligible clinicians who do not have access to any organizations providing HIE services at this time. While clinicians who do not participate in an HIE would not be able to attest for this measure, they would continue to be able to attest to the existing HIE objective measures.

Comment: Other commenters expressed concerns with the attestation statements as proposed. One commenter interprets the statements as meaning that clinicians are attesting that they have the *functional capability* to conduct bi-directional exchange for all patients during the performance period, not that physicians *must conduct* bi-directional exchange for all patients during the performance period. Another commenter recommended that CMS revise the attestation language proposed to ensure that the attesting clinician is not being held accountable for some features of his/her HIE that she might not know about or have control over.

Response: The first attestation statement for this measure requires eligible clinicians to attest that they participate in an HIE to enable bi-directional exchange for transactions for all of their patients. Enabling this functionality to occur for all of the patient records in an eligible clinician's HIE does not mean that clinicians would be required to share or request information when it is not clinically appropriate.

Comment: A commenter appreciated CMS' reference to CEHRT in the third attestation statement and suggested that CMS clarify that the minimum set of data needed to meet this measure's requirement for bi-directional exchange align with the Common Clinical Data Set (CCDS) soon to be the US Core Data for Interoperability (USCDI). The CCDS/USCDI serves as the baseline set of data required for interoperability and is what EHRs are commonly exchanging with HIEs today.

Response: The third attestation statement requires clinicians to attest that they use the functions of CEHRT to engage in bi-directional exchange. Similar to the guidance for the existing measures under the HIE objective, we are not defining a data set as part of the measure, but note that functions of CEHRT include technology certified to criteria which ensure a health IT module is capable of exchanging data contained in the CCDS, and subsequently the USCDI. As finalized in the 21st Century Cures Act final rule, existing references to the CCDS in these criteria will be updated to refer to USCDI consistent with the certification criteria in 45 CFR part 170.

Comment: A commenter requested clarification from CMS regarding the points a clinician is eligible for under this alternative measure. The proposed rule states that a clinician cannot earn more than 40 points, yet under the redistribution policy for exclusions, if a clinician can exclude the eRx measure, the 10 points for that measure are redistributed to the HIE measure, which would make it worth 50 points. The commenter requested that CMS clarify if this is still true if eligible clinicians choose this measure.

Response: The 40 points reflects the number of points available for the new HIE measure. It does not reflect the redistribution of points for the E-prescribing measure. If an exclusion is claimed for the E-Prescribing measure, the 10 points associated with that measure would be redistributed to the HIE objective resulting in 50 points available for the two existing HIE measures or the new HIE Bi-Directional exchange measure.

Comment: A commenter stated that clinicians should not have to attest to the capabilities of their HIE. There are great variances within HIE capabilities, and clinicians have no way of knowing all of them when selecting an HIE. Several commenters requested that HHS publish a list of common, widely known entities that would meet the definition of an HIE for the purposes of this measure.

Response: As discussed above, we decline to name specific entities who represent the attributes described in the second attestation statement, as we do not want to endorse specific organizations. Specifically, the second attestation statement specifies that clinicians attesting to the measure must participate in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate

EHRs, and does not engage in exclusionary behavior when determining exchange partners.

However, we believe that qualifying HIEs that can support eligible clinicians in attesting to this measure will have an interest in clearly communicating this fact to participants and potential participants. We encourage those HIEs that meet the description in the second attestation statement to publicly announce their availability to support this measure, both on their public website and through other communications methods. While a public announcement of availability to support this measure would not be required for an eligible clinician to leverage an HIE in order to attest to the measure, we believe that such activities will help to address commenters' concerns regarding how to determine whether an HIE meets the attributes described in the second attestation statement.

Comment: One commenter suggested CMS to allow for exclusions based on an individual patient's privacy request and potential state laws that would restrict information from being sent through an HIE.

Response: The first attestation statement requires eligible clinicians to attest that they participate in an HIE to enable bi-directional exchange for all of the patient records in their EHR. This is not intended to conflict with or supersede any applicable law including state, federal or tribal law governing access, exchange or use of electronic health information, the information blocking rules finalized at 45 CFR part 171, or any other patient privacy rules adopted by a specific HIE implementation such as policies permitting patients to opt out of sharing their health information through the HIE. Since attesting to this statement would not requiring sharing of information that is prohibited under existing laws, regulations and other policies, we do not believe it is necessary to specify additional exclusions. However, for additional clarity, we are revising the first attestation statement to specify that the bi-directional exchange is conducted ''in accordance with applicable law and policy.''

Comment: A commenter suggested phasing in language for every patient encounter beginning with transitions or referrals for new patients only. This is more reflective of where clinicians currently are with HIE integration and will encourage more robust future participation. In developing this new requirement, CMS should clarify that none of the language in the attestation statements conflict with applicable state law and guidance.

Response: We decline to phase in the measure requirement to enable bi-directional exchange based on subsets of patients as suggested by the commenter. We do not believe that there would be an appropriate reason to limit bi-directional exchange capabilities via an HIE to a subset of patients, such as new patients. Moreover, our goal in establishing this optional measure is to incentivize eligible clinicians to engage in HIE arrangements which enable bi-directional exchange for all of an eligible clinician's patient records, providing robust support for coordinated patient care. None of the requirements for this measure are intended to conflict with applicable federal, state, or tribal law or guidance. While eligible clinicians attesting to the first attestation statement attest that they have enabled bi-directional exchange for all of their patient records, enabling this functionality would not require clinicians to share information when sharing that information is prohibited by law or policy. We have revised the first attestation statement accordingly.

Comment: A commenter requested clarification on the content of information included in bi-directional exchange. It is unclear if, for example, portal messages must be included in the information exchanged with the HIE. The commenter requested guidance on how this can be implemented for practices on a portal that does not connect to an HIE.

Response: To successfully attest to this measure, the eligible clinician must use the capabilities defined for CEHRT to engage in bi-directional exchange via the HIE, which includes exchanging clinical data represented by the CCDS or included in the USCDI. Portal messages that are outside the CEHRT would not be included.

After consideration of the comments we received, we are adopting our proposals with the following modifications. Attestation statement 1 is as follows: ''I participate in an HIE in order to enable secure, bi-directional exchange to occur for every patient encounter, transition, or referral, and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy.''

Attestation statement 3 is as follows: ''I use the functions of CEHRT to support bi-directional exchange with an HIE.''

(d) Scoring Methodology

(1) Changes to the Scoring Methodology for the 2021 Performance Period

Table 48 summarizes the Promoting Interoperability performance category objectives and measures for CY 2021, including the changes adopted as final in the preceding sections of this final rule.

TABLE 48: Scoring Methodology for the Performance Period in CY 2021

Objective	Measure	Maximum Points
Electronic Prescribing	e-Prescribing	10 points
	Bonus: Query of PDMP	10 points (*bonus*)
Health Information Exchange OR	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
Health Information Exchange (alternative)	HIE Bi-Directional Exchange	40 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report to two different public health agencies or clinical data registries for any of the following: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Public Health Registry Reporting • Clinical Data Registry Reporting	10 Points

Notes: The Security Risk Analysis measure is required, but will not be scored.

Comment: A commenter supported the modified scoring methodology for the Promoting Interoperability performance category, which was initially finalized beginning with the 2019 performance year. The scoring methodology is less cumbersome and easier to understand, and is effective in highlighting important objectives of the category. We are pleased that the scoring methodology will continue in 2021.

Response: We appreciate the commenter for their support of the modified scoring methodology and agree that the approach is less cumbersome and easy to understand.

(e) Additional Considerations

(1) Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, and Certified Registered Nurse Anesthetists

We established a policy at § 414.1380(c)(2)(i)(A)(*5*) for the performance periods in 2017 through 2020 under section 1848(q)(5)(F) of the Act to assign a weight of zero to the Promoting Interoperability performance category in the MIPS final score if there are not sufficient measures applicable and available to NPs, PAs, CRNAs, and CNSs. We will assign a weight of zero only in the event that an NP, PA, CRNA, or CNS does not submit any data for any of the measures specified for the Promoting Interoperability performance category, but if they choose to report, they will be scored on the Promoting Interoperability performance category like all other MIPS eligible clinicians and the performance category will be given the weighting prescribed by section 1848(q)(5)(E) of the Act.

As in past years, we intend to use data from prior performance periods to further evaluate the participation of NPs, PAs, CRNAs, and CNSs in the Promoting Interoperability performance category and consider for subsequent years whether the measures specified for this category are applicable and available to these MIPS eligible clinicians. We have analyzed the data submitted for the 2017 performance period for the Promoting Interoperability performance category and have discovered that the vast majority of MIPS eligible clinicians submitted data as part of a group. Although we are pleased that MIPS eligible clinicians utilized the option to submit data as a group, it does limit our ability to analyze data at the individual NPI level. For the 2017 performance period, approximately 4 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for MIPS, and more than two-thirds of them did not submit data for the Promoting Interoperability performance category. For the 2018 performance period, approximately 34 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for the Promoting Interoperability performance category. In addition, the majority of MIPS eligible clinicians reported data for the Promoting Interoperability performance category for the 2017 and 2018 performance periods using the transition measure set. This set is unavailable for the 2019 performance period, which could have contributed to the decrease of MIPS eligible clinicians reporting data for Promoting Interoperability performance category. For the 2019 performance period, approximately 30 percent of MIPS eligible clinicians who are NPs, PAs, CRNAs, or CNSs submitted data individually for the Promoting Interoperability performance category, a reduction of 4 percent from the previous year.

For these reasons, we proposed at 85 FR 50302 through 50303 to continue the existing policy of reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2021, and to revise § 414.1380(c)(2)(i)(A)(*5*) to reflect the proposal.

The following is a summary of the comments we received and our responses.

Comment: A commenter supports this proposal until CMS can obtain more robust data. We continue to encourage the agency to provide technical assistance to clinicians with the goal of increasing EHR adoption and familiarity with the Promoting Interoperability performance category reporting requirements for all clinicians.

Response: We appreciate the commenter for their support in continuing the existing reweighting policy for NPs, PAs, CRNAs, and CNSs for the performance period in 2021 until we can obtain more robust data and

plan on continuing our support of stakeholders to increase EHR adoption and familiarity with the Promoting Interoperability performance category reporting requirements for all clinicians.

Comment: Another commenter appreciated the continued flexibility provided as CMS works to further assess the use of CEHRT by PAs and NPs. The commenter stated PAs are fully ready and capable to participate under the Promoting Interoperability performance category, with possible exception of small PA-owned practices that are unable to afford CEHRT systems that are fully compliant with current requirements. PAs in most practice settings have been using EHR systems for a number of years, often being the health profession who leads a practice's EHR system implementation and should be held to the same standards as physicians.

Response: We are pleased to hear that many PAs have the ability to participate in the Promoting Interoperability performance category and we hope those that are ready will submit data. For those who cannot, we will reweight the Promoting Interoperability performance category.

After consideration of the comments we received, we are finalizing our policy as proposed: We are continuing the existing policy of reweighting the Promoting Interoperability performance category for NPs, PAs, CRNAs, and CNSs for the performance period in 2021, and revising § 414.1380(c)(2)(i)(A)(*5*) to reflect this policy.

(2) Physical Therapists, Occupational Therapists, Qualified Speech-Language Pathologists, Qualified Audiologists, Clinical Psychologists, and Registered Dieticians or Nutrition Professionals

In the CY 2020 PFS final rule (84 FR 63003 through 63004), we adopted a policy at § 414.1380(c)(2)(i)(A)(*4*) to apply the same policy we adopted for NPs, PAs, CNSs, and CRNAs to other types of MIPS eligible clinicians who are NPPs (physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals) for the performance period in 2020. We stated that because many of these clinician types were or are not eligible to participate in the Medicare or Medicaid Promoting Interoperability Program, we have little evidence as to whether there are sufficient measures applicable and available to them under the Promoting Interoperability performance category.

For the reasons discussed in the proposed rule (85 FR 50302–50303), we proposed to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals for the performance period in 2021, and to revise § 414.1380(c)(2)(i)(A)(*4*) to reflect the proposal. We invited comments on the proposal.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: One commenter thanked CMS for continuing to reweight the Promoting Interoperability performance category for therapists as they have not received any financial incentives or support for implementing EHRs.

Response: We appreciate the commenter for their support.

Comment: One commenter supports the proposal to continue reweighting the Promoting Interoperability performance category to zero for certain NPPs and psychologists reporting under MIPS. The commenter stated that psychologists have never been eligible for the financial incentives offered to physicians to promote the use of CEHRT and because many do not utilize CEHRT in their private practices, most psychologists would not have enough Promoting Interoperability performance category measures to successfully report. The commenter supports the proposal to continue to reweight the Promoting Interoperability performance category to zero as it will protect psychologist and certain other NPPs from being unfairly penalized.

Response: We appreciate the commenter's support and are finalizing our proposal to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals.

After consideration of the comments, we are finalizing our proposals for the 2021 performance period to continue the existing policy of reweighting the Promoting Interoperability performance category for physical therapists, occupational therapists, qualified speech-language pathologist, qualified audiologists, clinical psychologists, and registered dieticians or nutrition professionals, and are revising § 414.1380(c)(2)(i)(A)(*4*) to reflect our policy.

(5) APM Entity Groups and APM Scoring Standard for MIPS Eligible Clinicians Participating in MIPS APMs

(a) Overview

The APM scoring standard, codified at § 414.1370, is the MIPS scoring methodology applicable for MIPS eligible clinicians participating in a MIPS APM for the applicable MIPS performance period. As discussed in the CY 2017 Quality Payment Program final rule (81 FR 77246), the APM scoring standard was designed to reduce reporting burden for participants in MIPS APMs by eliminating the need for such MIPS eligible clinicians to submit data for both MIPS and their respective APMs, and to ensure that these eligible clinicians were not assessed in multiple ways on the same performance activities. We also believed that the APM scoring standard would encourage APM participation and support the goal of encouraging APM participants to better manage care for patients within their respective APM Entities by tying their MIPS performance scores together.

As we have gained experience in implementing the APM scoring standard, we have learned that it is infeasible to fully implement it as it was originally designed, as was discussed in the CY 2020 PFS final rule (84 FR 63007). Public comments on the CY 2020 revised APM scoring standard finalized in the CY 2020 PFS final rule (84 FR 63010), and most comments in response to the request for comments on APM scoring beyond 2020, made clear that the complexity of the APM scoring standard and its inflexibility in adapting to changes in APM participation and design have resulted in confusion and unintended additional burden for APM Entities and their participant MIPS eligible clinicians.

With this insight in mind, and with the goal of better aligning MIPS reporting rules for all MIPS eligible clinicians, including those in MIPS APMs, we proposed to terminate the APM scoring standard as described at § 414.1370, effective January 1 of the 2021 performance year, by amending that regulation accordingly.

We further proposed in the CY 2021 PFS proposed rule (85 FR 50285), effective January 1, 2021, to establish an APM Performance Pathway and scoring rules that would be available for MIPS reporting for MIPS eligible clinicians in MIPS APMs.

(b) APM Entity Groups

We proposed to terminate the APM scoring standard effective January 1, 2021, however, beginning with the 2021 performance period, we proposed to

retain certain APM Entity group reporting policies that were established and finalized for reporting and scoring under MIPS beginning with the 2021 performance period (85 FR 50303 through 50304). Therefore, we proposed to redesignate in part the regulation that describes APM Entity group determinations, from § 414.1370(e) to § 414.1317, and to title that section ''APM Entity Groups.''

We received the following comments on these proposals.

Comment: A few commenters stated support for allowing MIPS quality reporting at an individual or group level as well as the APM Entity level. Commenters believe that this approach would reward high performers within APM Entities and enable specialists to be scored on quality measures that reflect their area of practice.

Response: We thank commenters for their support and will continue to consider additional ways in which we can continue to support and encourage APM participation.

Comment: A few commenters supported the proposal but requested that we extend the waiver of the cost performance category to all APM participants in MIPS, as the cost-containment requirements of the APMs are equally applicable to all APM Entities, regardless of how they chose to participate in MIPS.

Response: In the CY 2017 Quality Payment Program final rule (81 FR 77256, 77265), for the APM scoring standard, we finalized at § 414.1370(g)(2) a policy to waive the cost performance category uner the waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center APMs, and at section 1899(f) of the Act for the Medicare Shared Savings Program. In the CY 2021 PFS proposed rule (85 FR 50287), for the APP, we proposed to continue to waive the cost performance category under the same authorities, and we are finalizing this proposal in section IV.A.3.b. of this final rule. Upon further consideration, we recognize that the policy rationale for waiving the cost performance category is equally applicable to all APM Entities in MIPS APMs, regardless of whether an APM Entity chooses to participate in MIPS through the APP or through traditional MIPS reporting options. As we described in the CY 2017 Quality Payment Program final rule (81 FR 77256, 77265), and reiterated in the CY 2021 PFS proposed rule (85 FR 50287), we believe this use of waiver authority is justified for three reasons. First, APM Entities in MIPS APMs already are subject to cost performance assessment under their APMs, as the MIPS APM criteria would continue to include the assessment of participants based on cost. Second, MIPS APMs may measure cost performance in different ways than MIPS, for example, by basing cost on total cost of care, which measures a broader scope of cost or resource use than would necessarily be reflected in the narrower claims-based accountability standard under MIPS. Finally, MIPS APMs may attribute beneficiaries differently from MIPS for purposes of measuring cost, leading to an unpredictable degree of overlap between the sets of beneficiaries for whom the MIPS eligible clinicians would be responsible under their APM and under MIPS. We continue to believe that with an APM Entity's finite resources for engaging in efforts to improve quality and lower costs for a specified beneficiary population under the APM, it is necessary to give the APM Entity the ability to identify a single beneficiary population to prioritize in its cost-saving efforts so that the goals and evaluation associated with the APM are as clear and free of confounding factors as possible. With this flexibility, MIPS eligible clinicians who are attempting to strategically transform their respective practices would not jeopardize their ability to succeed in either MIPS or under the terms of their APM.

We believe the potentially conflicting or confounding incentives between the MIPS APMs and the MIPS cost performance category would still exist for APM Entities in MIPS APMs, regardless of which MIPS participation option an APM Entity chooses. Therefore, we will continue to waive the cost performance category for APM Entities in MIPS APMs under the waiver authority at section 1115A(d)(1) of the Act for CMS Innovation Center APMs, and at section 1899(f) of the Act for the Medicare Shared Savings Program, and weight the cost performance category at zero percent of an APM Entity's final score.

In addition, because we proposed to no longer rely on quality measures reported to an APM, as is required under the existing APM scoring standard, we no longer believe that there is substantial risk of the MIPS final scores being inappropriately influenced by MIPS eligible clinicians moving into or out of APM Entities late in the performance year, which was the impetus for the full-TIN APM policy. Therefore, we proposed to end the full-TIN APM policy currently codified at § 414.1370(e)(1), which allows for an APM Entity group to include eligible clinicians on the Participation List in a full-TIN APM on December 31 of the MIPS Performance Period only if the APM is a full-TIN APM as defined at § 414.1305. We also proposed that MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of any APM Entity participating in any MIPS APM on any of the three snapshot dates (March 31, June 30, August 31), as well as December 31 during a performance period, beginning in the 2021 MIPS performance period, would be considered participants in an APM Entity group. As the proposals would eliminate the need for the term ''full TIN APM,'' we also proposed to delete the defined term ''full TIN APM'' from § 414.1305.

We did not receive any comments on this proposal.

After consideration of the comments we received, we are finalizing the proposed policy as proposed. In addition, for the reasons discussed in our response to comments above, we are adoptiong a final policy at § 414.1317(b)(2) to weight the cost performance category at zero percent for APM Entities in MIPS APMs.

(c) APM Entity Group Eligibility

In the absence of the APM scoring standard and mandatory reporting to MIPS through the APM Entity group, it would no longer be necessary to conduct low-volume threshold determinations at the APM Entity group level. Therefore, along with the termination of the APM scoring standard under § 414.1370, we also proposed to terminate, effective January 1, 2021, the use of APM Entity level low-volume threshold determinations and remove the term APM Entity group from the definition of the low-volume threshold at § 414.1305, with corresponding changes to applicability at § 414.1310(b)(1).

Going forward, we would apply the same rules for MIPS eligibility to APM participants as to other MIPS eligible clinicians. For example, if an eligible clinician who is a participant in a MIPS APM is below the low-volume threshold he or she would not be required to report to MIPS as an individual; however, if the group TIN of which that eligible clinician is a part is MIPS eligible and does report to MIPS, that eligible clinician would be treated as a MIPS eligible clinician for purposes of MIPS scoring and payment adjustments, and would receive the higher of the group score and any available APM Entity group score. Being a participant in an APM Entity that reports to MIPS would not confer MIPS eligibility to an eligible clinician who would otherwise be excluded from MIPS.

We did not receive public comments on this propsal and we are finalzing it as proposed.

(d) APM Entity Group Scoring

Consistent with our past approach under the APM scoring standard at § 414.1370(f), we proposed at § 414.1317(b) that the MIPS final score calculated for the APM Entity would be applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment would be applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

Similar to our past approach under the APM scoring standard at § 414.1370(g)(4)(ii) and (iii), as originally discussed and finalized in the CY 2017 Quality Payment Program final rule (81 FR 77268), we proposed at § 414.1317(b)(1) that in all cases where an APM Entity reports to MIPS, but a performance category's data submission cannot be made at the APM Entity level, each MIPS eligible clinician in the APM Entity group would be assigned the highest available score for that performance category (either the individual or TIN-level score), and the scores for all MIPS eligible clinicians in the APM Entity group would be averaged in order to calculate the APM Entity level performance category score. In the event that a MIPS eligible clinician in an APM Entity receives an exception from the reporting requirements, such eligible clinician would be assigned a null score when we calculate the APM Entity's performance category score.

Similar to our past approach under the APM scoring standard at § 414.1370(g)(1)(iv), we proposed at § 414.1317(b)(2) that for an APM Entity for which we calculated a total performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, we would calculate an improvement score for each performance category for which a previous year's total performance category score is available as specified in § 414.1380(b). Note that unlike § 414.1370(g)(1)(iv), proposed § 414.1317(b)(2) would not be limited to the quality performance category, but will apply to any performance category.

We did not receive public comments on these proposals and are finalzing as proposed.

(e) Reweighting Based on Extreme and Uncontrollable Circumstances for APM Entity Groups

Section 414.1380(c)(2)(i) allows for the submission of an application to CMS to request reweighting of one or more MIPS performance categories due to extreme and uncontrollable circumstances. We proposed that an APM Entity may submit such an application beginning with the 2020 performance period/2022 MIPS payment year, at § 414.1317(b)(3). The request for reweighting in the application would apply for all four MIPS performance categories and all MIPS eligible clinicians in the APM Entity group. If the request for reweighting is approved by CMS, this would result in MIPS eligible clinicians participating in the APM Entity being excepted from MIPS reporting requirements for the applicable performance period, and the APM Entity would receive a final score equal to the performance threshold. Such request for reweighting would be approved or denied in its entirety.

We considered allowing an APM Entity to submit an application to request reweighting for individual performance categories, but rejected this approach. As discussed in the CY 2021 PFS proposed rule (85 FR 50304, we believe the amount of complexity at the intersection of the various performance category submission and scoring requirements, submitter types, and exception applications for MIPS eligible clinicians could place a burden on these clinicians and their representatives to continually invest in understanding their shifting obligations under such an approach. Furthermore, operationalizing a policy where an APM Entity would have the ability to request and receive reweighting for one or more, but not all, performance categories would be prone to error. In addition, such a piecemeal approach to addressing extreme and uncontrollable circumstances likely would cause scoring delays that could result in CMS being unable to timely provide performance feedback and payment adjustment information to all MIPS eligible clinicians.

We also proposed at § 414.1317(b)(3)(i) that an APM Entity must demonstrate in its application to CMS that greater than 75 percent of its participant MIPS eligible clinicians would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

Due to the unique and complex relationship between an APM Entity and its individual participant MIPS eligible clinicians, we noted that we believe it is appropriate to offer an APM Entity the opportunity to apply for reweighting based on extreme and uncontrollable circumstances for all performance categories, including the Promoting Interoperability performance category, rather than collecting Promoting Interoperability hardship exception applications from each MIPS eligible clinician in the APM Entity group as is currently required. However, we believe that setting a 75 percent threshold for the Promoting Interoperability performance category is appropriate as a means of assuring that the request for reweighting is only granted in cases where absent the reweighting, it would be impossible to calculate a score for that performance category that is truly representative of the APM Entity group's performance. We proposed a 75 percent threshold because such threshold is consistent with the Promoting Interoperability performance category reweighting policy for groups of hospital-based MIPS eligible clinicians and non-patient facing MIPS eligible clinicians, which similarly could face an administrative burden in attempting to secure approvals for individual reweighting requests for each MIPS eligible clinician in such groups. We noted that we recognize that as a result of the variety of participation requirements of different APMs, APM Entity groups may be composed of a wide range of health care provider types and sites of service. We stated that we believe scoring an entire APM Entity as the result of a single MIPS eligible clinician's submission of data for the Promoting Interoperability performance category could place an extreme administrative burden on APM Entity groups, and could potentially create unintended consequences for APM participation decisions among MIPS eligible clinicians.

In addition, we proposed at § 414.1317(b)(3)(ii) that if CMS approves the request for reweighting based on an APM Entity's application, and if MIPS data are submitted for the APM Entity for the applicable performance period, all four of the MIPS performance categories still would be reweighted for the APM Entity group notwithstanding the data submission. The data submission would not effectively void the request for reweighting and its approval. We proposed this policy because we do not believe it would be appropriate or desirable for an individual MIPS eligible clinician or for a group TIN with no direct affiliation with an APM Entity to accidentally override an APM Entity's application. This could happen if the MIPS eligible clinician or group TIN reports to MIPS either out of an abundance of caution or on behalf of a MIPS eligible clinician who is not in the APM Entity, but happens to share a billing TIN with an

eligible clinician who is in the APM Entity. We also recognized that there may be circumstances where an APM may require some form of quality reporting for purposes of the APM itself, such as is required for Shared Savings Program ACOs as described in the CY 2021 PFS proposed rule (85 FR 50233), but that in complying with such requirement an APM Entity may also be submitting quality performance category data that would result in scoring for purposes of MIPS when that APM Entity group would otherwise have been excepted from MIPS reporting.

We noted that under the proposal and the proposed changes to the MIPS scoring hierarchy, described in the CY 2021 PFS proposed rule (85 FR 50315), reporting done by a MIPS eligible clinician or group would result in a MIPS final score for only that MIPS eligible clinician or group, which may be used to determine a MIPS eligible clinician's payment adjustment.

To the extent that the proposed policies would constitute a change to the MIPS scoring or payment methodology for the 2022 MIPS payment adjustment after the start of the 2020 performance period, we noted that we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to establish these policies because of the PHE for COVID–19. We noted that we believe that the intersection of the 2020 APM scoring standard rules and the extreme and uncontrollable circumstances policies being put in place by APMs themselves in response to the PHE for COVID–19, such as the changes being proposed for participants in the Shared Savings Program, would make obtaining reweighting under MIPS based on extreme and uncontrollable circumstances unusually burdensome absent these proposed changes. For instance, the Shared Savings Program (85 FR 50239) will continue to require the submission of quality performance data by participating ACOs, and that data would be eligible to be used for MIPS quality scoring absent the proposal, which would have the result of not allowing Shared Savings Participants the option to take advantage of extreme and uncontrollable circumstances policies that are available to other MIPS eligible clinicians. This policy change is necessary to give participants in the Shared Savings Program the opportunity to request reweighting of the MIPS performance categories in the event that they believe the data reported for purposes of the Shared Savings Program do not adequately reflect the performance of the ACO Entity for purposes of MIPS quality performance category scoring.

The following is a summary of the comments we received and our responses.

Comment: Several commenters support our proposal to introduce APM Entity level requests for reweighting due to extreme and uncontrollable circumstances in light of the PHE for COVID–19.

Response: We appreciate the commenters for their support.

After consideration of the comments we received, we are finalzing this policy as proposed.

d. MIPS Final Score Methodology

(1) Performance Category Scores

(a) Background

For the 2023 MIPS payment year, we intend to continue to build on the scoring methodology we finalized for prior years. The scoring methodology allows for accountability and alignment across the performance categories and minimizes burden on MIPS eligible clinicians. We are maintaining many of our scoring policies, focusing on only making proposals to maintain stability. Specifically, in the CY 2021 PFS proposed rule (85 FR 50305 through 50310), we proposed the following:

- To implement scoring flexibility for quality measures with specification or coding changes during the performance year.
- To implement benchmark and topped out scoring policies that are responsive to potential low reporting rates for the 2019 performance year due to the national PHE for COVID–19.
- To implement scoring for all administrative claims-based measures.
- To continue policies for scoring quality measures based on achievement as well as policies for measures that do not meet case minimum, data completeness requirements, or have a benchmark.
- To continue bonuses in the quality performance category.
- To continue improvement scoring of the quality performance category comparing clinicians to a 30 percent baseline score if clinicians scored 30 percent or less.

We did not propose changes to scoring policies for the cost, improvement activities and Promoting Interoperability performance categories.

We have maintained our approach that MIPS eligible clinicians are scored against performance standards for each performance category and receive a final score, comprised of their performance category scores, and calculated according to the final score methodology. We refer readers to § 414.1380 for general policies on scoring. We refer readers to section IV. A.3.c.(5) of this rule for the discussion to remove the APM scoring standard and to section IV.A.3.b. of this rule for information on the APM Performance Pathway scoring.

(b) Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, CMS Web Interface Measures, the CAHPS for MIPS Survey Measure and Administrative Claims Measures

We referred readers to § 414.1380(b)(1) for our policies regarding quality measure benchmarks, calculating total measure achievement and measure bonus points, calculating the quality performance category percent score, including achievement and improvement points, and the small practice bonus (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, and 84 FR 63011 through 63018). We proposed to maintain many policies finalized in prior years to retain stable scoring in MIPS with minimal new proposals as we transition to MVPs.

Please refer to section IV.A.3.c.(1)(c) of this rule for more information about our proposal to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians, which we are finalizing with implementation delayed until the 2022 performance period. Scoring policies applicable to CMS Web Interface as a collection type will be in effect in the 2021 performance period. In the 2022 performance period CMS Web Interface will be removed as a collection type.

(i) Scoring Flexibility for Changes That Impact Quality Measures During the Performance Period

We proposed to expand the list of reasons that a quality measure may be impacted during the performance period in addition to revising when we would allow scoring of the measure with a performance period truncation (to 9 months of data) or the complete suppression of the measure if 9 months of data are not available. We noted that we previously established policies to provide scoring flexibilities in instances in which changes to measures during the performance period have impacted clinicians' ability to submit the quality measures for the entire 12-month performance period because of an ICD–10 coding change or when there are clinical guideline changes when we believe continued adherence to the

guideline in the existing measure could result in patient harm, or otherwise provide misleading results and render the measure no longer comparable to the historic benchmark. Specifically, in the CY 2018 Quality Payment Program Final rule (82 FR 53714 through 53716), we finalized that, beginning with the 2018 MIPS performance period, we will assess performance on measures considered significantly impacted by ICD–10 coding changes during the performance period based only on the first 9 months of the 12-month performance period. We noted that we believe that 9 months of data is sufficient to assess performance when 12 months of data is not available. We finalized that we would publish a list of measures requiring a 9 months of data on the CMS website by October 1st of the performance period if technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the 2020 performance period). We refer readers to § 414.1380(b)(1)(viii) for more on our policy for scoring flexibility for ICD–10 changes.

In the CY 2019 Quality Payment final rule (83 FR 59845 through 59847), we finalized policies beginning with the 2021 MIPS payment year to reduce the total available measure achievement points from the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted by clinical guideline changes or other changes when we believe adherence to the guidelines in the existing measures could result in patient harm or otherwise no longer be comparable to a historic benchmark. We refer readers to § 414.1380(b)(1)(vii)(A) for more information on the scoring flexibility policy.

We proposed, beginning with the 2021 performance period, a policy to truncate the performance period or suppress a quality measure if CMS determines that revised clinical guidelines, measure specifications or codes impact clinician's ability to submit information on the measure or may lead to potentially misleading results. Based on the timing of the changes to clinical guidelines, measure specifications or codes, we would assess the measure on 9 months of data, and if 9 consecutive months of data are not available, we would suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for each measure submitted that is impacted.

In addition to ICD–10 and clinical guideline changes, we noted that we believe that there may be instances when there are changes after the final approval of quality measures including changes to the measure specification, or updates to coding that may lead to misleading results. If there are no concerns with potential patient harm, we would like the ability to assess performance on the quality measure (not including the change) if we have sufficient data. Depending on the timing of the change during the performance period we would like to assess performance on the quality measure; we believe we can assess performance if we have 9 months of data and should suppress the measure if we have less than 9 months of data.

We will examine quality measures that are impacted by changes during the performance period to determine how the change may impact our ability to assess performance on the measure. Potential changes that may impact quality measures during the performance period include updates to clinical guidelines or measure specifications, such as revisions to medication lists, codes and clinical actions. For example, the introduction of a new drug class after the performance period began, would not be captured as numerator compliant by an existing measure specification but may meet the intent of the measure and its associated clinical actions. Assessment of clinician's performance on the measure would be hampered by the fact that the measure specification would not be able to be updated to collect information and assess performance related to use of the medication from the new drug class. As reflected at sections 1848(q)(2)(D)(1) and 1848(q)(2)(D)(1)(II)(cc) of the Act, quality measures adopted under MIPS, including substantive updates must be made through notice and comment rulemaking.

Additionally, we may examine a quality measure to determine if the change impacts the ability of clinicians to submit the measure, including the number of encounters a clinician may be able to submit, the number of clinicians who may be able to submit the measure, and the proportion of clinicians from a specialty who may be able to submit the measure. We would also assess if the change to a code would potentially lead to misleading results. For example, changes that impact the clinicians' ability to report a measure include changes to Common Procedural Technology (CPT) codes and the Healthcare Common Procedure Coding System (HCPCS) codes during the performance period, which may potentially produce misleading results. We believe that code changes that impact a clinician's ability to report a measure will be rare events, however, mid-year changes to CPT and HCPCS codes can be unanticipated when a clinician selects a quality measure and may introduce an additional burden if the clinician is unable to submit the quality measure.

When possible, we want an approach that allows us to score a quality measure even when there has been a change to the measure outside of the clinician's control during the performance period. We have finalized a policy that allows scoring on the first 9 months of data for a 12-month performance period data when there are ICD–10 code changes (82 FR 53714 through 53716). We assess performance on the first 9 months of data in the case of ICD–10 changes, which happen predictably in October on an annual basis, allowing us to truncate and remove the last quarter of the performance period from our assessment. However, as discussed in the CY 2021 PFS proposed rule (85 FR 50306 through 50307), we cannot anticipate when there will be a change to clinical guidelines, measure specifications, an inadvertent deletion, or revision of a code. These types of changes do not occur on an annual basis, and do not follow a predictable, consistent timeline. We become aware of changes to measures from feedback from clinicians, third parties and measure stewards. Updates to codes, which may not happen at a predictable time, may significantly impact how many cases a clinician can report and how a clinician performs on a measure. We want to account for instances such as coding changes during the performance period, in which scoring should be applied to the first 9 months of data from the performance period. If 9 consecutive months of data from the performance period is not available, we would have the ability to suppress the measure by reducing the total available measure achievement points from the quality performance category by 10 points for MIPS eligible clinicians for each measure submitted that is significantly impacted.

Therefore, as noted in the CY 2021 PFS proposed rule (85 FR 50307 through 50308), we proposed beginning with the 2021 performance period, a policy to truncate the performance period or suppress a quality measure if CMS determines revised clinical guidelines, measure specifications or codes impact the clinician's ability to submit the measure or may lead to potentially misleading results. As proposed, we would maintain the flexibility to assess the measure on 9

consecutive months of data when available and would suppress the measure if 9 consecutive months of data are not available. We proposed that we would publish a list of measures requiring 9 months of data on the CMS website as soon as technically feasible, but no later than the beginning of the data submission period (for example, January 2, 2021 for the 2020 performance period).

Accordingly, we proposed to consolidate § 414.1380(b)(1)(vii)(A) and (b)(1)(viii) at § 414.1380(b)(1)(vii)(A). The consolidated paragraph would provide that for each submitted measure that is impacted by significant changes that CMS determines may result in patient harm or misleading results, performance on the measure is assessed based on data for 9 consecutive months of the applicable CY performance period. If such data are not available, the total available measure achievement points are reduced by 10 points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes'' means changes to codes (including ICD–10, CPT, and HCPCS), clinical guidelines, or measure specifications. We noted that we will publish a list of all measures scored under this paragraph (b)(1)(vii)(A) on the CMS website as soon as technically feasible, but by no later than the beginning of the data submission period at § 414.1325(e)(1).

We invited public comments on our proposal to truncate the performance period or suppress a quality measures if CMS determines that there are significant changes that occurred during the performance period. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported expanding policies for scoring measures with significant changes during the performance period that did not allow comparison to historical benchmarks.

Response: We thank commenters for their support.

Comment: One commenter recommended that CMS consider extending the scoring policies for measures with significant changes to include instances in which clinicians have difficulty obtaining 12 months of data, because a contract with a facility is modified during the performance period.

Response: The policies address instances in which there are significant changes to measures specifications or coding that do not permit any clinicians that selected the measure to submit data or other circumstances where a measure may result in patient harm or misleading results. It is not intended to address instances in which individual clinicians have difficulty obtaining and submitting data, while other clinicians are able to be measured accurately on the measure. The policy relates to changes to the measure, measure specifications or other changes that are outside of the clinicians' control and is applied to all clinicians. For individual clinicians, we have other scoring flexibilities for individuals unable to submit data, such as the ability to apply for reweighting of the quality performance category based on extreme and uncontrollable circumstances as described in section IV.A.3.d.(2)(b)(iv) of this final rule.

Comment: One commenter expressed concerns that depending on how CMS identifies substantive changes, the policy may result in the lack of scorable measures for some clinicians for a performance period and recommended working with measure stewards to determine the most appropriate course of action in each case to ensure the most accurate data is used. The commenter asked for clarification on the expected scale of the impact of this change, including how many measures are expected to be impacted, and how performance may shift for clinicians.

Response: The proposal was built on previously established policies in which CMS identifies the rare instances in which measures had significant changes during the performance period where adherence to the guideline of the existing measure or calculating the measure could result in patient harm or misleading results. The policy allows us to identify changes to measures that are outside of the control of clinicians. We often become aware of the changes from feedback from clinicians, third parties and measure stewards. We will continue to work with measure stewards on how the changes during the performance period impact measures. For example, we are concerned that due to changes in health care processes and use of hospital services during the PHE for COVID–19, there are significant changes to administrative claims data used to calculate measures, which may lead to misleading results. For purposes of § 414.1380(b)(1)(vii)(A), we would like to expand our definition so that ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specifications. We do not anticipate that the proposed policy to identify mid-year changes to measures that require special scoring will result in no available and applicable measures for some clinicians.

Comment: One commenter did not support the suppression of scores for quality measures with significant changes during the performance period because they believed the policy added complexity to the program and recommended removing the quality measure and informing clinicians that they should select another measure. One commenter cautioned that allowing measures to be suppressed may inflate quality performance category scores and permit gaming because there was an incentive to submit measures that would be suppressed.

Response: We are concerned about program complexity but also realize that often clinicians select their measures in advance and establish workflows for the collection and reporting of data. We believe that expanding a previously finalized policy that truncates measures considered significantly impacted by ICD–10 coding changes during the performance period (82 FR 53714 through 53716) to include additional, significant changes to the measure outside of a clinician's control, will allow us to continue to use data that clinicians collected and reported. If data is available and does not cause patient harm or misleading results, our first priority is to utilize 9 months of data for scoring. We will attempt to make information available on a rolling basis about measures with significant changes; however, depending upon the timing, this might not allow sufficient time for clinicians to select another measure. When significant changes occur during the performance period, we believe that suppression of the measure or use of a truncated 9 months of data is appropriate, because clinicians are unaware of which measures will require the special scoring policies until after the performance period begins and all other submitted measures will be scored, we do not believe this will result in gaming or inflation of quality performance category scores.

Comment: A few commenters requested additional information about the approach to truncating the performance period of measures to 9 months of data. One commenter recommended that for measures that could only be scored on 9 months of data, that clinicians have the flexibility to select their 9-month reporting period. A few commenters asked if clinicians were able to submit 12 months of data for measures using a truncated 9 months of data, to be consistent with their reporting of other measures.

Commenters indicated that third party vendors would need to restructure reporting systems to limit reporting to 9 months of data.

Response: The policy to truncate the performance period to 9 months has been used when there are changes to measure coding, such as ICD–10 updates, in the final quarter of the performance period that are substantial enough to significantly impact the measure. We believe it is important to use data in these instances if there are no concerns that the 9 months of data could result in patient harm or misleading results. We would not allow clinicians to elect which 9 months of data to report because the truncation of the performance period occurs only if there is a change during the performance period that allows for 9 months of consecutive data; if there is a change during the performance period that does not allow for 9 months of data the measure will be suppressed. We believe that it is appropriate for clinicians to submit 9 months of data and recommend that clinicians work with third party intermediaries to allow submission of data.

Comment: One commenter indicated that the policy to truncate the performance period to 9 months of data would not be appropriate for quality measures affected by the increases of telehealth visits from March to August of 2020 because of the national PHE for COVID–19 and recommended greater flexibility in adjusting benchmarks for quality measures impacted by changes in patient access due to the national PHE in the 2020 performance year.

Response: We agree with the commenter that the policy to truncate the performance period can only be used if we have 9 consecutive months of data to assess performance. We will continue to monitor the impact of the use of telehealth and changes to clinical processes because of the national PHE for COVID–19, and work with measure stewards if they believe changes to clinical processes are significant enough to update clinical guidelines or trigger our scoring policies to suppress a measure. We continue to believe we should suppress a measure if the measure is impacted by significant changes that we determine may result in patient harm or misleading results. In section IV.A.3.d.(1)(b)(ii) of this final rule, we discuss our preference to use historical benchmarks when they are complete and reliable. If clinicians believe they are unable to submit quality measures for the 2020 performance period because of the national PHE for COVID–19, clinicians are allowed to submit an application for the reweighting of the quality performance category based on extreme and uncontrollable circumstances as described in section IV.A.3.d.(2)(b)(iv) of this final rule.

Comment: A few commenters urged caution in using less than a full year of measurement data. One commenter believes using only 9 months of data could potentially skew results. One commenter urged CMS to offer a review period and to work with measure stewards to determine the most appropriate course of action in each case to yield the most accurate data.

Response: We will continue to monitor how many measures are impacted by the scoring flexibility policies. Changes to measures specifications and coding often do not allow time for a public review period, however, we will continue to work with measure stewards when we believe that scoring flexibility polices are needed. As stated previously, we believe it is important to use data in these instances if there are no concerns that the 9 months of data could result in patient harm or misleading results.

Comment: One commenter requested clarification if policies to suppress or truncate data would be applied to all measures for the 2021 performance period.

Response: The policy will be applied to the 2021 performance period and beyond for each measure impacted by significant changes that CMS determines may result in patient harm or misleading results. To ensure that this includes all collection types, including administrative claims measures as well as all measures submitted by clinicians, we are modifying the proposal to update the finalized regulation text and consolidate § 414.1380(b)(1)(vii)(A) and (b)(1)(viii) at § 414.1380(b)(1)(vii)(A) to provide that for each measure that is submitted, if applicable, and impacted by significant changes that CMS determines may result in patient harm or misleading results, performance on the measure is assessed based on data for 9 consecutive months of the applicable CY performance period. If 9 months of data is not available, the measure will be suppressed.

After consideration of the public comments, we are finalizing our proposal with modification: We are finalizing the consolidation of § 414.1380(b)(1)(vii)(A) and (b)(1)(viii) at § 414.1380(b)(1)(vii)(A) to provide that for each measure that is submitted, if applicable, and impacted by significant changes, performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the beginning of the data submission period at § 414.1325(e)(1).

(ii) Quality Measure Benchmarks

We refer readers to the CY 2017, CY 2018, CY 2019, and CY 2020 Quality Payment Program final rules (81 FR 77277 through 77282, 82 FR 53699 through 53718, 83 FR 59841 through 59842, and 84 FR 63014 through 63016, respectively) for our previously established benchmarking policies.

In the CY 2017 QPP final rule (81 FR 77277 through 77282), we finalized that we would use performance in the baseline period to set benchmarks for the quality performance category, with the exception of new quality measures, quality measures that lack historical data, or where we do not have comparable data from the baseline period, for which we would set the benchmarks using performance in the performance period. We defined the baseline period to be the 12-month CY that is 2 years prior to the performance period for the MIPS payment year. For example, for CY 2021 performance period, the baseline period would be CY 2019 which is 2 years prior to the CY 2021 performance period (81 FR 77277). Additionally, we further clarified that CMS can establish benchmarks either by the applicable baseline or performance period in the CY 2019 PFS final rule (83 FR 59842), where we finalized the terminology change amending § 414.1380(b)(1)(ii) to remove the mention of each individual benchmark and instead state that benchmarks will be based on collection type, from all available sources, including MIPS eligible clinicians and APMs, to the extent feasible, during the applicable baseline or performance period.

Because of the flexibility provided to MIPS eligible clinicians to allow for no data submission for the 2019

performance period (see 85 FR 19277 through 19278), we may not have had as representative of a sample of data as we would have had without the national PHE for COVID–19. Therefore, we revisited our benchmarking policy for the 2021 performance period. We anticipated that we may have a gap in our data due to potentially receiving fewer submissions for CY 2019 which could skew the benchmarking results, as the triggering of this policy no longer requires clinicians to submit data. We believed this gap in data could result in different distributions of scores from what we normally see, thus skewing the benchmarks when using CY 2019 baseline period for the CY 2021 performance period. As a result, we considered two benchmarking options for CY 2021 performance period.

We intended to use performance period benchmarks for the CY 2021 performance period in accordance with § 414.1380(b)(1)(ii). As discussed in the CY 2021 PFS proposed rule (85 FR 50307), this would mean that benchmarks for the CY 2021 performance period are based on the actual data submitted during the CY 2021 performance period. We noted that we believed that using performance period benchmarks for the year where we are facing gaps in baseline data will allow us to ensure that we continue to have reliable and accurate data. We recognized that this methodology would not allow clinicians to know the benchmarks ahead of the performance period, but we believe that using the most current information has the potential to provide more accurate results for benchmarking purposes for CY 2021 performance period and could capture any changes in care that have occurred as a result of the national PHE for COVID–19.

We sought feedback on the criteria for using data from the 2019 MIPS performance period to calculate CY 2021 benchmarks. As an alternative to performance period benchmarks we considered and requested stakeholder comments and feedback on utilizing the historic benchmarks from the 2020 MIPS performance period (which are based on submissions for CY 2018 MIPS performance period) for the CY 2021 performance period. We noted that we believe that this option would allow clinicians to continue to receive advance notice for quality performance category measures so that MIPS eligible clinicians can set a clear performance goal for these measures for CY 2021 performance period. However, we remained concerned that utilizing outdated data could also potentially result in distributions of scores used for benchmarks that no longer reflect the standard of care.

We invited public comments on our intent to use performance period benchmarks for the CY 2021 performance period. The following is a summary of the comments we received and our responses.

Comment: Several commenters recommended that CMS monitor and analyze to determine if the 2019 data is a representative sample based on the number of submissions for 2019 before deciding and finalizing which benchmarks should be used. A few commenters suggested that we see if there are statistically significant fewer submissions for CY 2019 than were received in previous performance periods that constitutes the need to use performance period benchmarks.

Response: Based on our analysis of 2019 submissions, we believe that we have sufficient data to calculate historical benchmarks and do not believe it is necessary to use performance period benchmarks. The analysis showed minimal to no impact due to the national PHE for COVID–19 policies for the eCQM and Part B claims collection types. Overall, we generally saw an increase in eCQM submissions. In addition, we know we have complete data from Part B claims collection types because that submission ended before the PHE. For the other collection types for 2021, the MIPS CQM and QCDR measures, we generally saw decreases in submissions, but the decreased submissions appear to have a modest distributional effect for most measures and is likely due to an increase in group reporting and the increase in eCQM submissions. The national PHE for COVID–19 E/U circumstances policy led to only a slight increase in the number of clinicians not engaged with MIPS in 2019 compared to 2018 submission data.

Comment: Several commenters opposed the use of 2021 performance period benchmarks as this would not allow clinicians to have referenceable benchmarks as a guide to predict their scores or set performance goals or priorities, making it difficult to determine performance improvement opportunities and preferred the use of historical benchmarks from 2019 data. Several commenters did not support holding clinicians accountable for performance against a benchmark that would not be set until after the performance period is closed as the use of performance period benchmarks would burden clinicians by not providing time to understand how performance compares to benchmarks and could lead to lower performance and MIPS scores. Several commenters encouraged CMS to publish a benchmark file to provide guidance to evaluate and strategize reporting. A few clinicians stated that the use of performance period benchmarks would burden clinicians by not providing time to understand how performance compares to benchmarks and could lead to a decrease in performance and MIPS scores. A few commenters specifically supported using historical benchmarks from the 2019 MIPS performance period data over utilizing 2018 data for benchmarks because the 2019 performance period provides more recent data.

Additionally, one commenter stated that using performance period benchmarks would limit EHR vendors' ability to provide timely scoring feedback and insight into performance. One commenter suggested that CMS use 2019 benchmarks for 2021 performance and to limit the performance period to the months at the end of 2021 not impacted by the national PHE for COVID–19 to allow for comparison of data not influenced by the national PHE for COVID–19 in 2019 to 2021.

Response: We agree that providing a historical benchmark for the quality performance category allows MIPS eligible clinicians to know quality performance category benchmarks in advance. We believe there is value in the advance notice for quality performance measures so that MIPS eligible clinicians can benchmark themselves for quality measures when historical data is available. We agree with commenters that quality benchmarks should be made public and should be known in advance when possible so that MIPS eligible clinicians can understand how they will be measured and to not limit vendors from providing timely feedback and insight into performance. We will continue to rely on historical benchmarks for CY 2021 since data from CY 2019 has become available and is representative and comparable. We will continue to monitor the impact of the national PHE for COVID–19 on data in CY 2020 and CY 2021. The historical benchmarks based on CY 2019 data will be available prior to the CY 2021 performance period at *qpp.cms.gov*.

Comment: Many commenters supported the use of 2021 performance period benchmarks since they are based on current information that can provide accurate benchmarks from data that are reliable, accurate, complete, and representative of performance in 2021. The commenters expressed support given that performance period benchmarks capture any changes in care

due to the national PHE for COVID–19 and avoid unfairly penalizing practices for variations in performance compared to data from prior to the national PHE for COVID–19.

Response: Based on our analysis of the 2019 data, we believe that the data is reliable, complete, or representative and no longer believe we need to rely on performance period benchmarks. We realize there may be a risk for some measures that performance in CY 2021 might differ from CY 2019 given the automatic extreme and uncontrollable circumstances policy for CY 2019 quality performance category in response to the national PHE for COVID–19 (85 FR 19277 through 19278). We are continuing to evaluate the effects of the national PHE for COVID–19 on clinicians and will take this comment into consideration for the future, but we also understand and have previously stated, that there are benefits to knowing the benchmark target in advance and believe there is value to clinicians in having historical benchmarks. We believe there is more value in providing advance notice for quality performance category measures so that MIPS eligible clinicians can set a clear performance goal for these measures, provided that historical data is available.

Comment: Several commenters opposed the use of performance period benchmarks and supported the alternative to use historical benchmarks based on 2018 MIPS performance data to continue to receive advance notice of benchmarking targets, allow clinicians to understand how they are performing in real-time compared to the 2018 benchmarks, provide a degree of certainty, and help clinicians prepare in advance for selecting measures based on data that is not impacted by the national PHE for COVID–19. A few commenters recommended using historical benchmarks from 2018 data for the 2021 performance year if the participation rate dropped significantly from 2018 to 2019. A few commenters stated that CEHRT vendors rely on benchmarks to set dashboards and reports and having benchmarks from 2018 would allow developers to provide accurate information to clinicians. A few commenters stated that the data from 2019 might not be inclusive because of the extreme and uncontrollable circumstance policy for the national PHE for COVID–19 and performance period benchmarks will make it difficult for clinicians to predict how they will score. One commenter suggested the use of CY 2020 quality data as a baseline for benchmarking for CY 2021. One commenter suggested calculating benchmarks by combining 2017, 2018, and 2019 data to provide a larger sample to address concerns around skewed data while still providing target information.

Response: Based on our 2019 data analysis, we believe we have sufficient data to reliably generate historical benchmarks for CY 2021 and we will not need to rely on 2018 benchmarks to provide a known target for benchmarking. Using historical benchmarks based on the reliable and complete data from 2019 will allow us to provide benchmarks based on more recent data in advance for clinicians to prepare and since the data from 2019 is usable, representative, and more recent, we do not believe it necessary to use data from 2018 to create benchmarks for CY 2021, as it would be more out of data than data from 2019. Using the data from 2019, CEHRT vendors remain able to rely on the benchmarks for CY 2021 to set dashboards and reports to provide accurate information to clinicians. Additionally, we do not believe we need to combine benchmarks across years to create a reliable benchmark.

Comment: Several commenters suggested that we calculate two benchmarks, one historical and one performance period, and then have CMS use the more favorable of the two benchmarks for each measure. The commenters suggested this approach to provide baseline information to guide measure selection and advance notice to clinicians on possible benchmarks while considering the impact of the national PHE for COVID–19 and having complete, reliable data. One commenter suggested calculating both 2019 and 2020 performance year measure benchmarks and using the lower benchmark for each quality measure since CMS already calculated this data and will allow for comparing scores given the impact of the national PHE for COVID–19. One commenter recommended that CMS use CY 2019 data to publish a benchmark file and then score measures based on the average of 2021 and 2019 data. One commenter suggested setting a threshold to assess change in benchmarks and if the change threshold is not exceeded, a performance period benchmark would be appropriate. If change above the set threshold occurred, the historical benchmark would be used.

Response: Based on our 2019 data analysis, we can use historical benchmarks for CY 2021 that are complete and reliable and do not believe that we need to create two benchmarks or use an average of 2 years of data to create a benchmark. The data we received for CY 2019 is robust as we only saw a slight increase in the number of clinicians not engaged with MIPS in CY 2019 compared to CY 2018 submission data. This allows us to provide benchmarks in advance for clinicians to have baseline information to guide measure selection and gives advance notice to clinicians on benchmarks. The benchmarks based on CY 2019 data will be available prior to the CY 2021 performance period at *qpp.cms.gov*.

Comment: Several commenters recommended that CMS consider the impacts that the PHE for COVID–19 will have on participation and data from 2019, 2020, and potentially 2021 when setting future benchmarks. Commenters stated that the national PHE for COVID–19 will continue to disrupt patient volume, case mix, and patient outcomes, making data incomparable when comparing years impacted by the national PHE for COVID–19 to prior years without impact. A few commenters requested CMS to take major changes in care, including disruptions in the delivery of medical services, into account when comparing data from year to year. A few commenters suggested that CMS compute benchmarks with 2018, 2019, and 2020 data separately to understand the impact of the PHE on quality measures. One commenter stated that due to the removal of telehealth exclusion language from select measure specifications, data will not be comparable and will no longer be reliable for measures in the future.

Response: For performance year 2020, we continue to offer the extreme and uncontrollable circumstances policy in response to the national PHE for COVID–19, allowing clinicians to submit an application for the reweighting of the quality performance category based as described in section IV.A.3.d.(2)(b)(iv) of this final rule. We will continue to monitor the impacts of the national PHE for COVID–19 on data comparability, including due to the removal of telehealth exclusion language from select measure specifications, and will incorporate changes and offer flexibilities through future rulemaking cycles, as necessary, to account for changes in care delivery. Benchmarks from CY 2018 data have already been released publicly and benchmarks from CY 2019 data will be released prior to the start of CY 2021. Benchmarks from CY 2020 data will be released once the data is available. Those benchmarks will be available at *qpp.cms.gov*.

After consideration of the public comments, we are not finalizing our intent to use performance period benchmarks for the CY 2021

performance period and will use historical benchmarks for CY 2021 based on the 2019 data.

(iii) Minimum Case Requirements

In the CY 2017 Quality Payment program final rule (81 FR 77287 to 77289), we finalized that we will use 20 cases as the case minimum for all quality measures, with the exception of the hospital-wide readmission measure which has a minimum of 200 cases. As proposed in Table Group A within Appendix 1, the hospital-wide readmission measure is replacing the all-cause readmission measure and an additional administrative claims-based measure for hip/knee complications is being added to the program. In the case of the hospital-wide readmission measure, the case minimum will remain the same at 200 cases and will only apply to groups. For the new hip/knee complications measure, a case minimum of 25 is proposed and is applicable for individuals and groups. As noted in the CY 2021 PFS proposed rule (85 FR 50308), we proposed to amend § 414.1380(b)(1)(i) to clarify how administrative claims measures are scored. We proposed to amend § 414.1380(b)(1)(iii) to reflect that, except for administrative claims measures, the minimum case requirement is 20 cases. For each administrative claims-based measure, the minimum case requirement is specified in the annual list of MIPS measures.

We invited public comments on our proposal to amend § 414.1380(b)(1)(i) to clarify how administrative claims measures are scored and amend § 414.1380(b)(1)(iii) to reflect that, except for administrative claims measures, the minimum case requirement is 20 cases. The following is a summary of the comments we received and our responses.

Comment: One commenter did not support the proposal to define the minimum case requirement for administrative claims measures in the annual list of MIPS measures. One commenter recommends that CMS maintain the current regulatory process of limiting such requirements to amounts specifically listed in regulation (for example, for non-administrative claims measures, the minimum case requirement is 20 cases) to minimize negative impact in program compliance and to limit additional changes in an already nuanced quality reporting program.

Response: While we understand the commenter's concern regarding additional annual updates, we believe providing the specific minimum case requirements for administrative claims measures in the annual list of MIPS measures allows these measures to be reliably scored based on the case minimum specific to each measure. Based on the specifications, administrative claims measures may require a case minimum that is an exception to the 20 cases otherwise required. Any further changes in the case minimum requirement would be considered substantial and would go through rule making. Additionally, this exception is for administrative claims measures, which do not require reporting and are based on claims data we receive.

Comment: One commenter stated that a sample of 25 cases is insufficient to provide meaningful data for the newly added hip/knee complications measure.

Response: While we understand the commenter's concern about the proposed case minimum for the new hip/knee complications measure, we selected a minimum case count of 25 to ensure a measure result is available for most eligible clinicians and eligible clinician groups while maintaining measure reliability. We believe that for this measure, a minimum case count of 25 cases demonstrates reliability results consistent with standards of other measures within MIPS. We refer readers to Table Group A of Appendix 1 of this rule for discussion on new individual MIPS quality measures proposed for the 2023 MIPS payment year and future years.

After consideration of the public comments, we are finalizing our proposal as proposed.

(iv) Assigning Quality Measure Achievement Points

We refer readers to § 414.1380(b)(1)(i) for more details on our policies for scoring performance on quality measures (81 FR 77276 through 77307, 82 FR 53694 through 53701, 83 FR 59841 through 59856, and 84 FR 63011 through 63019).

(A) Scoring Measures Based on Achievement

We previously established at § 414.1380(b)(1)(i) a global 3-point floor for each scored quality measure, as well as for the hospital readmission measure (if applicable) for the 2019 through 2022 MIPS payment years. MIPS eligible clinicians receive between 3 and 10 measure achievement points for each submitted measure that can be reliably scored against a benchmark, which requires meeting the case minimum and data completeness requirements. In the CY 2017 Quality Payment Program final rule (81 FR 77282), we established that measures with a benchmark based on the performance period (rather than on the baseline period) would continue to receive between 3 and 10 measure achievement points for performance periods after the first transition year. For measures with benchmarks based on the baseline period, we stated that we would revisit the 3-point floor in future years.

For the 2023 MIPS payment year, we proposed to again apply a 3-point floor for each measure that can be reliably scored against the benchmark. As we move towards the MVP framework discussed the CY 2021 PFS proposed rule (85 FR 50308), we anticipated we will be able to score quality measures from 1 to 10 for measures in MVPs and as such will revisit and possibly remove the 3-point floor for traditional MIPS in future years. As a result, we discussed that we would wait until there is further policy development under the MVP framework before proposing to remove the 3-point floor. Accordingly, in the CY 2021 PFS proposed rule (85 FR 50308), we proposed to revise § 414.1380(b)(1)(i) to remove the years 2019 through 2022 and adding in its place the years 2019 through 2023 to provide that for the 2019 through 2023 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340.

We invited public comments on our proposal to again apply a 3-point floor for each measure that can be reliably scored against a benchmark for the MIPS 2023 payment year. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposal to continue the 3-point floor for each measure that can be reliably scored against a benchmark.

Response: We thank the commenters for their support.

Comment: One commenter recommended adopting a 5-point floor for each measure that can be reliably scored against a benchmark to help mitigate the disruptive effects of the PHE and to provide incentives for clinicians to report measures. A few commenters recommended adopting a universal scoring floor of 5 points to mitigate the disruptive effects of the national PHE for COVID–19 on benchmarks while incentivizing clinicians to report measures that

historically lack a benchmark and would increase use of under-reported measures and incentivize clinicians to report instead of opting out.

Response: We appreciate the commenter's concern. We do not want to mask performance with a floor above 3 points. Clinicians will know in advance what the benchmarks are, and we believe that the 3-point floor provides protection for clinicians.

After consideration of the public comments, we are finalizing our proposal as proposed.

(B) Scoring Measures That Do Not Meet Case Minimum, Data Completeness, and Benchmark Requirements

We refer readers to § 414.1380(b)(1)(i)(A) and (B) for more on our scoring policies for a measure that is submitted but is unable to be scored because it does not meet the required case minimum, does not have a benchmark, or does not meet the data completeness requirement (84 FR 63012).

In the 2017 QPP final rule (81 FR 77288) and the 2018 QPP final rule (82 FR 53727), we identified ''classes of measures'' which were intended to characterize measures for the ease of discussion. Class 1 measures are measures that can be scored based on performance because they have a benchmark, meet the case minimum and data completeness requirements. Class 2 measures are measures that cannot be scored based on performance because they do not have a benchmark or do not meet the case minimum which is generally 20 cases. Class 3 measures are measures that do not meet the data completeness requirement. We also noted that policies for Class 2 and Class 3 measures would not apply to measures submitted with the CMS Web Interface or administrative claims-based measures.

We did not propose to modify how we score these measures within MIPS, as we consider policies for transitioning to MVPs. For class 2 measures, for the 2023 MIPS payment year, we proposed to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark, due to fewer than 20 individual clinicians or groups adequately reporting the measure, or meet the case minimum requirement. Accordingly, in the CY 2021 PFS proposed rule (85 FR 50308 through 50309), we proposed to revise § 414.1380(b)(1)(i)(A)(*1*) to remove the years 2019 through 2022 and add in its place the years 2019 through 2023 to provide that except as provided in paragraph (b)(1)(i)(A)(*2*) (which relates to CMS Web Interface measures and administrative claims-based measures), for the 2019 through 2023 MIPS payment years, MIPS eligible clinicians would receive 3 measure achievement points for each submitted measure that meets the data completeness requirement, but does not have a benchmark or meet the case minimum requirement.

We invited public comments on our proposal to again apply the special scoring policies for measures that meet the data completeness requirement but do not have a benchmark or meet the case minimum requirement for the MIPS 2023 payment year. The following is a summary of the comments we received and our responses.

Comment: One commenter supported the continuation of the policies as proposed.

Response: We appreciate the commenter for their support.

Comment: A few commenters did not support the proposal to continue the 3 measure achievement points for measures without a benchmark because the commenters believed that the policy provides a disincentive to submit more specialized measures and recommended that CMS provide bonus points for submitting measures without a benchmark.

Response: We recognize the commenters' concerns regarding the assignment of 3 points to measures without a benchmark. We are continuing to evaluate our approach to scoring measures without a benchmark and will take these comments into consideration for the future.

After consideration of the public comments, we are finalizing our proposal as proposed.

A summary of the policies for the CY 2021 MIPS performance period is provided in Table 49.

TABLE 49: Quality Performance Category: Scoring Policies for the CY 2021 MIPS Performance Period*

Measure type	Description	Scoring rule for Traditional MIPS
Class 1	Measures that can be scored based on performance. Measures that are submitted or calculated that meet all the following criteria: (1) Has a benchmark; (2) Meets case minimum; and (3) Meets the data completeness standard (generally 70 percent for 2021.)**	For the 2021 MIPS performance period: 3 to 10 measure achievement points based on performance compared to the benchmark.
Class 2	For the 2020 MIPS performance period: Measures that are submitted and meet data completeness, but do not have either of the following: (1) A benchmark; and (2) Meets case minimum.	For the 2021 MIPS performance period: 3 measure achievement points.
Class 3	Measures that are submitted, but do not meet data completeness threshold, even if they have a measure benchmark and/or meet the case minimum.	Beginning with the 2020 MIPS performance period: MIPS eligible clinicians other than small practices will receive zero points for this measure. Small practices will continue to receive 3 points.

*The Class 2 and 3 measure scoring policies are not applicable to CMS Web Interface measures or administrative claims-based measures.

**We refer readers to § 414.1335(a)(3) for our policy on data completeness.

(v) Assigning Measure Achievement Points for Topped Out Measures

We refer readers to § 414.1380(b)(1)(iv) for our previously finalized policies regarding the identification of topped out measures and § 414.1380(b)(1)(iv)(B) for our finalized policies regarding the scoring of topped out measures. Under § 414.1380(b)(1)(iv), we will identify topped out measures in the benchmarks published for each Quality Payment Program year. Under § 414.1380(b)(1)(iv)(B), beginning with the 2021 MIPS payment year, measure benchmarks (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years will receive a maximum of 7 measure achievement points beginning in the second year the measure is identified as topped out (82 FR 53726 through 53727).

We noted in the CY 2021 PFS proposed rule (85 FR 50307) that we intended to use performance period benchmarks for the 2021 MIPS performance period, which would mean we would not be able to publish measures that are topped out prior to the 2021 MIPS performance period. As discussed in that proposed rule (85 FR 50309), this also means we would not be able to identify those that have been topped-out for 2 or more consecutive years for purposes of the topped out scoring of 7 measure achievement points. We noted that we believe it is still important to retain a topped-out scoring cap of 7 measure achievement points so that clinicians have incentives to pick alternate measures that are not topped out. We also noted that a measure may not always be topped out and we believe that if a measure is not topped out in the 2021 performance period benchmark, then it should have the ability to achieve up to 10 measure achievement points.

Therefore, for the 2021 MIPS performance period, as an exception from the general rule at § 414.1380(b)(1)(iv)(B), we proposed at § 414.1380(b)(1)(iv)(B)(*1*) to apply the 7 measures achievement point cap to measures that meet the following two criteria. The first criterion would be that the measures have been topped out for 2 or more periods based on the published 2020 MIPS performance period historical benchmarks (which are based on submissions for the 2018 MIPS performance period). The second criterion would be the measures remain topped out after the 2021 MIPS performance period benchmarks have been calculated. We noted that we believe these two criteria collectively would provide clinicians the information to know prior to the 2021 MIPS performance period which measures would have the topped-out scoring applied but would also account for the scenario where a measure is no longer topped out. We would not limit the number of measure achievement points for measures that have not been topped out for at least 2 years as published in the 2020 MIPS performance period historical benchmarks.

We invited public comments on our proposal to apply the 7 measures achievement point cap to measures that meet the two criteria. The following is a summary of the comments we received and our responses.

Comment: Several commenters do not support the proposal to apply the scoring cap of 7 achievement points for the 2021 performance period for measures that are found to be topped out and based this rationale on the thinking that the cap would apply to topped out measures for 2 or more consecutive years, including the 2021 MIPS performance period benchmarks. A few commenters discussed concerns over not knowing which measures will have the cap prior to the 2021 performance period and could put clinicians at risk of inadvertently reporting on measures with topped out

benchmarks, resulting in a capped score for the measure.

Response: We appreciate the commenters' responses for this proposal. As discussed in section IV.A.3.d.(1)(b)(ii) of this rule, we no longer intend to use performance period benchmarks and will use historical benchmarks for CY 2021. This allows us to provide benchmarks in advance for clinicians to have baseline information to guide measure selection. Because we are using historical benchmarks, we no longer need an exception to identify topped out measures, instead we will follow our normal topped out lifecycle process.

Comment: A few commenters requested that CMS suspend the topped-out measure scoring cap for the 2021 MIPS performance period due to the national PHE for COVID–19 and since many topped-out measures remain the most meaningful measures on which certain clinicians can report.

Response: We appreciate the commenters' concern about the scoring cap for topped out measures. As MIPS is a performance-based program, we do not believe that MIPS eligible clinicians electing to report topped out measures should be able to receive the same maximum score as other measures that demonstrate variations in performance and room for improvement. We therefore continue to believe it necessary to maintain the 7-point cap for measures identified as topped out. Additionally, please refer to *qpp.cms.gov/about/covid19* for our national PHE for COVID–19 response and flexibilities provided within QPP.

Comment: Several commenters supported the proposed criteria for determining which measures should have the 7-point cap applied in 2021 performance year based on the use of performance period benchmarks as it provides important protections for clinicians given the impact of the national PHE for COVID–19.

Response: We appreciated the commenters for their support for this policy based on the intended use of the performance period benchmarks, but note that we are not finalizing the use of performance period benchmarks policy as discussed in section IV.A.3.d.(1)(b)(ii) of this rule.

After consideration of public comments, we are not finalizing our proposal to create an exception from the general rule at § 414.1380(b)(1)(iv)(B) that we had proposed at § 414.1380(b)(1)(iv)(B)(*1*). Instead, we will continue our policy that the 7-point cap will be applied to measures (except for measures in the CMS Web Interface) that are identified as topped out for 2 or more consecutive years, beginning in the second year the measure is identified to be topped out.

(vi) Incentives To Report High-Priority Measures

We refer readers to § 414.1380(b)(1)(v)(A) for our previously finalized policies regarding incentives to report high priority measures. In the CY 2017 Quality Payment Program final rule (81 FR 77293), we established the scoring policies for high priority measure bonus points to encourage the selection of additional high-priority and outcome measures that impact beneficiaries and were closely aligned to our measurement goals. In the CY 2019 PFS final rule (83 FR 59850), we discontinued awarding measure bonus points to CMS Web Interface reporters for reporting high priority measures since CMS Web Interface reporters have no choice in measures.

We stated in the CY 2019 PFS proposed and final rules (83 FR 35950, 59851) that as part of our move towards fully implementing high value measures, we believe that bonus points for high priority measures for all collection types may no longer be needed, and as a result, we intended to consider in future rulemaking whether to modify our scoring policy to no longer offer high priority bonus points after the 2021 MIPS payment year. We noted in the CY 2019 PFS final rule (83 FR 59851) that measure bonus points were created as transition policies which were not meant to continue through the life of the program. We believe with the finalized framework for transforming MIPS through MVPs (84 FR 62948), we will find ways in the future to emphasize high priority measures without needing to incentivize with bonus points. As a result, we noted that we would wait until there is further policy development under the MVP framework before proposing to remove our policy of assigning bonus points for high priority measures.

As noted in the CY 2021 PFS proposed rule (85 FR 50309 through 50310), we proposed to maintain the cap on measure points for reporting high priority measures for the 2023 MIPS payment year. Accordingly, we proposed to revise § 414.1380(b)(1)(v)(A)(*1*)(*ii*) to remove the years 2019 through 2022 and adding in its place the years 2019 through 2023 to provide that through the 2023 MIPS payment year, the total measure bonus points for high priority measures cannot exceed 10 percent of the total available measure achievement points.

We invited public comments on our proposal to maintain the cap on measure points for reporting high priority measures for the 2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to continue the high priority bonus. Commenters expressed the belief that these bonuses can help clinicians meet the performance threshold.

Response: We thank the commenters for their support.

Comment: One commenter did not support our stated intention to phase out high priority measure bonus points in the future because commenter believes these bonuses are important to ensure benchmarks are established for these high priority measures through incentivizing reporting.

Response: We appreciate the commenter's concerns and will take their recommendations into consideration for the future. We envision that the progression of the MIPS program under the MVP framework will allow us to remove some of the scoring complexity associated with the MIPS program. We anticipate that removing bonuses would be part of this framework. We also understand the interest in being as flexible as possible in awarding clinicians for supporting the goals of the program such as reporting high priority measures and creating benchmarks. While bonuses do not directly affect the calculation of benchmarks, we will continue to consider the best ways to support our goals in future rulemaking.

After consideration of the public comments, we are finalizing our proposal as proposed.

(vii) Incentives To Use CEHRT To Support Quality Performance Category Submissions

Section 1848(q)(5)(B)(ii) of the Act requires the Secretary to encourage MIPS eligible clinicians to report on applicable quality measures through the use of CEHRT. In the CY 2017 Quality Payment Program final rule (81 FR 77297), we established the measure bonus point and bonus cap for using CEHRT for end-to-end reporting. We refer readers to § 414.1380(b)(1)(v)(B) for our previously finalized policies regarding measure bonus points for end-to-end electronic reporting. We believe that with the framework for transforming MIPS through MVPs discussed in the CY 2020 PFS proposed rule (84 FR 40739) and the CY 2021 PFS proposed rule (85 FR 50279 through 50285), we will find ways to incorporate digital measures without needing to incentivize end-to-end reporting with

bonus points. In the CY 2018 Quality Payment Program final rule (82 FR 53636), we encouraged stakeholders to consider electronically specifying their quality measures as eCQMs, to encourage clinicians and groups to move towards the utilization of electronic reporting. As noted in the CY 2019 PFS final rule (83 FR 59851), bonus points were created as transition policies which were not meant to continue through the life of the program. As a result, we noted that we would wait until there is further policy development under the finalized MVP framework (84 FR 62948) before proposing to remove our policy of assigning bonus points for end-to-end electronic reporting.

As noted in the CY 2021 PFS proposed rule (85 FR 50310), we proposed to continue to assign and maintain the cap on measure bonus points for end-to-end electronic reporting for the 2023 MIPS payment year. Accordingly, we proposed to revise § 414.1380(b)(1)(v)(B)(*1*)(*i*) to remove the years 2019 through 2022 and add in its place the years 2019 through 2023 to provide that for the 2019 through 2023 MIPS payment years, the total measure bonus points for measures submitted with end-to-end electronic reporting cannot exceed 10 percent of the total available measure achievement points.

We invited public comments on our proposal to maintain the cap on measure bonus points for end-to-end electronic reporting for the 2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported and urged CMS to continue the bonus for end-to-end reporting using CEHRT because it would drive electronic reporting and maintain stability in the program.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal as proposed.

(viii) Improvement Scoring for the MIPS Quality Performance Category Percent Score

We refer readers to § 414.1380(b)(1)(vi)(C)(*4*) for more on our policy stating that for the 2020 through 2022 payment years, for the purpose of improvement scoring, we will assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year.

As noted in the CY 2021 PFS proposed rule (85 FR 50310), we proposed to continue our previously established policy for improvement scoring for the 2023 MIPS payment years and to revise § 414.1380(b)(1)(vi)(C)(*4*) to remove the phrase ''2020 through 2022 MIPS payment year'' and adding in its place the phrase ''2020 through 2023 MIPS payment years'' to indicate that for each MIPS payment year through 2023, we will assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year. Specifically, for the 2023 MIPS payment year, we would compare the MIPS eligible clinician's quality performance category achievement percent score for the 2021 MIPS performance period to an assumed quality performance category achievement percent score of 30 percent if the MIPS eligible clinician earned a quality performance score less than or equal to 30 percent for the 2020 MIPS performance period.

We invited public comments on our proposal to assume a quality performance category achievement percent score of 30 percent in the previous year if a MIPS eligible clinician earned a quality performance category score less than or equal to 30 percent in the previous year for the 2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters expressed support for improvement scoring for the quality performance category because it better rewards high quality performers and promotes strategic priorities of CMS.

Response: We thank the commenters for their support.

After consideration of the public comments, we are finalizing our proposal as proposed.

(2) Calculating the Final Score

For a description of the statutory basis and our policies for calculating the final score for MIPS eligible clinicians, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019 and CY 2020 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785, 83 FR 59868 through 59878, 84 FR 63020 through 63031, respectively). In the CY 2021 PFS proposed rule (85 FR 50310 through 50315), we proposed to continue the complex patient bonus for the 2023 MIPS payment year, and we also proposed to modify the complex patient bonus for the 2022 MIPS payment year as established in prior rulemaking due to the PHE for COVID–19. In addition, we proposed performance category redistribution policies for the 2023, 2024, and future MIPS payment years.

(a) Complex Patient Bonus

(i) Background

Section 1848(q)(1)(G) of the Act requires us to consider risk factors in our MIPS scoring methodology. Specifically, it provides that the Secretary, on an ongoing basis, shall, as the Secretary determines appropriate and based on an individual's health status and other risk factors, assess appropriate adjustments to quality measures, cost measures, and other measures used under MIPS; and assess and implement appropriate adjustments to payment adjustments, final scores, scores for performance categories, or scores for measures or activities under MIPS. In doing so, the Secretary is required to take into account the relevant studies conducted under section 2(d) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act)) (Pub. L. 113–185, enacted on October 6, 2014) and, as appropriate, other information, including information collected before completion of such studies and recommendations. In the CY 2018 Quality Payment Program final rule, under the authority in section 1848(q)(1)(G) of the Act, we established at § 414.1380(c)(3) a complex patient bonus of up to 5 points to be added to the final score for the 2020 MIPS payment year (82 FR 53771 through 53776). In subsequent rulemaking, we continued the complex patient bonus at § 414.1380(c)(3) for the 2021 and 2022 MIPS payment years (83 FR 59870 and 84 FR 63023). We refer readers to these final rules for additional details on the background, statutory authority, policy rationale, and calculation of the complex patient bonus.

We intended for this bonus to serve as a short-term strategy to address the impact patient complexity may have on MIPS scoring while we continue to work with stakeholders on methods to account for patient risk factors. The overall goal, when considering a bonus for complex patients, is two-fold: (1) To protect access to care for complex patients and provide them with excellent care; and (2) to avoid placing MIPS eligible clinicians who care for complex patients at a potential disadvantage while we review the completed studies and research to address the underlying issues. We used

the term ''patient complexity'' to take into account a multitude of factors that describe and have an impact on patient health outcomes; such factors include the health status and medical conditions of patients, as well as social risk factors. We believe that as the number and intensity of these factors increase for a single patient, the patient may require more services, more clinician focus, and more resources in order to achieve health outcomes that are similar to those who have fewer factors. In developing the policy for the complex patient bonus, we assessed whether there was a MIPS performance discrepancy by patient complexity using two well-established indicators in the Medicare program: Medical complexity as measured through Hierarchical Condition Category (HCC) risk scores, and social risk as measured through the proportion of patients that are dually eligible for Medicare and Medicaid (82 FR 53771 through 53776).

(ii) Complex Patient Bonus for the 2023 MIPS Payment Year

As discussed in the CY 2021 PFS proposed rule (85 FR 50310), we intended the complex patient bonus as a short-term solution to address the impact patient complexity may have on MIPS scoring. However, we noted that we currently do not believe we have sufficient information available to develop a long-term solution to account for patient risk factors in MIPS that we could include as a proposal for the 2023 MIPS payment year. In the CY 2020 PFS proposed and final rules, we considered whether newly available data from the Quality Payment Program still supported the complex patient bonus at the final score level. More specifically, within the data analysis, we did not observe a consistent linear relationship for any reporting type or complexity measure, HCC risk score or dual eligible status (84 FR 40793 through 40795 and 84 FR 63021 through 63023). However, we only have a few years of data and believe that more recent data may bring different results than the findings we explained in detail in the CY 2020 PFS final rule. We refer readers to the CY 2020 PFS final rule for further details on the methodology and findings (84 FR 63021 through 63023).

As stated previously in this final rule, section 1848(q)(1)(G) of the Act requires us to take into account the relevant studies conducted under section 2(d) of the IMPACT Act and, as appropriate, other information, including information collected before completion of such studies and recommendations. ASPE completed its first report in December 2016, which examined the effect of individuals' socioeconomic status on quality, resource use, and other measures under the Medicare program, and included analyses of the effects of Medicare's current value-based payment programs on clinicians serving socially at-risk beneficiaries and simulations of potential policy options to address these issues. We also noted, in the CY 2020 PFS final rule, that a second ASPE report on social risk factors within CMS value-based purchasing programs was expected. This second report, Social Risk and Performance in Medicare's Value-Based Purchasing Programs, was publicly released in June 2020, which builds on the analyses included in the initial report and provides additional insight for addressing risk factors in MIPS and other value-based payment programs.[126] More specifically, the report has a 3-pronged strategy approach to measure and report quality; to set high, fair quality standards; and to reward and support better outcomes for beneficiaries with social risk. As a part of this 3-pronged strategy, the report supports the use of the complex patient bonus in MIPS, explaining that it is well supported because this policy gives additional points to clinicians who treat patients with high social risk factors and does not lower the standard of care. Further, the report suggested that CMS should not include the complex patient bonus within the final score that is publicly reported to ensure that patients can see the true clinician performance. As we continue to review the findings from the report, we intend to consider its recommendations, along with any updated data that would become available, for future rulemaking. Hence, based on our data analysis from the CY 2020 PFS final rule (84 FR 63022) and the lack of currently available additional data sources, for the 2021 MIPS performance period/2023 MIPS payment year, we proposed to continue the complex patient bonus without any modifications (as finalized for the 2020 MIPS performance period/2022 MIPS payment year) and to revise § 414.1380(c)(3) accordingly. We noted that we plan to continue working with ASPE, the public, and other key stakeholders on this important issue to identify longer term policy solutions that achieve the goals of attaining health equity for all beneficiaries, minimizing unintended consequences, and would propose modifications to the complex patient bonus in future rulemaking as appropriate.

We invited public comments on our proposal to continue the complex patient bonus for the 2021 MIPS performance period/2023 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to continue the complex patient bonus of up to 5 points for the 2021 MIPS performance period/2023 MIPS payment year. Another commenter supported the complex patient bonus but requested that we increase the complex patient bonus.

Response: We thank the commenters for their support to maintain the complex patient bonus for the 2021 MIPS performance period/2023 MIPS payment year. We plan to review available information, including any updated data, in future years to determine if it is appropriate to modify our approach to adjusting for social risk factors.

Comment: Many commenters encouraged CMS to finalize the proposed policy, discussed in the CY 2021 PFS proposed rule (85 FR 50311), of doubling the complex patient bonus for the CY 2020 performance period, and to continue doubling the complex patient bonus into the CY 2021 performance period, because the impact of the national PHE for COVID–19 will likely continue, as well as the associated increased complexity due to COVID–19.

Response: We understand that both direct and indirect impacts of the PHE for COVID–19 will likely continue into CY 2021. We will continue to assess and better understand the implications of the national PHE of COVID–19 on care delivery and complex patient care during 2021 and will consider whether to make any policy changes in future rulemaking. At this time, we continue to offer the application-based extreme and uncontrollable circumstances policy for CY 2021, as referenced in section IV.A.3.d.(2)(b)(iv)(B) of this final rule, and we believe we do not need to continue to double the complex patient bonus for the 2021 performance period/2023 MIPS payment year, although we intend to reevaluate after we gather more data and learn more about both the direct and indirect impacts of the PHE for COVID–19. We will continue to assess our complex patient bonus policy regarding both the value of the points and the calculation methodology and ensure that we do not risk artificially increasing MIPS final scores while providing enough flexibility to clinicians to account for increased patient complexity.

[126] ASPE. Second Report to Congress on Social Risk and Medicare's Value-Based Purchasing Programs. June 29 2020. *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress.*

Comment: A few commenters pointed out perceived limitations in the use of the HCC risk score in calculating the complex patient bonus. More specifically, they believed that the existing methodology does not fully and appropriately capture the clinical and social complexity of patients and encouraged CMS to find more appropriate and long-term solutions. A few commenters suggested that CMS consider other medical and social risk factors outside of what is already captured in the HCC and dual-eligible status, when determining patient complexity. Another commenter requested that CMS develop an alternative applicable to all clinician types. One commenter suggested that CMS include ICD–10 Z codes, such as Z590.0 homelessness, Z65.0 unemployed, or Z59.5 extreme poverty to capture additional social risk factors.

Response: We thank the commenters for their suggestions and will take them into consideration as we consider options for updating the complex patient bonus in future years. Further, while the ASPE's second report is supportive of the complex patient bonus, they have specific recommendations as to how to further incorporate risk adjustment at the MIPS program level which we plan to address in future rulemaking. Additionally, although the ASPE report found dual eligibility to be a reliable indicator of social risk, we understand there may be some limitations. However, we are not aware of data sources and/or methodologies to account for other social indicators such as income and education that are readily available for all Medicare beneficiaries that would be more complete indices of a patient's complexity. Further, we continue to believe that average HCC risk scores are a valid proxy for medical complexity that are also used by other CMS programs. Therefore, we have decided to continue to pair the HCC risk score with the proportion of dually eligible patients to create a more complete complex patient indicator than can be captured using HCC risk scores alone. We will evaluate additional, more comprehensive options, such as the utilization of ICD–10 Z codes, in future years based on any updated data or additional information, including to better account for social risk factors while minimizing unintended consequences and consider these as we move forward.

Comment: One commenter expressed concerns with calculating the complex patient bonus points given the substantial disruptions to patient care due to the national PHE for COVID–19, which could cause data, used for the lookback period, to be either compromised or unreliable.

Response: When we calculate the complex patient bonus points, we rely on dual eligibility status and the HCC risk score, which should not be impacted by potential coding modifications or disruptions for the CY 2020 performance period. Pursuant to § 414.1380(c)(3)(i), in order to calculate an average HCC risk score, CMS uses the model adopted under section 1853 of the Act for Medicare Advantage risk adjustment purposes, for each MIPS eligible clinician or group; that average HCC risk score is used as a part of the complex patient bonus calculation. We refer readers to the CY 2018 QPP final rule (82 FR 53771) for more details on how we calculate the average HCC risk score for a MIPS eligible clinician or group. Specifically, we average HCC risk scores for beneficiaries cared for by the MIPS eligible clinician or clinicians in the group during the second 12-month segment of the eligibility period during the prior performance period. HCC risk scores for beneficiaries would be calculated based on the calendar year immediately prior to the performance period. For example, for the 2020 MIPS performance period, the HCC risk scores would be calculated based on beneficiary services from CY 2019, which is prior to the year in which the PHE occurred. Additionally, as the claims coding for the HCC occurred prior to this proposal, we believe this approach mitigates the risk of potential coding modifications or disruptions to get higher expected costs, which could happen if concurrent risk adjustments were incorporated. However, we acknowledge some of the policy flexibilities we established for the national PHE for COVID–19 potentially could have an effect on data for CY 2020. Given that this is the primary source of data available to us to calculate the complex patient bonus for CY 2021, for now, we plan to utilize this data, and we will monitor and consider making additional adjustments, as necessary.

After consideration of the public comments, we are finalizing the proposal to continue the complex patient bonus for the 2021 performance period/2023 MIPS payment year as proposed and to revise § 414.1380(c)(3) accordingly.

(iii) Complex Patient Bonus for the 2022 MIPS Payment Year

In this section of the final rule, we discuss the proposed policy to modify the complex patient bonus for the 2022 MIPS payment year in response to the PHE for COVID–19 (85 FR 50311). In the CY 2020 PFS final rule, we continued the complex patient bonus for the 2020 performance period/2022 MIPS payment year (84 FR 63021 through 63023). More specifically, we continued to utilize our two established complexity indicators, HCC risk scores and dual eligible status, because we believed that they continued to account for the multitude of factors that describe and have an impact on patient health outcomes. Further, risk scores are based on a beneficiary's age and sex; whether the beneficiary is eligible for Medicaid, first qualified for Medicare on the basis of disability, or lives in an institution (usually a nursing home); and the beneficiary's diagnoses from the previous year.[127] Additionally, the HCC model also accounts for the number of conditions a beneficiary has, making an adjustment as the number of diseases or conditions increases, and includes additional diagnosis codes related to mental health and substance use disorders, and chronic kidney disease.[128] However, due to the national PHE for COVID–19 during performance period 2020, we noted that we need to re-evaluate the previously established policy for the complex patient bonus for the 2022 MIPS payment year. We acknowledged that there are direct effects of COVID–19 for those patients who have the disease and indirect effects of COVID–19 for other patients, including increased complexity and barriers such as postponing care, accessing care in a different way (for example, via telecommunications), and disruptions to lab results and medications, which are not accounted for in our existing final score calculations using these complexity indicators. We noted that we realize that the first year of the novel virus may add complexity that we have not already captured via the complex patient bonus. This complexity includes patients who have gotten sick, as well as patients who may now have complications or other factors because of delayed care or disruptions to lab services or medications due to COVID–19. Government guidelines, such as the Centers for Disease Control and Prevention (CDC) guidance on ''Groups

[127] CMS, Medicare Fee-For-Service Provider Utilization & Payment Data Physician and Other Supplier Public Use File: A Methodological Overview'': *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Downloads/Medicare-Physician-and-Other-Supplier-PUF-Methodology.pdf.*

[128] CMS, ''Report to Congress: Risk Adjustment in Medicare Advantage'': *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.*

at Higher Risk for Severe Illness'', indicate that COVID–19 patients who are already high-risk due to pre-existing medical conditions are at further risks of increased COVID–19 related hospitalizations and mortality.[129] Further, literature also indicates that those patients who are already high-risk due to social factors are also at further risk of serious illness related to COVID–19.[130]

Further, during this time, hospitals reported that medical systems delayed and canceled care, resulting in reduced utilization of healthcare services and a changing care delivery system.[131] Although access to Medicare telehealth services was expanded so that beneficiaries could receive a wider range of services from clinicians without having to travel to a healthcare facility,[132] this only partially filled the gap in services from the reduction in delivery of care, as not all specialties can utilize telehealth. We recognized the increased challenges of providing care to complex patients in the context of the national PHE for COVID–19. Patients with comorbidities (as measured by HCC risk score) and social risk (measured by dual eligible status) are disproportionately likely to be severely affected by COVID–19.[133] [134] [135] More specifically, findings from our recently released data reinforces previous findings by the CDC that older Americans and those with chronic health conditions are at the highest risk for COVID–19. The data also show that COVID–19 has disproportionately impacted lower income adults, further confirming longstanding healthcare disparities in dually eligible populations.[136] Additionally, in light of the care delivery changes, we noted that clinicians may see patients in 2020, with medical or social risk factors, whose health conditions may have been exacerbated due to delayed care. Patients with comorbidities and social risk are likely to suffer adverse outcomes due to delaying or not receiving care.[137] [138] [139] Given that the limited available literature and data on COVID–19 suggests that patients with social risk factors or underlying conditions have increased complexity, we believe that our existing complexity indicators, HCC risk score and dual eligibility, could serve as a proxy for capturing increased complexity due to the PHE for COVID–19.

Currently, the complex patient bonus is worth up to 5 points. However, given the anticipated increase in complexity due to the national PHE for COVID–19, we proposed at § 414.1380(c)(3)(iv) that for the CY 2020 performance period/2022 MIPS payment year, the complex patient bonus would be calculated pursuant to the existing formulas in § 414.1380(c)(3)(i) and (ii), and the resulting numerical value would then be multiplied by 2, but the complex patient bonus cannot exceed 10. The doubled numerical value (subject to the 10-point cap) would be added to the final score. Additionally, we proposed to revise § 414.1380(c)(3)(iii) to state that the complex patient bonus cannot exceed 5.0 except as provided in § 414.1380(c)(3)(iv). As proposed, clinicians could receive up to 10 complex patient bonus points added to their final score. For example, if a MIPS eligible clinician were to receive 4 complex patient bonus points under the existing formulas, the MIPS eligible clinician would receive 8 complex patient bonus points (doubling the bonus points) under our proposal for the CY 2020 performance period/2022 MIPS payment year. In instances where clinicians would have received the maximum of 5 complex patient bonus points, they would receive the maximum of 10 complex patient bonus points under our proposal for the CY 2020 performance period/2022 MIPS payment year. To the extent that the proposed change constitutes a change to the MIPS scoring or payment methodology for the 2022 MIPS payment adjustment after the start of the 2020 performance period, we noted that we believe that, consistent with section 1871(e)(1)(A)(ii) of the Act, it would be contrary to the public interest not to account for increased patient complexity due to the national PHE for COVID–19. We believe it would be contrary to the public interest if MIPS scores do not adequately recognize this increased patient complexity that could not have been accounted for during the CY 2020 rulemaking. More specifically, as discussed in the CY 2021 PFS proposed rule, we are unable to measure the magnitude of the direct and indirect effects of the PHE for COVID–19 on MIPS scores, and we remain concerned about potentially misidentifying poor performance with regard to the care delivered in CY 2020 due to the PHE for COVID–19 (85 FR 50312). Hence, we believe this approach of doubling the complex patient bonus recognizes the difficulty of managing complex patients during the PHE for COVID–19 and lowers the risk of inaccurately identifying a clinician as a ''poor performer'' when the underlying issue is caring for increasingly complex patients due to both direct and indirect effects of COVID–19.

Due to limited data available related to the PHE for COVID–19, we noted that it is difficult to gauge whether the proposal would be artificially increasing MIPS final scores or not providing enough flexibility to clinicians to account for increased patient complexity during the CY 2020 performance period. Given the challenges we assumed clinicians may be facing, we noted that doubling the complex patient bonus would be a reasonable and operationally feasible approach. In developing our proposal, we considered several alternatives, including maintaining the complex patient bonus as it currently is (up to 5 points), as well as whether it would be appropriate to triple (up to 15 points) the complex patient bonus. However, due to the limited data available, we did not propose those options as we were concerned that an approach of tripling

[129] CDC, ''Groups at Higher Risk for Severe Illness'': *https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html*.

[130] Kaiser Family Foundation, ''Low-Income and Communities of Color at Higher Risk of Serious Illness if Infected with Coronavirus'': *https://www.kff.org/coronavirus-covid-19/issue-brief/low-income-and-communities-of-color-at-higher-risk-of-serious-illness-if-infected-with-coronavirus/*.

[131] American Hospital Association, ''Hospitals and Health Systems Face Unprecedented Financial Pressures Due to COVID–19'': *https://www.aha.org/guidesreports/2020–05–05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due*.

[132] CMS, ''Medicare Telemedicine Healthcare Provider Fact Sheet'': *https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet*.

[133] The Journal of the American Medical Association Network, ''Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized with COVID–19 in the New York City Area'': *https://jamanetwork.com/journals/jama/fullarticle/2765184*.

[134] Morbidity and Mortality Weekly Report/CDC COVID–19 Response Team, ''Preliminary Estimates of the Prevalence of Selected Underlying Health Conditions Among Patients with Coronavirus Disease 2019—United States, February 12–March 28, 2020'': *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7119513/pdf/mm6913e2.pdf*.

[135] The Commonwealth Fund, ''Assessing Underlying State Conditions and Ramp-Up Challenges for the COVID–19 Response'': *https://www.commonwealthfund.org/publications/issue-briefs/2020/mar/assessing-underlying-state-conditions-and-ramp-challenges-covid*.

[136] CMS, ''Medicare COVID–19'' Data Release Blog'': *https://www.cms.gov/blog/medicare-covid-19-data-release-blog*.

[137] Kaiser Health News, ''Nearly Half of American Delayed Medical Care Due to Pandemic'': *https://khn.org/news/nearly-half-of-americans-delayed-medical-care-due-to-pandemic/*.

[138] The British Medical Journal, ''Delayed presentation of acute ischemic strokes during the COVID–19 crisis'': *https://jnis.bmj.com/content/early/2020/05/27/neurintsurg-2020-016299*.

[139] US National Library of Medicine National Institutes of Health, ''Hospitalization for Ambulatory-care-sensitive Conditions in Taiwan Following the SARS Outbreak: A Population-based Interrupted Time Series Study'': *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7135451/*.

the bonus could artificially increase final scores and maintaining the current bonus (up to 5 points) may not be sufficient to account for the increased patient complexity during the CY 2020 performance period. Additionally, we noted that we believe that by doubling the complex patient bonus, clinicians whose MIPS performance may be negatively affected by the challenges of caring for a complex patient population during a PHE will be less likely to have the maximum negative adjustment due to circumstance beyond their control.

We also considered whether we should add a new indicator of patient complexity, such as establishing a threshold for the percentage of patients with COVID–19. We expressed concern about this alternative approach for two reasons. First, we did not believe the effects of COVID–19 are limited to those patients who are experiencing the illness. Second, there was uncertainty of the consistency of diagnosis coding for both patients who are experiencing the illness or who are being treated for the sequelae of the illness.

We requested comments on our proposal, the alternatives we considered, and any other approaches to account for patient complexity during the PHE for COVID–19 that commenters believe we should consider, as well as alternative data sources for patient complexity. We invited public comments on our proposal to double the complex patient bonus for the CY 2020 performance period/2022 MIPS payment year. The following is a summary of the comments we received and our responses.

Comment: Many commenters supported our proposal to double the complex patient bonus for the CY 2020 performance period/2022 MIPS payment year. One commenter appreciated CMS' proposal to double the complex patient bonus points but suggested that CMS provide additional flexibility, including further modifying the complex patient bonus policy to create accountability for achieving equity for all Medicare beneficiaries, both within and outside the context of the PHE for COVID–19.

Response: We will continue to assess and expand our understanding of both the direct and indirect impact of the PHE for COVID–19 and will incorporate additional data and findings in future rulemaking. We want to note that in addition to the complex patient bonus proposal, we also announced that clinicians and practices affected by the PHE for COVID–19 could apply for reweighting of the MIPS performance categories due to extreme and uncontrollable circumstances. We refer readers to *https://qpp.cms.gov/about/covid19* for the flexibilities provided during the PHE for COVID–19.

Comment: A few commenters agreed that the complex patient bonus for the CY 2020 performance period should be increased but recommended CMS to consider alternatives. One commenter suggested that CMS consider providing more than 10 complex patient bonus points in areas of the country that are most impacted by COVID–19. For example, the commenter suggested that CMS look at areas that are among the top ranking in positive cases. Another commenter suggested that doubling the complex patient bonus is fair but suggested CMS to consider increasing the complex patient bonus points by more than double. A few commenters encouraged CMS to make this increase permanent and one specifically recommended a permanent increase until more clinically appropriate quality measures are developed. Another commenter suggested that CMS increase the complex patient bonus points for CY 2020 to 15 points and then 10 points for CY 2021 to recognize the ongoing effects of the national PHE.

Response: We thank the commenters for their support and their suggestions to further revise the complex patient bonus policy. With regard to assessing which areas of the country are more impacted by COVID–19, we believe it is difficult to assess the true impact in certain areas. More specifically, it could be possible that the impacted areas may change throughout the year, making it difficult to assess which areas are treating more complex patients. For example, back in spring of 2020, New York faced an initial surge of COVID–19 cases.[140] However, overtime, data is indicating that certain areas in the Midwest region are now seeing an influx of COVID–19 cases as cases in New York are decreasing.[141] Furthermore, we have identified the PHE for COVID–19 as a national event, and therefore, we believe it is appropriate to apply one policy for the national event as opposed to establishing different policies for varying geographic areas. However, we will continue to assess the impact of the PHE and consider whether to further modify the policy in future rulemaking. Additionally, as indicated in the comment summary above, a few commenters suggested that we consider further increasing the complex patient bonus points beyond 10 points. As noted in the CY 2021 PFS proposed rule (85 FR 50312), we considered several alternatives, including maintaining the complex patient bonus as it currently is (up to 5 points), as well as whether it would be appropriate to triple (up to 15 points) the complex patient bonus. However, due to the limited data available, we decided not to propose those options because we were concerned that tripling the bonus could artificially increase final scores and maintaining the current bonus (up to 5 points) may be insufficient to account for the increased patient complexity during the CY 2020 performance period. We acknowledge that the impact of the national PHE for COVID–19 may affect CY 2021 and intend to continue to offer the application-based extreme and uncontrollable circumstances policy for CY 2021, as referenced in section IV.A.3.d.(2)(b)(iv)(B) of this final rule, while we continue to assess the impact and our established related policies. Hence, we continue to believe this one-time adjustment of doubling the complex patient bonus is important and believe that an increase of up to 10 points is appropriate.

Comment: A few commenters stated concerns with doubling the complex patient bonus points for the CY 2020 performance period/CY 2022 MIPS payment year. One commenter stated that offering up to 10 complex patient bonus points could potentially mask poor performance and reward clinicians who did not treat significant numbers of complex COVID–19 patients. The commenter also stated concerns with clinicians potentially upcoding due to this policy change. Another commenter stated concerns with potentially diluting the overall MIPS score for groups and potentially skewing the national average. Another commenter said it would be inappropriate to have complex patient bonus points tied to the number of COVID–19 cases a particular clinician sees.

Response: We thank the commenters for their responses. We acknowledge that doubling the complex patient bonus could potentially mask poor performance or skew the national average, but we are weighing these potential effects against the unforeseen complexity of caring for complex patients during the national PHE for COVID–19. We disagree that doubling the complex patient bonus would dilute the overall score. As discussed above, we considered a complex patient bonus of up to 15 points but believe that a bonus of up to 10 appropriately

[140] John Hopkins University & Medicine, ''Coronavirus Resource Center'' *https://coronavirus.jhu.edu/data/state-timeline/new-confirmed-cases/new-york.*

[141] Modern Healthcare, ''Hospitals feel squeeze as coronavirus spikes in Midwest'': *https://www.modernhealthcare.com/hospitals/hospitals-feel-squeeze-coronavirus-spikes-midwest.*

balances our desire to account for the PHE without artificially increasing scores. Additionally, we rely on dual eligibility status and the HCC risk score, in order to calculate the complex patient bonus for the performance period. We believe this methodology would continue to appropriately account for the increased complexity we are seeing in light of the PHE while balancing the impact of caring for patients with both medical and social risks. We also acknowledge that doubling the complex patient bonus could potentially reward clinicians who did not treat significant number of complex COVID–19 patients. We intend to provide this one-time adjustment of doubling the complex patient bonus because we recognize that there are both direct and indirect effects of the national PHE for COVID–19. For example, clinicians who have not cared for COVID–19 patients are, nevertheless, dealing with the indirect impact of delayed care for complex patients. Alternatively, for clinicians who have cared for COVID–19 patients, we believe this adjustment would account for the medical complexity the clinician directly faces in treating these patients. Hence, we continue to believe that an adjustment of up to 10 points is appropriate to account for both direct and indirect potential impacts on clinicians and care delivery due to the PHE. Finally, we disagree that this policy proposal could encourage upcoding. As we explained in a previous response to comments, when we calculate the complex patient bonus points, we rely on dual eligibility status and the HCC risk score, which should not be impacted by potential coding modifications or disruptions for the CY 2020 performance period. The HCC risk score for CY 2020 is calculated based on data from CY 2019, the year prior to the national PHE for COVID–19.

Finally, the proposed policy would be calculated pursuant to the existing formulas in § 414.1380(c)(3)(i) and (ii), and we do not intend to alter the formula based on the number of COVID–19 cases a clinician sees. As we noted in the CY 2021 PFS proposed rule (85 FR 50313), we considered whether we should add a new indicator of patient complexity, such as establishing a threshold for the percentage of patients with COVID–19, and we continue to be concerned about this alternative approach for two reasons including: (1) The effects of COVID–19 are not limited to those patients who are experiencing the illness; and (2) we are still uncertain of the consistency of diagnosis coding for both patients who are experiencing the illness or who are being treated for the sequelae of the illness.

Comment: One commenter stated concerns with doubling the complex patient bonus points given that the additional resources utilized to treat COVID–19 patients are already being accounted for through Part A and Part B reimbursement, such as lab tests and medically necessary hospitalizations, and should not be additionally funded by the Quality Payment Program.

Response: We disagree that doubling the complex patient bonus points would be redundant of Part A and Part B reimbursement. The purpose of the complex patient bonus is to account for risk factors through appropriate adjustments to MIPS scoring. The policy is not intended to reimburse clinicians for costs associated with treating more complex patients.

After consideration of the public comments, we are finalizing our proposal for the complex patient bonus for the CY 2020 performance period/2022 MIPS payment year as proposed. We are finalizing § 414.1380(c)(3)(iv), under which the complex patient bonus will be calculated pursuant to the existing formulas in paragraphs (c)(3)(i) and (ii), and the resulting numerical value will then be multiplied by 2, but cannot exceed 10.0. The doubled numerical value (subject to the 10-point cap) will be added to the final score. Additionally, we finalize our proposal to revise paragraph (c)(3)(iii) to state that the complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv).

(b) Final Score Performance Category Weights

(i) General Weights

Section 1848(q)(5)(E)(i) of the Act specifies weights for the performance categories included in the MIPS final score: In general, 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category. For more of the statutory background and descriptions of our current policies, we refer readers to the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2020 PFS final rules (81 FR 77320 through 77329, 82 FR 53779 through 53785, 83 FR 59870 through 59878, and 84 FR 62950 through 84 FR 62959, respectively). In section IV.A.3.c.(2)(a) of the CY 2021 PFS proposed rule, we proposed that the cost performance category would make up 20 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. In section IV.A.3.c.(1) of that proposed rule, we proposed the quality performance category would thus make up 40 percent of a MIPS eligible clinician's final score for the 2023 MIPS payment year and 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year. In sections III.K.3.c.(1)(b) and III.K.3.c.(2)(a) of this final rule, we finalized these proposed weights for the quality and cost performance categories for the 2023, 2024, and subsequent MIPS payment years as proposed. Table 50 summarizes the weights for each performance category.

TABLE 50: Weights by MIPS Performance Category for the 2023, 2024, and Future MIPS Payment Years

Performance Category	2023 MIPS Payment Year	2024 and Future MIPS Payment Years
Quality	40%	30%
Cost	20%	30%
Improvement Activities	15%	15%
Promoting Interoperability	25%	25%

(ii) Flexibility for Weighting Performance Categories

Under section 1848(q)(5)(F) of the Act, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of zero) for each performance category based on the extent to which the category is applicable to the type of MIPS eligible clinician involved and for each measure and activity with respect to each performance category based on the extent to which the measure or activity is applicable and available to the type of MIPS eligible clinician involved. Under section 1848(q)(5)(B)(i) of the Act, in the case of a MIPS eligible clinician who fails to report on an applicable measure or activity that is required to be reported by the clinician, the clinician must be treated as achieving the lowest potential score applicable to such measure or activity. In this scenario of failing to report, the MIPS eligible clinician generally would receive a score of zero for the measure or activity, which would contribute to the final score for that MIPS eligible clinician. Under certain circumstances, however, a MIPS eligible clinician who fails to report could be eligible for an assigned scoring weight of zero percent and a redistribution of the performance category weights. For a description of our existing policies for reweighting performance categories, please refer to § 414.1380(c)(2) and the CY 2020 PFS final rule (84 FR 63023 through 63027).

(iii) Redistributing Performance Category Weights

In the CY 2017 through CY 2018 Quality Payment Program final rules, and CY 2019 through CY 2020 PFS final rules (81 FR 77325 through 77329, 82 FR 53783 through 53785, 83 FR 59876 through 59878, and 84 FR 63027 through 63031), and at § 414.1380(c)(2)(ii), we established policies for redistributing the weights of performance categories in the event that a scoring weight different from the generally applicable weight is assigned to a category or categories. Under these policies, we generally redistribute the weight of a performance category or categories to the quality performance category because of the experience MIPS eligible clinicians have had reporting on quality measures under other CMS programs. For the 2020 MIPS performance period and 2022 MIPS payment year, we did not redistribute performance category weights to improvement activities, except for the scenario where the only two performance categories being scored are improvement activities and cost (84 FR 63028). Also for that year in scenarios when the cost performance category weight is redistributed while the Promoting Interoperability performance category weight is not, we redistributed a portion of the cost performance category weight to the Promoting Interoperability performance category, as well as to the quality performance category (84 FR 63027). As stated in CY 2020 PFS final rule, we continue to believe this redistribution policy is appropriate given our focus on working with the Office of the National Coordinator for Health IT (ONC) on implementation of the interoperability provisions of the 21st Century Cures Act (the Cures Act) (Pub. L. 114–255, enacted on December 13, 2016) to ensure seamless but secure exchange of health information for clinicians and patients and emphasize the importance of interoperability without overwhelming the contribution of the quality performance category to the final score (84 FR 63027).

In the CY 2021 PFS proposed rule (85 FR 50293), we proposed a weight for the cost performance category of 20 percent for the 2023 MIPS payment year. For the 2023 MIPS payment year, we proposed similar redistribution policies as finalized for the 2022 MIPS payment year, with minor modifications to account for the cost performance category being 20 percent. As proposed, we would once again only redistribute weight to the cost performance category in cases when the cost and improvement activities performance categories are the only categories scored (each of these performance categories would be 50 percent in this scenario). We noted that we do not believe it is appropriate to redistribute more weight to the cost performance category, because cost would not yet be at the maximum weight specified by the statute (30 percent), and because clinicians still have relatively limited experience being scored on and receiving feedback on cost measures compared with quality measures. Our proposed redistribution policies for the 2023 MIPS payment year, which we proposed to codify at § 414.1380(c)(2)(ii)(E), are included in Table 45 of CY 2021 PFS proposed rule (85 FR 50314).

In the CY 2021 PFS proposed rule (85 FR 50294), we proposed to weight the cost performance category at 30 percent for the 2024 MIPS payment year and each subsequent MIPS payment year, as required by section 1848(q)(5)(E)(i)(II)(aa) of the Act. Given that 2024 would be the first year that cost would be set at the maximum weight prescribed by the statute, we noted that we did not believe it would be prudent to begin redistributing more weight to cost for the 2024 MIPS payment year, except in cases when only the cost and improvement activities performance categories are scored. For the improvement activities performance category, we are only assessing whether a MIPS eligible clinician completed certain activities (83 FR 59876 through 59878). Because MIPS eligible clinicians will have had several years of experience reporting under MIPS, we noted that it is important to prioritize performance on measures that show a variation in performance, rather than the activities under the improvement activities performance category, which are based on attestation of completion. We also noted that we believe this helps to reduce incentives to not report measures for the quality performance category in circumstances when a clinician may be able to report but chooses not to do so. For example, when a clinician may be able to report on quality measures, but chooses not to report because they are located in an area affected by extreme and uncontrollable circumstances as identified by CMS and qualify for reweighting under § 414.1380(c)(2)(i)(A)(8). Therefore, we noted that we continue to believe that weighting the cost and improvement activities performance categories each at 50 percent would be an appropriate balance (84 FR 63027). As for the other reweighting scenarios, we plan to revisit our redistribution policies in future rulemaking and may consider redistributing more weight to the cost performance category after clinicians have more experience with cost being weighted at 30 percent. Our proposed redistribution policies for the 2024 MIPS payment year, which we proposed to codify at § 414.1380(c)(2)(ii)(F), are included in Table 46 of CY 2021 PFS proposed rule (85 FR 50315).

We invited public comments on our proposed redistribution policies for the 2023 and 2024 MIPS payment years. The following is a summary of the comments we received and our responses.

Comment: A few commenters were supportive of CMS' proposal to redistribute the category weights. One commenter specifically agreed with CMS' reweighting proposals in instances when only the quality performance category and the improvement activities performance category are scored. A few commenters specifically supported CMS' proposal to not redistribute weight to the cost

performance category except in cases when only cost and improvement activities performance categories are scored. One commenter stated that the reweighting polices builds confidence in the program and demonstrates transparency.

Response: We thank the commenters for their support. We agree that our reweighting policies allow for flexibility, leading to confidence and transparency within the program. We also appreciate commenters' support in our policy rationale for not redistributing weight to the cost performance category except in cases when only cost and improvement performance categories are scored.

Comment: One commenter requested that CMS should not redistribute weights to the cost performance category until that performance category has more relevant and applicable cost measures available across all specialties.

Response: We agree with the commenter that there is currently a limited set of cost measures within the cost performance category. However, we do have concerns with redistributing a substantial portion of the performance category weights to the improvement activities performance category for several reasons. Specifically, through our redistribution policies, we aim to prioritize interoperability, performance on measures that show a variation in performance, and performance categories that have some or all measures that focus on performance, as compared to the activities under the improvement activities performance category, which are solely based on attestation of completion. We continue to believe that we should not redistribute weight to the improvement activities performance category. We also note that, given that 2024 would be the first year that cost would be set at the maximum weight prescribed by the statute, we continue to believe it would not be prudent to begin redistributing more weight to cost for the 2024 MIPS payment year, except in cases when only the cost and improvement activities performance categories are scored. We should give clinicians more time to adjust to new and revised cost measures before redistributing more weight to the cost performance category. However, similar to all performance categories of MIPS, there are continued opportunities to improve the measures and activities used to assess performance. We also continue to provide detailed performance feedback on the cost measures to clinicians and expect to provide detailed feedback on any new and revised cost measures in the future, providing clinicians a further opportunity to improve their performance within cost measures. Hence, we continue to believe that reweighting the cost and improvement activities performance categories each at 50 percent would appropriately continue to balance our concerns with redistributing weight to the improvement activities performance category.

Comment: One commenter requested that if CMS finalizes the proposal to increase the cost performance category weight, then CMS take the Promoting Interoperability and improvement activities performance category weights and further redistribute them within the cost performance category due to a concern that these two performance categories do not reward the actual results on improvement in quality of care.

Response: As is reflected in our proposals, we do not intend to redistribute a substantial portion of the performance category weight to the improvement activities performance category given that we intend to prioritize performance on measures that show a variation in performance, rather than the activities under the improvement activities performance category, which are based on attestation of completion. However, we believe that both the Promoting Interoperability and improvement activities performance categories reflect important aspects of quality improvement performance. More specifically, over time, we want to redistribute more weight to the cost and Promoting Interoperability performance categories, and less to the quality performance category, to have better alignment between the cost and quality performance categories and due to our focus on interoperability. We also disagree that we should redistribute more weight within the cost performance category than we have proposed, as clinicians are still adjusting to newly developed cost measures. As noted in our previous response, we do not believe that the cost performance category weight should be minimized but should also remain at the proposed 50 percent weight in instances of where only the cost and improvement activities performance categories are scored.

After consideration of the public comments, we are finalizing our proposed redistribution policies for the 2023 and 2024 MIPS payment years as proposed, and the codification of those policies at § 414.1380(c)(2)(ii)(E) and (F). Our finalized redistribution policies for both the 2023 and 2024 MIPS payment years are included in Table 51 and 52.

TABLE 51: Performance Category Redistribution Policies Finalized for the 2023 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	40%	20%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	65%	20%	15%	0%
-No Quality	0%	20%	15%	65%
-No Improvement Activities	55%	20%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	80%	20%	0%	0%
-No Quality and no Improvement Activities	0%	20%	0%	80%

TABLE 52: Performance Category Redistribution Policies Finalized for the 2024 MIPS Payment Year

Reweighting Scenario	Quality	Cost	Improvement Activities	Promoting Interoperability
No Reweighting Needed				
- Scores for all four performance categories	30%	30%	15%	25%
Reweight One Performance Category				
-No Cost	55%	0%	15%	30%
-No Promoting Interoperability	55%	30%	15%	0%
-No Quality	0%	30%	15%	55%
-No Improvement Activities	45%	30%	0%	25%
Reweight Two Performance Categories				
-No Cost and no Promoting Interoperability	85%	0%	15%	0%
-No Cost and no Quality	0%	0%	15%	85%
-No Cost and no Improvement Activities	70%	0%	0%	30%
-No Promoting Interoperability and no Quality	0%	50%	50%	0%
-No Promoting Interoperability and no Improvement Activities	70%	30%	0%	0%
-No Quality and no Improvement Activities	0%	30%	0%	70%

(iv) MIPS Applications for Reweighting for the 2021 and 2023 MIPS Payment Years Based on Extreme and Uncontrollable Circumstances

(A) MIPS Applications for Reweighting for the 2021 MIPS Payment Year Based on Extreme and Uncontrollable Circumstances

Recognizing the urgency of the PHE for COVID–19, we published the March 31st COVID–19 IFC modifying Medicare rules, including the PFS, so that physicians and other practitioners and clinicians are allowed added flexibilities due to the PHE for COVID–19. To provide relief to individual clinicians, groups, and virtual groups for whom sufficient MIPS measures and activities may not be available for the 2019 MIPS performance period due to the PHE for the COVID–19, we extended the deadline to submit an application for reweighting the quality, cost, and improvement activities performance categories (§ 414.1380(c)(2)(i)(A)(*6*)), as well as the Promoting Interoperability performance category (§ 414.1380(c)(2)(i)(C)(*2*)) based on extreme and uncontrollable circumstances from December 31, 2019 to April 30, 2020, or a later date that we may specify (85 FR 19278). The extended deadline is available only for applications that demonstrate the clinician has been adversely affected by the PHE for the COVID–19. We also modified the policy at § 414.1380(c)(2)(i)(A)(*6*) to create an exception for the 2019 performance period/2021 MIPS payment year only, such that if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the PHE for the COVID–19, but also submits data for the quality, cost, or improvement activities performance categories, the performance categories for which data are submitted would still be reweighted (subject to CMS' approval of the application), and the data submission would not effectively void the application for reweighting (85 FR 19278). We also modified the policy at

§ 414.1380(c)(2)(i)(C) to create a similar exception for the Promoting Interoperability performance category for the 2019 performance period/2021 MIPS payment year only (85 FR 19278).

We invited public comments on these interim final policies. The following is a summary of the comments we received and our responses.

Comment: Several commenters expressed support for CMS' efforts to reduce administrative burden for physicians through increased availability of the extreme and uncontrollable circumstances policies. Commenters expressed their belief that these changes are necessary because it may be difficult for clinicians to meet data submission requirements for the Quality Payment Program due to circumstances beyond their control.

Response: We thank commenters for their support of our policies.

Comment: A few commenters requested that we modify our extreme and uncontrollable circumstances policies so that if clinicians do not submit an application for extreme and uncontrollable circumstances and submit data and achieve a score above the performance threshold, we use that score for payment purposes. However, in cases where clinicians achieve a score below the performance threshold, we will not use that score for payment purposes.

Response: We do not believe the approach requested by the commenters would be consistent with the statute. We do not believe the statute gives us discretion to disregard scores below the performance threshold and only apply the MIPS payment adjustments based on scores above the performance threshold.

Comment: One commenter stated that we should not require clinicians to demonstrate that they are impacted by the PHE for COVID–19 in order to receive reweighting under our extreme and uncontrollable circumstances policies.

Response: We note that we assume most clinicians are impacted by the PHE for COVID–19. However, we recognize that not all clinicians and practices have been impacted to the same extent, and therefore, may not all need reweighting. We requested that clinicians select COVID–19 as the reason for requesting reweighting and provide a brief narrative describing how they have been impacted. More information is available at *https://qpp.cms.gov/about/covid19?py=2020*.

Comment: One commenter expressed the belief that we should provide reweighting automatically under our extreme and uncontrollable circumstances policies unless clinicians opt in for participation in the Quality Payment Program.

Response: We believe that requiring clinicians to opt in to be scored within the Quality Payment Program would place undue burden on clinicians who submitted information intending to participate in the program.

After consideration of the public comments, we are adopting these interim final policies as final without any modifications. We are finalizing the regulation text at § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C).

(B) MIPS Applications for Reweighting for the 2023 MIPS Payment Year Based on Extreme and Uncontrollable Circumstances

We anticipate that the national PHE for COVID–19 will continue into and through CY2021. Therefore, we remind clinicians that the application-based extreme and uncontrollable circumstances policy, as described in § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(*2*), will be available for the 2021 performance period/2023 MIPS payment year (please refer to *https://qpp.cms.gov/about/covid19?py=2020* for details). The application allows clinicians, groups, and virtual groups significantly impacted by the PHE for COVID–19 to request reweighting for any or all MIPS performance categories. Under this policy, however, if a clinician, group, or virtual group decides to submit data for the 2021 performance period, the data submission will override the application, and the clinician, group, or virtual group will be scored on the data submitted. We believe this approach maintains a balance of encouraging participation in the Quality Payment Program while still providing for flexibility in weighting the performance categories for those who have been affected by the COVID–19 pandemic. Please refer to *https://qpp.cms.gov/about/covid19?py=2021* for more information.

e. MIPS Payment Adjustments

(1) Background

For our previously established policies regarding the final score hierarchy used to determine MIPS payment adjustments, we refer readers to the CY 2020 PFS final rule (84 FR 63031 through 63045), CY 2019 PFS final rule (83 FR 59878 through 59894), CY 2018 Quality Payment Program final rule (82 FR 53785 through 53799) and CY 2017 Quality Payment Program final rule (81 FR 77329 through 77343). In the CY 2021 PFS proposed rule (85 FR 50315 through 50321), we proposed to modify these policies: (1) To reflect the discontinuation of the APM scoring standard and the addition of the APM Performance Pathway (APP), both as proposed in the CY 2021 PFS proposed rule (85 FR 50303); (2) to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized; and (3) to potentially revisit and revise the prior estimate of the performance threshold for the 2024 MIPS payment year.

(2) Final Score Hierarchy Used in Payment Adjustment Calculation

In some cases, a TIN/NPI could have more than one final score associated with it from a performance period, if the MIPS eligible clinician submitted multiple data sets. In the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we established the following final score hierarchy that applies as displayed in Table 53 when more than one final score is associated with a TIN/NPI.

TABLE 53: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Example	Final Score Used to Determine Payment Adjustments
TIN/NPI has more than one APM Entity final score.	The highest of the APM Entity final scores.
TIN/NPI has an APM Entity final score and also has an individual score.	APM Entity final score.
TIN/NPI has an APM Entity final score that is not a virtual group score and also has a group final score.	APM Entity final score.
TIN/NPI has an APM Entity final score and also has a virtual group score.	APM Entity final score.
TIN/NPI has a virtual group score and an individual final score.	Virtual group score.
TIN/NPI has a group final score and an individual final score, but no APM Entity final score and is not in a virtual group.	The highest of the group or individual final score.

With the proposed discontinuation of the APM scoring standard and addition of the APP in section IV.A.2.b.(5) of the CY 2021 PFS proposed rule, we proposed to modify the existing final score hierarchy beginning with the 2021 performance period/2023 MIPS payment year. In the CY 2018 Quality Payment Program final rule (82 FR 53785 through 53787), we finalized prioritizing the APM Entity final score over any other score for a TIN/NPI by using the waiver authority for Innovation Center models under section 1115A(d)(1) of the Act and the Shared Savings Program waiver authority under section 1899(f) of the Act to waive section 1848(q)(5)(I)(i)(I) and (II) of the Act so that we could use the APM Entity final score instead of the virtual group final score for a TIN/NPI. This hierarchy was intended to incentivize APM participation; however, we proposed to terminate the APM scoring standard in section IV.A.2.b.(5) of the CY 2021 PFS proposed rule, and while we believe it is important to still encourage movement to APMs, we stated that we do not believe that prioritizing an APM Entity score over other reported MIPS data would necessarily further our goal of increasing APM participation. The proposed modifications to the final score hierarchy would include MIPS eligible clinicians who are reporting through the APP, which is designed to provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation. MIPS eligible clinicians who are already participating in APMs, and therefore, have different reporting obligations than MIPS eligible clinicians, who have not already taken that step, can opt to report through the APP and receive an APP final score that may be used in the MIPS payment adjustment calculation. Beginning with the 2021 performance period/2023 MIPS payment year, if a TIN/NPI has a virtual group final score associated with it, we proposed to use the virtual group final score to determine the MIPS payment adjustment. If a TIN/NPI does not have a virtual group final score associated with it, we proposed to use the highest available final score associated with the TIN/NPI to determine the MIPS payment adjustment. We stated that the proposal was consistent with section 1848(q)(5)(I)(i) of the Act, which requires us to prioritize a virtual group final score over other final scores such as individual and group scores (82 FR 53786). We stated that we believe that using the highest final score available regardless of how the clinician chose to submit data to MIPS would benefit all MIPS eligible clinicians. For example, we have noticed some instances where prioritizing the APM Entity final score over other final scores has resulted in some clinicians not receiving the highest final score associated with their TIN/NPI, which may have the unintended consequence of moving clinicians away from APM participation. As we seek to move more clinicians into APMs, we believe using their highest score regardless of participation method would benefit all MIPS eligible clinicians. With the establishment of MVPs, we intend to revisit policies regarding the final score hierarchy used for payment adjustment determinations in future rulemaking.

Table 54 illustrates the proposed modified final score hierarchy.

TABLE 54: Hierarchy for Final Score When More than One Final Score Is Associated with a TIN/NPI

Scenario	Final Score Used to Determine Payment Adjustments
TIN/NPI has a virtual group final score, an APM Entity final score, an APP final score, a group final score, and/or an individual final score.	Virtual group final score.
TIN/NPI has an APM Entity final score, an APP final score, a group final score, and/or an individual final score, but is not in a virtual group.	The highest of the available final scores.

The following is a summary of the comments we received on the proposal regarding the final score hierarchy used in payment adjustment calculation.

Comment: A few commenters did not support CMS's proposal to modify the scoring hierarchy because of their belief that it may de-emphasize the role of ACOs and may create additional complexity and confusion, urging CMS to minimize the year-to-year changes to scoring policies. One commenter believed that the previous scoring hierarchy, where ACO entities scores took precedent over all other scores, worked well for ACOs and also urged CMS to not make year-to-year changes.

Response: We disagree that the modified scoring hierarchy would de-emphasize the role of ACOs, as we believe it is still important to encourage movement to APMs as we have demonstrated through our policies for the APP and MVPs. As described further in section II.E.1. of this final rule, ACOs participating in the Medicare Shared Savings Program would be required to report through the APP for purposes of determining shared savings under that program; but MIPS eligible clinicians participating in these ACOs also would have the option of reporting outside the APP for purposes of being scored under MIPS, like all other MIPS APM participants, if they should choose to do so. As the APP is optional for purposes of MIPS scoring, MIPS APM participants may report through the APP or through any other available MIPS reporting mechanism they choose. We do not intend to create additional confusion or complexity with our annual policy modifications, but rather provide a predictable and consistent MIPS reporting standard to reduce reporting burden and encourage continued APM participation.

Comment: A few commenters supported CMS's proposal to modify the final score hierarchy because of their belief that the final score hierarchy allows for flexibility that rewards high performing clinicians, encourages clinicians to continue to participate in the program, simplifies the MIPS final score determination, and benefits all MIPS eligible clinicians. One commenter stated that the modified final score hierarchy may also prevent MIPS APM participants from getting a lower payment adjustment that is based on their APM Entity final score.

Response: We agree that the modified final score hierarchy incentivizes MIPS program participation, simplifies final score determinations and provides beneficial flexibilities for all MIPS eligible clinicians. Although it is not our intent to shield clinicians from payment consequences through our policy changes, it is our intent to encourage continued participation in MIPS, to include APM participants, as well as to provide pathways for participating clinicians to be successful in the program.

Comment: Commenters supported the proposal to modify the existing final score hierarchy and understand that there is a statutory requirement to prioritize the virtual group score, if applicable. The commenters appreciate, that otherwise, CMS would allow use of the best score attributable through individual, group, or APM entity scoring.

Response: We agree that using the highest final score available, regardless of how a MIPS eligible clinician submits data to CMS, would benefit all MIPS eligible clinicians.

After consideration of the public comments received, we are finalizing our proposal, as proposed, to modify the existing final score hierarchy beginning with the 2021 performance period/2023 MIPS payment year.

(3) Establishing the Performance Threshold

Under section 1848(q)(6)(D)(i) of the Act, for each year of MIPS, the Secretary shall compute a performance threshold with respect to which the final scores of MIPS eligible clinicians are compared for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act for a year. The performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary.

Section 1848(q)(6)(D)(iii) of the Act included a special rule for the initial 2 years of MIPS, which requires the Secretary, prior to the performance period for such years, to establish a performance threshold for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act and an additional performance threshold for purposes of determining the additional MIPS payment adjustment factors under section 1848(q)(6)(C) of the Act, each of which shall be based on a period prior to the performance period and take into account data available for performance on measures and activities that may be used under the performance categories and other factors determined appropriate by the Secretary. Section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) amended section 1848(q)(6)(D)(iii) of the Act to extend the special rule to apply for the initial 5 years of MIPS instead of only the initial 2 years of MIPS.

In addition, section 51003(a)(1)(D) of the Bipartisan Budget Act of 2018 added a new clause (iv) to section 1848(q)(6)(D) of the Act, which includes an additional special rule for the third, fourth, and fifth years of MIPS (the 2021 through 2023 MIPS payment years). This additional special rule provides, for purposes of determining the MIPS payment adjustment factors under section 1848(q)(6)(A) of the Act, in addition to the requirements specified in section 1848(q)(6)(D)(iii) of the Act, the Secretary shall increase the performance threshold for each of the third, fourth, and fifth years to ensure a gradual and incremental transition to the performance threshold described in section 1848(q)(6)(D)(i) of the Act (as estimated by the Secretary) with respect to the sixth year (the 2024 MIPS payment year) to which the MIPS applies.

In the CY 2020 PFS final rule (84 FR 63031 through 63037) at § 414.1405(b)(7) and (8), we finalized the performance thresholds for the 2022 and 2023 MIPS payment years at 45 and 60 points, respectively, an increase of 15 points each year until the 2024 MIPS payment year, where we estimated the performance threshold would be 74.01 points (based on actual year 1 performance data and estimates for the third and fourth years) as depicted in Table 55. However, we also stated that we may revisit the performance threshold for the 2023 MIPS payment year in future rulemaking, if we receive additional data that changes our estimate of the performance threshold for the 2024 MIPS payment year.

TABLE 55: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	2022 MIPS Payment Year	2023 MIPS Payment Year	*Estimated 2024 MIPS Payment Year
	Year 1	Year 2	Year 3	Year 4	Year 5	*Year 6
Performance Threshold	3 points	15 points	30 points	45 points	60 points	*74.01 points
Difference in PT (year n minus (year n-1))	N/A	12 points	15 points	15 points	15 points	*14.01 points

* Prior estimate for the 2024 MIPS payment year (84 FR 63031-63037). This is the estimated performance threshold for year 6 based on modeling projections and is not the finalized performance threshold for year 6.

In the CY 2021 PFS proposed rule (85 FR 50317), we stated that we believe that we should reexamine the performance threshold for year 5 (2021 performance period/2023 MIPS payment year) due to the disruptions caused by the PHE for COVID–19. We anticipated some clinicians not having sufficient measures and activities available to participate for the fourth year (2020 performance period/2022 MIPS payment year) and opting to use flexibilities provided for MIPS participation through the extreme and uncontrollable circumstances and hardship exception policies. Furthermore, in considering the effect of the PHE for COVID–19 on clinicians, we stated that we believe that this is enough of a disruption to revisit the performance threshold for year 5, especially for clinicians who are unable to participate in year 4 due to the PHE for COVID–19.

We stated that clinicians who are unable to participate in the fourth year of MIPS due to the PHE for COVID–19, would face an abrupt and large increase in the performance threshold if they return to full participation in the fifth year, lacking the opportunity to work to improve performance. We considered a range of performance threshold values for the fifth year, from 50 to 60 points, and believe that a performance threshold above 50 could be challenging for clinicians affected by the PHE for COVID–19, especially those with small practices. We stated that preliminary analysis has shown that when applying a performance threshold of 50 points to the data we received from the 2021 regulatory impact analysis as summarized in the CY 2021 PFS proposed rule (85 FR 50383), around 31,376 TIN/NPIs (or 5.6 percent of MIPS eligible clinicians) would have payments adjustments that go from negative to positive with a performance threshold of 50 points compared to 60 points. For example, the analysis showed with the previously finalized performance threshold of 60 points, 24.4 percent of engaged small practices would receive a negative payment adjustment, whereas with a performance threshold of 50 points, 18.8 percent of engaged small practices would receive a negative payment adjustment. In analyzing the range of performance threshold values and the impact on high performers as detailed in the CY 2021 PFS proposed rule (85 FR 50383), we saw that in setting the performance threshold at 50 points, the maximum payment adjustment is 6.89 percent whereas when setting the performance threshold at 60 points, the maximum payment adjustment is 7.36 percent, a decrease in percentage by 0.47. To continue to incentivize high performers, we did not revisit the additional performance threshold in the proposed rule, which is set at 85 points for year 5. We proposed to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized at § 414.1405(b)(8). The performance threshold would remain at 30 points in the third year, increase to 45 points in the fourth year, and increase to 50 points in the fifth year. The increase between the third and fifth year would total 20 points. Additionally, and as discussed in more detail below in our discussion of revising the prior estimate of the performance threshold for the 2024 MIPS payment year, we stated that we are open to considering alternatives for the performance threshold for the 2023 MIPS payment year. We solicited comments on the proposed performance threshold of 50 points, the range of values we considered, and any alternatives that commenters believe we should consider for the performance threshold for the 2023 MIPS payment year.

Table 56 depicts the performance threshold for the 2019 MIPS payment year through 2024 MIPS payment year, including the potential change to the performance threshold for the fifth year.

TABLE 56: Performance Thresholds for the 2019 MIPS Payment Year through 2024 MIPS Payment Year

	2019 MIPS Payment Year	2020 MIPS Payment Year	2021 MIPS Payment Year	*2022 MIPS Payment Year	**2023 MIPS Payment Year	2024 MIPS Payment Year
	Year 1	Year 2	Year 3	*Year 4	**Year 5	Year 6
Performance Threshold	3 points	15 points	30 points	*45 points *N/A for those who do not participate in year 4	**50 points	74.01 points
Difference in PT (year n minus (year n-1))	N/A	12 points	15 points	*15 points *N/A for those who do not participate in year 4	**5 points for those who participate in year 4 **20 points for those who do not participate in year 4	24.01 points

*Assumed affected payment year due to PHE for COVID-19 resulting in measures not being available for reporting for MIPS participants.

** Proposed new performance threshold for the fifth year.

At the time of publication of the CY 2021 PFS proposed rule, we did not have actual performance scores and other data for year 3 (2019 performance period/2021 MIPS payment year). Since the publication of the CY 2021 PFS proposed rule, we now have the CY 2019 performance year data, where the mean final score is 79.8 and the median final score is 85.27. We note these values are estimates and that the mean and median may change as we finish the targeted review process for the 2021 MIPS payment year. We stated that in the event this information becomes available with sufficient time to inform our policy decisions for the final rule, we proposed to revisit and potentially revise in the final rule our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year. We stated that we anticipated that the actual performance scores for the 2019 performance period/2021 MIPS payment year may be different than the estimates that we published in our regulatory impact analysis estimate (84 FR 63033) because the PHE for COVID–19 occurred during the data submission period. We also expected that the 2019 performance period data may be unusual due to the PHE for COVID–19 occurring during the submission period. We requested comments on our proposal to revisit and potentially revise our prior estimate of the performance threshold for year 6. In particular, we sought comment on what indicators (for example, if the distribution of scores is skewed due to the PHE for COVID–19), if any, should be used to evaluate whether or not the 2019 performance period data are appropriate to use to revise our prior estimate.

Lastly, in the event that we decide to revise our prior estimate of the performance threshold for the 2024 MIPS payment year (either higher or lower) in the final rule, we proposed to consider the revised estimate when we decide on an appropriate numerical value for the performance threshold for the 2023 MIPS payment year. We gave the example that, if we believe that the estimate for the 2024 MIPS payment year performance threshold should be higher than 74.01 (say 80 or 85 points), then we anticipate the performance threshold for the 2023 MIPS payment year would be higher than 50 (likely 55 points, 60 points) to reflect the change in the estimate. We seek to ensure a gradual and incremental transition to the estimated performance threshold for the 2024 MIPS payment year, and thus, we stated that we believe that we should take into account the revised estimate when determining the performance threshold for the 2023 MIPS payment year. We solicited comments on the proposal to consider the revised estimate for the 2024 MIPS payment year when we select a performance threshold for the 2023 MIPS payment year.

The following is a summary of the comments we received on the proposal to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized.

Comment: One commenter did not support lowering the performance threshold to 50 points from the previously finalized performance threshold of 60 points for the CY 2023 MIPS payment year, and asked CMS to maintain the performance threshold at 60 points. They referenced the statutory requirement to set the performance threshold to the mean or median of the final scores for a prior period by the CY 2024 MIPS payment year, sharing their concern that lowering the performance threshold for the CY 2023 MIPS payment year may result in a drastic increase when the performance threshold is established for the CY 2024 MIPS payment year. They indicated that this may put undue stress on clinicians who participate in MIPS. A few commenters did not support the change in the performance threshold because MIPS is budget neutral, and thus, decreasing the performance threshold provides little incentive to participate in the program, especially for practices which have made efforts to implement technology, workflows, and improve patient care. One commenter also believed that because of the increase in the complex patient bonus, practices will already be provided relief from the PHE for COVID–19.

Response: We acknowledge the commenter's concern. We agree and believe that maintaining the previously finalized performance threshold of 60 points for the CY 2023 payment year could help to ensure a more consistent increase in the performance threshold from year to year and avoid a potentially

drastic increase between the 2023 and 2024 MIPS payment years. Although we acknowledge that a performance threshold above 50 points could be challenging for clinicians affected by the PHE for COVID–19, we believe it still necessary to incentivize clinicians who are able to participate in MIPS and perform highly despite the PHE. We agree that because the statute includes a budget neutrality requirement for MIPS, decreasing the performance threshold could discourage high performance by decreasing the magnitude of the positive payment adjustments. We want to ensure that there are appropriate incentives for clinicians to continue their participation in MIPS for the 2021 performance period despite the PHE for COVID–19, hence our proposed increase in the complex patient bonus for the 2020 performance period. While we remain concerned with the impact of the PHE for COVID–19 on clinicians, we also want to continue to motivate clinicians to participate in MIPS and strive for high performance on the measures and activities.

Comment: A few commenters supported setting the performance threshold at 50 points for the CY 2021 MIPS performance period/2023 MIPS payment year instead of 60 points as was previously finalized. They believe reducing the performance threshold by 10 points is an appropriate reduction, allows for a small but gradual increase in the performance threshold from year-to-year, and addresses the difficult circumstances practices are facing during the PHE for COVID–19. One commenter also expressed that given uncertainties with the quality benchmarks, they believed a 10-point reduction would be prudent. A few commenters believed that the 10-point reduction in the performance threshold may help small practices in particular, viewing this policy change as consistent with the statute, as well as helping to maintain programmatic stability within MIPS.

Response: We thank the commenters for their recommendations and acknowledge concerns regarding potential challenges for clinicians associated with the PHE for COVID–19. While there are continued uncertainties regarding the impact of the PHE on MIPS eligible clinicians' ability to report for 2020 and 2021 performance period, we cannot ignore that the vast majority of clinicians have been able to successfully report for the 2019 performance period despite the PHE. Data analysis for the 2019 performance period showed fewer requests for reqeighting the MIPS performance categories based on extreme and uncontrollable circumstances than previously expected; however, clinicians impacted by the PHE for COVID–19 may submit an application for reweighting for the 2021 performance period, as discussed in section IV.A.3.d.(2)(b)(iv)(B) of this final rule. We want to ensure that there are appropriate incentives for clinicians, including those with small practices, to continue their participation in MIPS for the 2021 performance period even if the PHE for COVID–19 continues. It is also our intent to prepare clinicians for participation in the MIPS program beyond the PHE for COVID–19 and believe maintaining the performance threshold at 60 points for the 2023 MIPS payment year would align with increasing standards for performance necessary for successfully participating in MIPS in future years.

Comment: One commenter did not support lowering the performance threshold to 50 points from the previously finalized performance threshold of 60 points for the CY 2023 MIPS payment year because of their concerns around performance category weights and reweighting policies. They stated the performance threshold for the CY 2023 MIPS payment year should be lowered to 45 points because they believe it would be hard for some clinicians to meet the performance threshold if the cost and Promoting Interoperability performance categories are reweighted to zero percent due to clinician type, as well as a lack of applicable measures.

Response: We acknowledge the commenters concerns and recommendation to set the performance threshold at 45 points for the CY 2023 MIPS payment year. However, we believe that setting the performance threshold at 45 points for the CY 2023 MIPS payment year would create a larger and more abrupt increase in the performance threshold for clinicians who are unable to participate for the 2021 performance period due to the PHE for COVID–19 but choose to participate for the 2022 performance period. Those clinicians would be subject to a minimum of a 29.01 point increase in the performance threshold for the 2022 performance period/2024 MIPS payment year, based on our estimated performance threshold for the 2024 MIPS payment year. Under the policy we are adopting in section XXX of this final rule, if the cost and Promoting Interoperability performance categories are reweighted to zero percent, the quality and improvement activities performance categories will be reweighted to 85% and 15%, respectively. This could provide a scenario that creates greater ease of reaching the performance threshold for clinicians participating in MIPS.

Comment: Several commenters did not support lowering the performance threshold to 50 points from the previously finalized performance threshold of 60 points for the CY 2023 MIPS payment year because they believed the performance threshold should be further reduced due to the PHE for COVID–19, limiting regulatory burden for clinicians during that time. Several commenters suggested lowering the performance threshold to 45 points, the same threshold as the CY 2022 MIPS payment year, while one commenter suggested lowering the performance threshold to 30 points, which is the same as the 2021 MIPS payment year. One commenter expressed their belief that further decreasing the performance threshold to 45 points may especially help small and rural practices. Some commenters stated that clinicians who received reweighting of the MIPS performance categories based on extreme and uncontrollable circumstances for the CY 2019 and CY 2020 MIPS performance periods would experience a significant increase in the performance threshold. Another commenter stated that since the final rule may not be published until December 1, 2020, CMS should set the performance threshold to 45 points for the CY 2022 MIPS payment year to provide clinicians with more time to familiarize themselves with the policy changes and decrease the risk of receiving a negative adjustment.

Response: We thank the commenters for their recommendations and acknowledge concerns regarding potential challenges for clinicians due to the PHE for COVID–19. Although small and rural practices may benefit from a lower performance threshold, we believe that it is important to ensure that there are appropriate incentives for clinicians, including small and rural practices, to continue their participation in MIPS for the 2021 performance period and future years, even if the PHE for COVID–19 continues. As discussed in section IV.A.3.d.(2)(b)(iv)(B) of this final rule, the extreme and uncontrollable circumstances application is an available flexibility for clinicians impacted by the PHE for COVID–19. Clinicians who receive reweighting based on extreme and uncontrollable circumstances for the CY 2019, CY 2020, and CY 2021 MIPS performance periods would experience a larger jump in the performance threshold for the CY 2022 MIPS performance period than those who

participated in MIPS for the CY 2019, CY 2020, and CY 2021 MIPS performance periods. However, we believe that maintaining the previously finalized performance threshold of 60 points for the CY 2023 MIPS payment year lends consistency to the program, which may be especially important during this challenging time.

The following is a summary of the comments we received on the proposal to revisit and potentially revise in the final rule our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year.

Comment: One commenter expressed their appreciation and belief that CMS has worked to create a smooth transition in increasing the performance threshold in accordance with the statute for the CY 2024 MIPS payment year.

Response: We appreciate the support and acknowledgement of our efforts to provide an ease of transition to the performance threshold for the CY 2024 MIPS payment year.

Comment: One commenter urged CMS to work with Congress on developing a legislative fix to change the statutory requirements for the CY 2024 MIPS payment year performance threshold, believing that because of the PHE for COVID–19, a change may be needed to ease the transition of increasing the performance threshold over time.

Response: We acknowledge the commenter's concern and recommendation. Given that we do not know the magnitude of impact that the PHE for COVID–19 will have on clinician participation in MIPS for the CY 2023 payment year, we believe it would be premature to seek a legislative change at this time. However, we intend to consider these concerns and potentially address them in the future.

Comment: A few commenters expressed their concern with the estimated performance threshold of 74.01 points for the CY 2024 MIPS payment year. One commenter recommended that the performance threshold increase no more than 10 percent year-over-year beginning with the CY 2024 payment year, while another commenter recommended setting the year 6 performance threshold at 75 points, since it is a round number. Commenters stated that the PHE for COVID–19 will continue into the CY 2021 performance period and may cause unforeseen consequences. They urged CMS to use any flexibilities available in setting the performance threshold for the CY 2024 MIPS payment year.

Response: We understand the commenters concern. We understand that both direct and indirect impacts of the PHE for COVID–19 will likely continue into CY 2021. We stated in the CY 2021 PFS proposed rule (85 FR 50318) that in the event that the CY 2019 MIPS performance year data becomes available, with sufficient time to inform our policy decisions for the final rule, we proposed to revisit and potentially revise our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year. However, after analyzing the data for the CY 2019 performance period, we have decided not to revise our prior estimate of the performance threshold for the 2024 MIPS payment year. The statute requires that, beginning with the 2024 MIPS payment year, the performance threshold for a year must be either the mean or median (as selected by the Secretary, and which may be reassessed every 3 years) of the final scores for all MIPS eligible clinicians for a prior period specified by the Secretary. The data for the CY 2019 MIPS performance period estimates the mean final score as 79.8 and the median final score as 85.27, which are significantly higher than our prior estimate of 74.01 points for the 2024 MIPS payment year performance threshold. We plan to continue utilizing performance data, as it becomes available, to inform policy decisions in future rulemaking.

After consideration of the public comments received, we are not finalizing our proposal to set the performance threshold at 50 points for the 2023 MIPS payment year, instead of 60 points as previously finalized at § 414.1405(b)(8). We are maintaining the performance threshold at 60 points, as previously finalized, at § 414.1405(b)(8). We are also not finalizing our proposal to revisit and potentially revise our prior estimate of 74.01 points for the performance threshold for the 2024 MIPS payment year.

(4) Example of Adjustment Factors

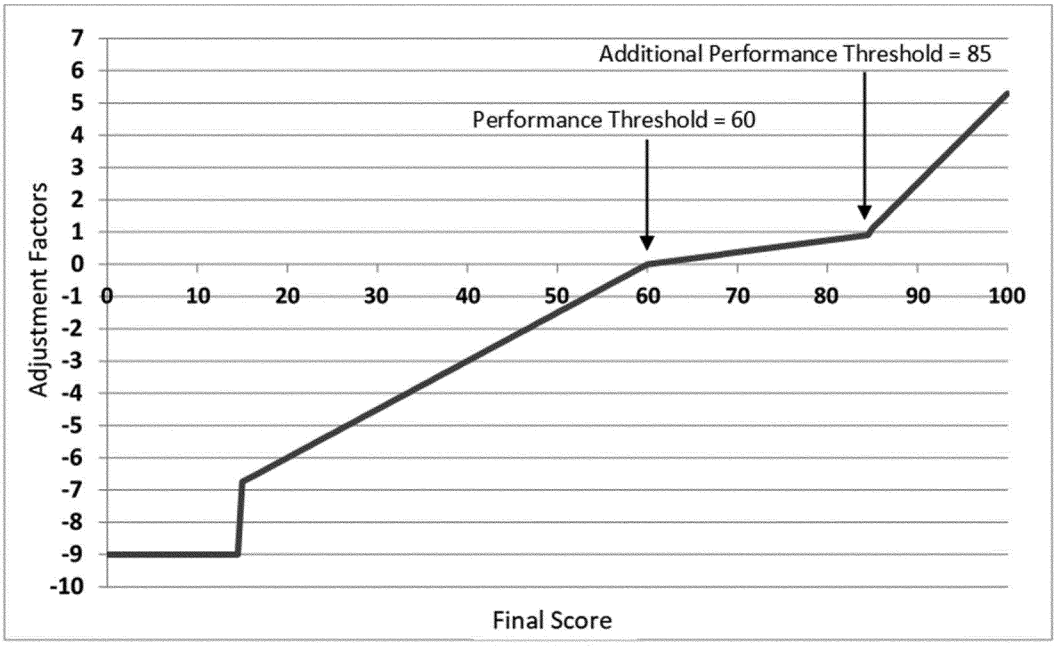
Figure A provides an illustrative example of how various final scores would be converted to a MIPS payment adjustment factor and potentially an additional MIPS payment adjustment factor, using the statutory formula and based on our policies for the 2023 MIPS payment year. In Figure A, the performance threshold is set at 60 points. The applicable percentage is 9 percent for the 2023 MIPS payment year. The MIPS payment adjustment factor is determined on a linear sliding scale from zero to 100, with zero being the lowest possible score which receives the negative applicable percentage (negative 9 percent for the 2023 MIPS payment year) and resulting in the lowest payment adjustment, and 100 being the highest possible score which receives the highest positive applicable percentage and resulting in the highest payment adjustment. However, there are two modifications to this linear sliding scale. First there is an exception for a final score between zero and one-fourth of the performance threshold (zero and 15 points based on the finalized performance threshold of 60 points for the 2023 MIPS payment year). All MIPS eligible clinicians with a final score in this range would receive the lowest negative applicable percentage (negative 9 percent for the 2023 MIPS payment year). Second, the linear sliding scale line for the positive MIPS payment adjustment factor is adjusted by the scaling factor, which cannot be higher than 3.0.

If the scaling factor is greater than zero and less than or equal to 1.0, then the MIPS payment adjustment factor for a final score of 100 would be less than or equal to 9 percent. If the scaling factor is above 1.0 but is less than or equal to 3.0, then the MIPS payment adjustment factor for a final score of 100 would be greater than 9 percent.

Only those MIPS eligible clinicians with a final score equal to 60 points (which is the finalized performance threshold) would receive a neutral MIPS payment adjustment. Because the performance threshold is 60 points, we anticipate that more clinicians will receive a positive adjustment than a negative adjustment and that the scaling factor would be less than 1 and the MIPS payment adjustment factor for each MIPS eligible clinician with a final score of 100 points would be less than 9 percent.

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Figure A: Illustrative Example of MIPS Payment Adjustment Factors Based on Final Scores and Performance Threshold and Additional Performance Threshold for the 2023 MIPS Payment Year



Note: The adjustment factor for final score values above the performance threshold is illustartive. For MIPS eligible clinicians with a final score of 100, the adjustment factor would be 9 percent times a scaling factor greater than zero and less than or equal to 3.0. The scaling factor is inteded to ensure budget neutrality, but cannot be higher than 3.0. MIPS eligible clinicians with a final score of at least 85 points would also receive an additional adjustment factor for expectional performance. The additional adjustment factor starts at 0.5 percent, cannot exceed 10 percent, and is also mulitiplied by a scaling factor that is greather than zero and less than or equal to 1. MIPS eligible clinicians at or above the additional performance threshold will receive the amount of the adjustment factor plus the additional adjustment factor. This example is illustartive as the actual payment adjustments may vary based on the distribution of final scores for MIPS eligible clinicians.

Table 57 illustrates the changes in payment adjustment based on the final policies from the CY 2020 PFS final rule (84 FR 63031 through 63045) for the 2022 and 2023 MIPS payment year, as well as the applicable percent reqired by section 1848(q)(6)(B) of the Act.

TABLE 57: Illustration of Point System and Associated Adjustments Comparison between the Finalized 2022 MIPS Payment Year and the Finalized 2023 MIPS Payment Year

2022 MIPS Payment Year		Previously Finalized 2023 MIPS Payment Year	
Final Score Points	**MIPS Adjustment**	**Final Score Points**	**MIPS Adjustment**
0.0-11.25	Negative 9%	0.0-15.0	Negative 9%
11.26-44.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale	15.01-59.99	Negative MIPS payment adjustment greater than negative 9% and less than 0% on a linear sliding scale
45.0	0% adjustment	60.0	0% adjustment
45.01-84.99.	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality	60.01-84.99	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality
85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 45.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance.	85.0-100	Positive MIPS payment adjustment greater than 0% on a linear sliding scale. The linear sliding scale ranges from 0 to 9% for final scores from 60.00 to 100.00. This sliding scale is multiplied by a scaling factor greater than zero but not exceeding 3.0 to preserve budget neutrality. PLUS An additional MIPS payment adjustment for exceptional performance. The additional MIPS payment adjustment starts at 0.5% and increases on a linear sliding scale. The linear sliding scale ranges from 0.5 to 10% for scores from 85.00 to 100.00. This sliding scale is multiplied by a scaling factor not greater than 1.0 in order to proportionately distribute the available funds for exceptional performance

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f. Review and Correction of MIPS Final Score

(1) Feedback and Information To Improve Performance

Under section 1848(q)(12)(A)(i) of the Act, we are at a minimum required to provide MIPS eligible clinicians with timely (such as quarterly) confidential feedback on their performance under the quality and cost performance categories beginning July 1, 2017, and we have discretion to provide such feedback regarding the improvement activities and Promoting Interoperability performance categories. In the CY 2018 Quality Payment Program final rule (82 FR 53799 through 53801), we finalized that on an annual basis, beginning July 1, 2018, performance feedback will be provided to MIPS eligible clinicians and groups for the quality and cost performance categories, and if technically feasible, for the improvement activities and advancing care information (now called the Promoting Interoperability) performance categories.

On July 1, 2018, we provided the first performance feedback for the Quality Payment Program. The second performance feedback was provided on July 1, 2019. However, for this year due to the PHE for COVID–19, we stated in the proposed rule (85 FR 50321) that we may provide performance feedback after July 1, 2020 (that is, performance feedback based on data submitted for the performance period in 2019). We stated that although we aim to provide performance feedback on or around July 1 of each year, it is possible that the release date could be later than July 1 depending on the circumstances. We estimated that we would provide performance feedback in late July or early August, although we noted this timeframe could be subject to change. We directed readers to *qpp.cms.gov* for more information.

On August 5, 2020, we released the third performance feedback for the Quality Payment Program, which was for the 2019 performance period. Additional information is available at *https://qpp.cms.gov/about/deadlines?py=2019*. We received public comments on our expected timeframe for providing performance feedback.

Comment: One commenter noted their appreciation for the updates on the PHE delaying the release of performance year

2019 feedback reports but expressed concern that the online portal for QPP feedback reports is confusing and difficult to navigate. The commenter recommended sharing additional scoring information with MIPS eligible clinicians.

Response: We appreciated the commenters for their feedback and support. We refer readers to *qpp.cms.gov* Resource Library where the 2019 MIPS Performance Feedback Resources user guide details how to access and how CMS scores these reports.

g. Third Party Intermediaries

We refer readers to §§ 414.1305 and 414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), and the May 8th COVID–19 IFC (85 FR 27594 through 27595) for our previously established policies regarding third party intermediaries.

In the CY 2021 PFS proposed rule (85 FR 50321 through 50331), we proposed to make several changes to requirements for (1) third party intermediaries generally, (2) QCDRs, (3) qualified registries, and (4) remedial action.

(1) Generally

(a) Requirements for MIPS Performance Categories That Must Be Supported by Third Party Intermediaries

We refer readers to § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364), and as further revised in the CY 2019 PFS final rule (83 FR 60088) and CY 2020 PFS final rule (84 FR 63049 through 63052) at § 414.1400(a)(2) for our current policy regarding the types of MIPS data that third party intermediaries may submit. Through the CY 2021 PFS proposed rule (85 FR 50321 through 50322), we intended to clarify our requirements of QCDRs, qualified registries, and health IT vendors with regards to submitting data for purposes of the MIPS program through revisions to our regulation codified at § 414.1400(a)(2), particularly for those third party intermediaries who are interested in supporting MVPs in the future. Therefore, we proposed to revise § 414.1400(a)(2) as follows:

Except as provided under § 414.1400(a)(2)(ii), QCDRs, qualified registries, and health IT vendors must be able to submit data for all of the following MIPS performance categories:

- Quality, except:

++ The CAHPS for MIPS survey; and

++ For qualified registries and health IT vendors, QCDR measures;

- Improvement activities; and
- Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*)).

Health IT vendors that do not support MVPs, must be able to submit data for at least one of the MIPS performance categories described above. We requested comments on the proposals.

We received public comments on the proposed requirements for MIPS performance categories that must be supported by third party intermediaries. The following is a summary of the comments we received and our responses.

Comment: One commenter agreed with the requirement that health IT vendors who do not support MVPs must submit data for at least one of the MIPS performance categories. The commenter stated submitting data is necessary for at least the quality category as all vendors need to be certified for submitting the QRDA file.

Response: We thank commenters for their support.

Comment: One commenter supported the reporting exception for QCDRs and qualified registries whose clinicians fall under reweighting policies.

Response: We thank the commenter for their support. For the Promoting Interoperability performance category, we currently reweight clinicians that are non-patient facing, hospital-based or who are one of the NPP types eligible for reweighting. We refer readers to review our reweighting policies at § 414.1380(c)(2).

After consideration of public comments, we are finalizing our policy as proposed at § 414.1400(a)(2).

(i) Reporting MVPs Through Third Party Intermediaries

We refer readers to section IV.A.3.a. of this final rule where we discuss reporting MVPs through third party intermediaries and summarized our proposal that QCDRs, qualified registries, and health IT vendors who support the Quality, Promoting Interoperability, and Improvement Activities performance categories may also support the reporting of MVPs.

(ii) Reporting APM Performance Pathway (APP) Through Third Party Intermediaries

We refer readers to section IV.A.3.b. of this final rule where we reiterate our proposal and include responses to public comments that beginning with the CY MIPS 2023 payment year, MIPS eligible clinicians scored under the APP would be scored on the quality measure set finalized for that MIPS performance period. Three quality measures (Quality ID# 001: Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%), Quality ID#: 134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan, and Quality ID# 236: Controlling High Blood Pressure) were proposed to be reported using the MIPS CQM and eCQM collection types.

(b) Approval Criteria for Third Party Intermediaries

(i) Background

We refer readers to § 414.1400(a)(4), the CY 2019 PFS final rule (83 FR 59894 through 59895, 60088), the CY 2020 PFS final rule (84 FR 63052 through 63053), and the May 8th COVID–19 IFC (85 FR 27594 through 27595) for previously finalized policies related to the approval criteria for third party intermediaries.

(ii) New Approval Considerations—Past Performance and Conduct

During past years of the MIPS program we have encountered third party intermediaries failing to meet program requirements and engaging in other conduct that could harm the integrity of the MIPS program. Some examples of third party intermediaries failing to meet program requirements include, but are not limited to: Failing to meet requirements to submit data for a performance category; failing to provide services throughout the entire performance period and applicable data submission period; and providing data that is not true, accurate, or complete. Additionally, we have also encountered third party intermediaries who have provided inaccurate information to the clinicians and groups they support regarding the obligation to submit data to CMS that are true, accurate and complete. For example, we are aware of third party intermediaries offering services and tools to eligible clinicians that encouraged the selection of misrepresentative data to maximize scores, commonly referred to as ''cherry-picking,'' that would result in the submission of data that did not accurately represent of the clinician's or group's performance.

In preparation for future years of the program, we believe it is important to

disapprove third party intermediaries that have demonstrated their failure to comply with program requirements or have provided inaccurate information regarding MIPS program requirements to clinicians. In the CY 2021 PFS proposed rule (85 FR 50322), we discussed that we are concerned with the potential adverse program effect of this conduct, such as delayed and erratic reporting if third party intermediaries fail to support MIPS reporting for the entire performance period and reporting period, and the possibility of inaccurate data submissions. As a result, we noted that we believe it is important to consider these factors when making determination regarding whether to approve a third party intermediary for future participation in the MIPS program.

Therefore, we proposed to amend the current § 414.1400(a)(4) to add paragraph (a)(4)(ii):

The determination of whether to approve an entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician. We noted that we intend on utilizing all available information to make these approval determinations, including without limitation, information collected through compliance audits under our existing audit authority as described in § 414.1400(g). Third party intermediaries may be selected during the performance period to be audited for a given requirement. As a part of our outreach to a selected third party intermediary, we intend on providing additional direction with regard to the timeline and information needed for the audit. The results of the audit will be reviewed to inform future approval of a third party intermediary, and if remedial action is warranted, we noted that we will utilize our existing authority as described in § 414.1400(f). We believe use of this information in approval determinations will help reduce the risk of third party intermediaries that are unreliable, thereby avoiding a possible increase in burden to clinicians who may inadvertently select an unreliable third party intermediary for purposes of reporting for the MIPS program. We requested comments on the proposals; specifically, on whether there are other factors that should inform our considerations when approving third party intermediaries.

The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposal to take into account past performance and conduct when determining whether to approve an entity as a third party intermediary for a MIPS performance period. However, commenters requested that CMS clarify that an entity which may have failed to comply with a requirement of the MIPS program will not result in automatic disqualification as a third party intermediary for a future MIPS performance period if that entity has entered into an CMS approved Corrective Action Plan.

Response: We thank commenters for their support.

We also clarify that this policy does not establish that particular conduct or the existence of a Corrective Action Plan would automatically disqualify a third party intermediary from approval in a future performance year. Rather, this policy establishes that failure to comply with the requirements of this section for any prior MIPS payment year is a factor the agency may take into account when making a determination of whether to approve an entity as a third party intermediary for a MIPS performance period. We generally do not anticipate that conduct for which CMS has approved a Corrective Action Plan standing alone would be the basis for CMS not approving the TPI for participation in a future MIPS Performance period.

After consideration of public comments, we are finalizing our policy as proposed at § 414.1400(a)(4).

(iii) Third Party Intermediary Training and Support

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77374) and (81 FR 77384 through 77386), we established our expectation that QCDRs and qualified registries perform certain functions related to data submission. One of those expectations is participation in ongoing support conference calls hosted by CMS (approximately one call per month) and an in-person kick-off meeting (if held) at our headquarters in Baltimore, MD. (81 FR 77368) and (81 FR 77384). The purpose of these meetings is to provide approved QCDRs and qualified registries program updates from subject matter experts who work across the Quality Payment Program. At these meetings, CMS subject matter experts and our contractors provide approved QCDRs and qualified registries with updates, answer questions, and provide technological demonstrations. In light of the PHE for COVID–19 and consistent with the goal of infection control, we reevaluated our expectations and have decided to adopt a policy allowing for flexibility moving forward. With the health and safety of our stakeholders in mind, we noted that we believe virtual meetings would be sufficient when in-person meetings are not possible. We proposed to codify these expectations in a proposed requirement at § 414.1400(a)(4)(iii) that third parties intermediaries participate in an annual meeting and training calls as deemed necessary by CMS.

In the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382), we stated our expectations for health IT vendors that serve as third party intermediaries by obtaining data from the CEHRT of a MIPS eligible clinician and submitting such data to CMS for participation in MIPS. For further discussion of CEHRT, we refer readers to sections III.M.3 and IV.A.3.g.(1)(iv) of this final rule. Because the submission requirements and policies that may be added or modified from year to year have the potential to alter expectations for all third party intermediaries, we believe that mandatory meetings and training calls would also be appropriate for health IT vendors that will serve as third party intermediaries. Hosting training calls for health IT vendors would give us an opportunity to provide a review of requirements, answer questions, and explain updates to the annual submission process and other policies as applicable. Thus, we proposed the requirement that third party intermediaries participate in an annual meeting and training calls as deemed necessary by CMS including those third party intermediaries that are health IT vendors. We solicited comments on the best method to reach health IT vendors so that we can invite them to required meetings and share additional information. We noted that we are considering listserv communications through the QPP listserv but would welcome suggestions for other communication mechanisms.

We previously finalized the CMS-approved survey vendor approval criteria in § 414.1400(e) as discussed in the CY 2018 PFS final rule (83 FR 59907 through 59908). Among the approval criteria, § 414.1400(e)(3) established the requirement that the entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors. In the CY 2021 PFS

proposed rule, (85 FR 50323), we noted that we continue to believe these previously finalized requirements are of importance to CMS-approved survey vendors, such as CAHPS for MIPS vendors. In addition, because the submission requirements and policies that may be added or modified from year to year have the potential to alter expectations for all third party intermediaries, we noted that we believe that the proposed requirement that third parties intermediaries participate in an annual meeting and training calls as deemed necessary by CMS should also be applicable to CMS-approved survey vendors.

In summary, we believe making support calls and trainings mandatory for all third-party intermediaries will provide an abundance of value to all approved third party intermediaries themselves, as well as to the MIPS program and the clinicians who rely on third party intermediaries to make complete, accurate, usable and timely data on their behalf. We believe uniformly codifying this language is appropriate to hold all third party intermediaries accountable for the training and support. Therefore, we proposed to codify at § 414.1400(a)(4)(iii) that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS. We affirmed that, in addition to the obligations under this policy, CMS-approved survey vendors must also continue to meet the requirements at § 414.1400(e)(3).

The following is a summary of the comments we received and our responses.

Comment: One commenter supported the proposal for health IT vendors to be required to attend monthly training and support calls and requested additional opportunities to attend trainings and ask questions.

Response: We thank the commenter for their support for Health IT vendor training. We believe participation in training and support sessions will be very beneficial and educational for health IT vendors. CMS agrees that regular dialogue is an important element to help vendors receive the latest information and reminders and to give third party intermediaries the best opportunity for success of the vendor and their clinician participants. For clarification, the requirement, which applies beginning with the 2021 MIPS performance year/2023 MIPS payment year does not specifically establish mandatory monthly calls for health IT vendors but rather establishes that attendance and completion of training and support sessions will be ''in the form and manner, and at the times, specified by CMS''. We will take into account the commenter's suggestion that training opportunities for health IT vendors should be more frequent than monthly when developing these training and support sessions.

Additionally, we did not receive comments on our proposal to message health IT vendors the same way that that we message to other third party intermediaries by utilizing our listserv communications through the QPP listserv. We are adopting this approach to communication with health IT vendors and encourage health IT vendors, if they have not already, to sign up for listserv messages at *https://qpp.cms.gov/.*

Comment: One commenter supported the proposal to require QCDRs and qualified registries to attend training and support calls.

Response: We thank the commenter for their support.

After consideration of public comments, we are finalizing our proposals as proposed.

(iv) Future Safeguards for All Third Party Intermediaries

We understand our obligation to ensure the integrity of the MIPS program and will continue to assess opportunities to strengthen program safeguards. Certain safeguards apply to all third party intermediaries, including those described in § 414.1400(a), (f), and (g). In sections IV.A.3.g.(2)(a) and IV.A.3.g.(3) of the CY 2021 PFS proposed rule, we proposed additional program safeguards in regard to data validation audit and targeted audit requirements that would apply specifically to QCDRs and qualified registries. As discussed there, the proposals would require QCDRs and qualified registries to conduct validation on data prior to the data being submitted to CMS for purposes of the MIPS program. We limited those proposals to QCDRs and qualified registries, but we solicited feedback on expanding the proposed requirements to all third party intermediaries through future rulemaking. We refer readers to sections IV.A.3.g.(2)(a) and IV.A.3.g.(3) in this final rule for a discussion of our finalized policies.

The Office of the National Coordinator for Health Information Technology's (ONC) Health IT Certification Program provides for the certification of certain health IT. The requirements for ONC certification are based on standards, implementation specifications, and certification criteria adopted by the Secretary. The Quality Payment Program adopted a definition of certified electronic health record technology (CEHRT) at § 414.1305.

For a discussion of the updates to 2015 Edition certification criteria referenced in the CEHRT definition adopted for the Quality Payment Program, we refer readers to section III.M. of the CY 2021 PFS proposed rule (85 FR 50323) and section IV.A.3.c.(4) of this final rule.

It is important to note that a health IT vendor which acts as a third party intermediary for purposes of the MIPS program may or may not be the same entity as a health IT developer which certifies health IT products as part of the certification program. While health IT developers may act as third party intermediaries for their customers, other service providers who do not develop health IT products may also assist MIPS eligible clinicians by submitting data obtained from CEHRT on their behalf and thereby function as a health IT vendor for purposes of the MIPS program. Furthermore, the entities that are not health IT developers must only submit data on behalf of eligible clinicians that has already been captured and calculated using the functions of CEHRT. Unlike QCDRs and qualified registries, third party intermediaries that are health IT vendors may or may not also possess expertise related to quality improvement and analysis/validation of clinical quality data, and we do not currently require these organizations to attest that they possess these capabilities.

We are increasingly aware of data integrity issues that have impacted data submitted by health IT vendors that obtain data from MIPS eligible clinician's CEHRT and serve as third party intermediaries to submit this data on behalf of MIPS eligible clinicians. We are aware of instances in which health IT vendors have submitted data that are inaccurate and unusable. These data issues may result in improper payments or otherwise undercut the integrity of the MIPS program. In some instances, data issues caused by health IT vendors may have downstream negative impacts to the clinicians whose data the health IT vendor is submitting, such as negative payment adjustments and inaccurate data publically posted on the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

Although we did not propose to add data validation requirements for health IT vendors in the proposed rule, we noted that we were considering ways to

impose such requirements in the future. We solicited comment on whether we should impose data validation requirements on health IT vendors as part of the third party intermediary approval process and if so, how the data validation requirements for health IT vendors should differ, if at all, from those we proposed for QCDRs and qualified registries. We noted that we believe that potentially requiring health IT vendors to validate the data they submit to us for purposes of the MIPS program will lead to the submission of data that can be considered more reliable and accurate. Therefore, we sought comment on the future application of such requirements on health IT vendors and if there are factors unique to health IT vendors that should be considered when developing such a policy. We also sought comments on: Whether health IT vendors currently submitting data on behalf of MIPS eligible clinicians possess the capabilities to engage in the data validation processes we proposed for QCDRs and Qualified Registries; the burden on health IT vendors of adopting the data validation requirements as proposed for QCDRs and qualified registries and whether the imposition of these requirements on health IT vendors would discourage health IT vendors from serving as third party intermediaries; whether alternative requirements for health IT vendors would impose less burden on these third parties' intermediaries while still ensuring that the data submitted is accurate and complete; and how any future data validation processes should impact certification under the ONC Health IT Certification Program for health IT developers who also serve as a health IT vendor third party intermediary for the purposes of MIPS.

For CMS-approved survey vendors, such as CAHPS for MIPS vendors, we did also not propose any new data validation requirements. In the CY 2018 PFS final rule (83 FR 59907 through 59908) we previously finalized requirements at § 414.1400(e) that address the validity of data submitted to CMS for CMS-approved survey vendors. Specifically, we previously finalized at § 414.1400(e)(4) that as a condition of approval the entity must have submitted a quality assurance plan and other materials relevant to survey administration, as determined by CMS, including cover letters, questionnaires and telephone scripts. We noted that we believe this previously finalized requirement at § 414.1400(e) is sufficient to address potential concerns about the accuracy of data submitted by survey vendors; however, we solicited feedback on whether the audit requirements in the proposal should be expanded to include survey vendors.

The following is a summary of the comments we received on potential future notice-and-comment to impose new data validation requirements on health IT vendors and CMS-approved survey vendors and our responses to those comments. We refer readers to sections IV.A.3.g.(2)(a) and IV.A.3.g.(3) in this final rule for a discussion of comments and responses to our current proposed policies for data validation by QCDRs and qualified registries, respectively.

Comment: Several commenters supported future requirements for health IT vendors to perform data validation. One commenter believes that it is the responsibility of the health IT developer to ensure the validity of the data their CEHRT is producing, and that a health IT developer's certification should be tied to its ability to capture and calculate data accurately. Another commenter believes that any entity that is submitting data on behalf of a clinician to CMS (for example, QCDR or health IT vendor) should be held to the same data validation requirements of a QCDR and without these requirements, the two different standards for registries and health IT vendors would undermine the goal of standard data integrity and place increased financial burden on non-profit QCDRs above that of health IT vendors.

Response: We appreciate the support and believe additional data validation could help to promote health IT vendor accountability for the accuracy of the data they submit to CMS. We have shared with ONC the commenter's support for any future data validation process impacting certification under the ONC Health IT Certification Program for health IT developers who also serve as a health IT vendor third party intermediary for the purposes of MIPS.

Comment: Several commenters did not support health IT vendors being required to perform data validation. These commenters believe CMS requirements for data validation by health IT vendor third party intermediary for the purposes of MIPS would be costly and burdensome and duplicative and unnecessary in light of the oversight these health IT vendors receive under the ONC regulatory framework, including the recently adopted Real World Testing requirement under the 21st Century Cures Act. One commenter requested that CMS monitor results of the Condition and Maintenance of Certification Real World Testing requirement prior to proposing requirements in MIPS. Another commenter requested that if CMS undertakes imposes additional requirements in MIPS for health IT vendors to validate data submitted on quality measures, the CMS requirements should replace work already required by ONC through the ONC certification program and real world testing, to avoid duplicative efforts.

One commenter stated that health IT developers already have to certify to each measure they offer as an eCQM and will soon be required to meet real-world testing requirements under the new Conditions and Maintenance of Certification provisions which should include testing based on current year measure specifications for the eCQM criteria. The commenter further believes that centrally validating eCQM data can be difficult because eCQM data collection can vary between each health IT developer and potentially between every provider organization depending on how a system is implemented by the provider organization. The commenter also expressed its concern with who would need to meet the eCQM data validation requirements, when they would need to meet the requirements, and for what measures the validation would need to be performed. The commenter requested that CMS work with the Electronic Health Record Association (EHRA) and its members to outline potential options for validation of measures as it relates to HIT Developers and encouraged CMS to consider means by which these requirements may be met by other activities the health IT developer is engaged in for meeting the Conditions and Maintenance of Certification such as by real-world testing. Another commenter requested CMS differentiate between developers of certified health IT and other health IT vendors due to their belief that that developers of certified health IT inherently already performs data validation.

Response: We appreciate the commenters' concerns regarding potential overlap between potential CMS data validation requirements for a health IT vendor third party intermediary for the purposes of MIPS and existing policies for oversight of health IT developers. We agree that any new data validation requirements for health IT vendors that submit data to CMS as third party intermediaries should take into account existing requirements designed to ensure these entities enable accurate reporting of data. As part of this effort, we plan to consider the real world testing Condition of Certification finalized

under ONC's 21st Century Cures Act final rule (85 FR 25765), which focuses on how certified health IT functionality is deployed in real-world settings and could potentially include activities related to validation of data reported using certified health IT. We understand that ONC's requirement does not necessarily require validation of data reported to CMS using certified health IT. Rather, we understand that the ONC condition of certification allows developers the flexibility to select measures to demonstrate how their certified health IT products function in real world environments. While data validation of eCQMs could conceivably be used as part of those real-world testing measures, we do not believe it is not a requirement to meet the Condition of Certification. We also appreciate the suggestion that CMS work with stakeholders, and plan to reach out to both health IT vendors and other interested parties prior to further action on new requirements to identify ways to minimize burden and align with existing programs.

As noted above, we will continue to work with ONC going forward as we consider any future rulemaking in this area.

Comment: One commenter did not support future requirements for CAHPS survey vendors to conduct data audits due to its belief that it would be burdensome and potentially duplicative given that CAHPS vendors are currently required to adhere to established quality control processes as outlined in the Quality Assurance Guidelines (QAGs) for each survey administration which include the requirement to maintain and submit a Quality Assurance Plan to CMS' subcontractor on an annual basis; keep records of CAHPS for MIPS quality assurance activities; and participate in other CAHPS Survey oversight activities, which can include auditing of submitted data, on-site visits and/or conference calls, and other activities as instructed by CMS.

Response: We agree with the commenter. We believe our previously finalized requirement at § 414.1400(e) is sufficient to address potential concerns about the accuracy of data submitted by survey vendors, and do not anticipate adding any new data validation requirements for CAHPS for MIPS vendors.

(2) Qualified Clinical Data Registries (QCDRs)

We generally refer readers to section 1848(m)(3)(E) of the Act, as added by section 601(b)(1)(B) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240, enacted January 2, 2013), which requires the Secretary to establish requirements for an entity to be considered a QCDR and a process to determine whether or not an entity meets such requirements. We refer readers to section 1848(m)(3)(E)(i)(v) of the Act, the CY 2019 PFS final rule (83 FR 60088), the CY 2020 PFS final rule (84 FR 63053 through 63058), May 8th COVID–19 IFC (85 FR 27594 through 27595) and § 414.1400(a)(4) through (b) for previously finalized policies about third party intermediaries generally and QCDRs specifically. In the CY 2021 PFS proposed rule (85 FR 50324), we proposed a technical update to § 414.1400(b) title to rename it from ''QCDR approval criteria'' to ''QCDRs'', to better align the title with the content of the regulation. In addition, we proposed policies related to QCDR: (1) Data validation audits and targeted audits; and (2) measure requirements.

(a) Data Validation Audit and Targeted Audit Requirements

In the CY 2017 Quality Payment Program final rule, we discussed our expectation that QCDRs and qualified registries would conduct validation on the data they intend on submitting for the MIPS performance period (81 FR 77366 through 77367) and provide the results of the data validation to CMS in the form of a data validation execution report by May 31st of the year following the performance period. Our intention was to establish our expectation that QCDRs would establish a process to assess whether the data are true, accurate, and complete prior to submitting them to CMS for purposes of the MIPS program. We noted that we believe it is important to establish a requirement that QCDRs conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. In instances where a QCDR discovers data are inaccurate or incomplete, the entity must correct the issue prior to submitting the data to CMS in order to provide accurate certification in accordance with § 414.1400(a)(5). A QCDR that submits a false certification submits data that is inaccurate, unusable or otherwise compromised to CMS for purposes of the MIPS program may be subject to remedial action or termination under § 414.1400(f). We also noted that we believe requiring QCDRs to validate the accuracy of the data they are submitting is an important safeguard to promote accurate payments under the MIPS program. Therefore, we proposed to codify at § 414.1400(b)(2)(iv) and (v) requirements beginning with the 2023 MIPS payment year as condition of approval each QCDR must conduct annual data validation audits and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits. We also proposed specific obligations for those audits as discussed below.

- We proposed to codify at § 414.1400(b)(2)(iv)(A), that the QCDR must conduct data validation for the payment year prior to submitting any data for that payment year to CMS for purposes of the MIPS program. We believe it is important for QCDRs to conduct validation audits to identify and fix concerns regarding data accuracy prior to submitting data to us, including potential issues related to data aggregation and calculation. Conducting the data validation prior to data submission will lead to data being more reliable and promote compliance with the requirement of data being true, accurate, and complete. In the CY 2017 Quality Payment Program final rule, we described this auditing using the term randomized audit (81 FR 77366). We proposed instead to refer to this audit as the data validation audit in an effort to be abundantly clear regarding our expectations that the QCDR will purposefully construct a sample and conduct an audit that complies with specific regulatory requirements and also to distinguish these audits from the targeted audits discussed below and proposed at § 414.1400(b)(2)(v).
- We proposed to codify at § 414.1400(b)(2)(iv)(B), the QCDR must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories. We believe that it is important that data validation is performed across all performance categories for which the QCDR submits data since QCDRs must attest that data submitted to CMS is true, accurate, and complete and data for each of these performance categories can influence score calculation and payment adjustments.
- We proposed to codify at § 414.1400(b)(2)(iv)(C), that the QCDR must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants. We believe it is important for the data submitted to CMS be accurate for all clinicians and groups for which the QCDR intends on submitting data to the MIPS program, regardless of whether they are required to participate, have opted in, or have chosen to voluntarily participate.

Therefore, we proposed to require that the data validation audits should account for all types of submitters that are utilizing the QCDR to submit data to CMS for purposes of the MIPS program. We noted the importance of validating data for all submitter types regardless of its use for payment or public reporting. Even clinicians who voluntarily report to MIPS and whose data are not used for payment purposes could have their data publically posted on the Physician Compare website. We noted that we believe all data the QCDR submits, regardless of its use for payment or public reporting, should be true, accurate, and complete.

• We proposed to codify at § 414.1400(b)(2)(iv)(D) that the QCDR must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed. If the data a QCDR intends to submit to CMS for purposes with the MIPS program are to demonstrate that a clinician did a particular clinical activity or achieved a particular clinical outcome, we noted that we believe meaningful validation of such data requires the QCDR to use clinical documentation to confirm that the activity occurred or was performed.

• We proposed to codify at § 414.1400(b)(2)(iv)(E) that the QCDR shall conduct each data validation audit using a sampling methodology that meets the following requirements:

++ Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR may use a sample size of 50 TIN/NPIs.

++ Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

We believe the aforementioned sampling methodology is appropriate for multiple reasons. First, the sampling methodology criteria are consistent with the methodology established under the legacy Physician Quality Reporting System (PQRS) program and as described in the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367). As this methodology has been used for many years under the legacy program, we believe stakeholders are well versed in executing data validation audits using this sampling methodology. Second, the proposed methodology accounts for QCDRs and qualified registries of varying sizes. Data validation requires a level of effort on the part of the QCDR to execute a data validation plan, identify a sample, and collect information for purposes of chart review; therefore, we are cognizant that requiring a larger sample size would create additional burden on QCDRs and clinicians to account for a larger volume in TIN/NPIs and medical records for review.

• We proposed to codify at § 414.1400(b)(2)(iv)(F) that each QCDR data validation audit must include the following:

++ Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant. We believe that it is important for the QCDR to track the eligibility status of each clinician and group that wishes to use a third party intermediary to report, because accurate information regarding eligibility is important to ensuring payment adjustments are properly applied. Furthermore, verification of eligibility status is consistent with the requirement for QCDRs to track opt-in participants, as described at § 414.1400(a)(4)(iv) and in the context of clinicians who voluntarily report to MIPS helps ensure the accuracy of data publically posted on the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

++ Verification of the accuracy of Tax Identification Numbers (TINs) or National Provider Identifiers (NPIs). Correct TINs and NPIs are critical to ensure data submitted by the QCDR are attributed to the correct clinicians and groups. Inaccurate NPIs or TINs may lead to inadvertent downstream impacts to the way clinicians and groups are scored, and assigned a payment adjustment.

++ Calculation of reporting and performance rates (for example, formulas included in the quality measure specifications). QCDRs must follow the measure specifications when calculating reporting and performance rates. Calculations that deviate the formulas included in the quality measure specifications undercut efforts to ensure data are consistent, reliable, and have been calculated in a uniform manner.

++ Verification that only MIPS quality measures and QCDR measures that are relevant to the performance period will be utilized for MIPS submission. Measure specifications for the MIPS quality measures and QCDR measures go through maintenance on an annual basis. Use of outdated measure specifications would likely result in the QCDR submitting inaccurate or compromised data for the clinicians and groups they support. While not all measures go through substantive changes on an annual basis, there are changes to codes that do occur annually that should be accounted for when programing measures. Therefore, we noted that we believe it is important that QCDRs are utilizing the most current version of the measure specification, relevant to the performance period in which they are participating.

• We proposed to codify at § 414.1400(b)(2)(iv)(G), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. We noted that we believe it is important that the results of the data validation be shared with us in order for us to understand the types of issues the QCDRs have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education. It is our belief that the report will be largely comprised of issues that were identified and resolved. However, if an issue has been identified and could not be resolved, we would want to understand what the issue is and why it could not be resolved. We emphasized that all data submitted to CMS by a QCDR on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge as described in § 414.1400(a)(5). If a QCDR submits a false certification or data that are data that are inaccurate, unusable, or otherwise compromised, the QCDR may be subject to remedial action or termination as described at § 414.1400(f).

• We proposed to codify at § 414.1400(b)(2)(v)(A), that if a data validation audit under § 414.1400(b)(2)(iv) identifies one or more deficiency or data error, the QCDR must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year. We noted that we believe targeted audits are important to further evaluate the impact of deficiencies or data errors to the cohort of clinicians

and groups that the QCDR intends to submit data for, and for QCDRs to determine the reason the deficiency or data error occurred.

- We proposed to codify at § 414.1400(b)(2)(v)(B), that the QCDR must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year. To promote the accuracy of the data submitted to the MIPS program for the payment year and to reduce the risk that the agency initiates payment calculations in reliance on inaccurate data, it is important for the QCDR to conduct required targeted audits and correct any deficiencies and data errors identified through those audits prior to submitting the data to CMS.
- We proposed to codify at § 414.1400(b)(2)(v)(C), the QCDR must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(2)(iv)(E). The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

We noted that we believe the sampling methodology we proposed for data validation audits is equally appropriate for the conduct of targeted audits. We believe that adopting the same methodology for both audit types would be less burdensome on QCDRs than requiring these entities to apply a separate sampling methodology for their targeted audits. Provided that data in the sample for the targeted audit does not overlap with the data that was reviewed in the data validation audit, we believe the targeted audit would provide the QCDR with a reasonable perspective into impact and root cause of deficiencies and data errors across the data to be submitted without imposing the burden that would result from maintaining a separate sampling methodology for targeted audits.

- We proposed to codify at § 414.1400(b)(2)(v)(D), in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected. As is the case with the results of data validation audits, we noted that we believe it is important that the results of the targeted audits be shared with us in order for us to understand the types of issues the QCDRs have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education.

We requested comments on the aforementioned proposals, including whether stakeholders are concerned with implementing the policies for the 2023 MIPS payment year, and if so, what barriers do they believe they would face in implementing these requirements.

The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to require data validation audits and targeted audits.

Response: We thank the commenters for their support.

Comment: A few commenters supported the proposal to require QCDRs to be held accountable to report on and correct QCDR measure logic issues or other errors generated by the QCDR.

Response: We clarify that the proposed data validation requirements for QCDRs is not targeted specifically to errors generated by the QCDR but rather to more broadly help ensure the data submitted to CMS by QCDRs is true, accurate and complete.

Comment: Some commenters stated that while they can advise the eligible clinician or group to correct their documentation practices or workflow errors, they cannot hold them accountable to act and at the point in the performance year at which this audit occurs, the QCDR will already be contractually bound to report for the eligible clinician or group based on CMS required agreements. Other commenters believe that CMS should take responsibility for disciplining eligible clinicians that refuse to make data corrections or participate in focused reviews and implement a proposal regarding such clinicians which would allow registries to submit their data, along with notification of their refusal(s).

Response: We disagree with the commenter's suggestion that CMS requires third party intermediaries to enter into agreements that would contractually bind the third party intermediary to submit data to CMS for the eligible clinician or group that the third party intermediary knows the data are not true, accurate and complete. All data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge. Therefore, in instances where a QCDR determines there is no documentation to support that a given quality action or activity was completed, the QCDR should advise the eligible clinician or group to correct their documentation practices and workflows, and the QCDR must also refrain from submitting inaccurate data to CMS. If a third party intermediary determines that the data it received for a clinician is not true, accurate or complete, and the clinicians refuse to correct the error, then the a third party intermediary should not submit the inaccurate data on their behalf. We emphasize that we do not want inaccurate data submitted to us, and we do not want a third party intermediary to submit incorrect data on behalf of non-compliant clinicians. Furthermore, as described in the CY 2020 PFS final rule (84 FR 63023 through 63027), if we determine a MIPS eligible clinician has knowingly submitted compromised data for a performance category the clinician's performance category score would be zero and the scoring weight for the category will not be redistributed. A third party intermediary that submits inaccurate data to CMS, may be subjected to the remedial action and termination under § 414.1400(f) even in instances where clinicians refuse to correct the data.

Comment: One commenter requested CMS provide a standardized process for third party intermediaries to disclose of issues prior to and after data submission.

Response: While we appreciate the commenter's request for a standardized process for third party intermediaries to disclose data issues, we believe some flexibility is needed to accommodate the range of scenarios that arise. We will issue guidance on how QCDRs and qualified registries should operationalize the required reporting on the results of each data validation audit and targeted audit in which identified data issues that have arisen prior to submission and have been corrected should be described. To disclose data issues identified in other contexts, a third party intermediary should submit a ticket to the Quality Payment Program Service Center by phone: 1–866–288–8292 (TRS: 711) from Monday–Friday, 8 a.m.–8 p.m. eastern standard time, or may contact the QPP Service Center by email: *QPP@cms.hhs.gov.*

QCDRs must disclose of data issues as a part of their data validation execution report. Furthermore, QCDRs are required to conduct this validation prior to submitting the data to CMS, so that

data issues may be identified and corrected. As a reminder, all QCDRs must follow the data validation audit and targeted audit requirements at § 414.1400(b)(2)(iv) and (v).

Comment: Several commenters believe that CMS should not require collection of more protected health information (PHI) than is necessary to achieve its purpose due to their concern that the codification of multiple auditing requirements related to clinical documentation and patient information could jeopardize their business models and trust with clinicians. The commenters also expressed their belief that CMS should narrowly define what should be collected via an audit, with such criteria preserving the confidentiality of patient information and not subjecting QCDRs to additional risks that they would not otherwise assume. One commenter believes that many QCDRs do not receive PHI from their participants; rather, the participants submit PHI to vendors engaged by the registry and vendors subsequently submit de-identified data to the QCDR for MIPS reporting.

Response: We do not believe that the requirement proposed at § 414.1400(b)(2)(iv)(D) would improperly increase risk to the confidentiality of patient information. Collection standards established for QCDRs are consistent with program audit requirements already established and there is no indication that this creates additional risks. CMS respects patient privacy and will not use or disclose PHI except as permitted by applicable privacy and security laws, including, but not limited to, the HIPAA Privacy Rule. Third party intermediaries are generally required to have HIPAA compliant business associate agreements with any HIPAA covered entities for which they create, receive, maintain, or transmit PHI. This should help mitigate concerns regarding receiving or viewing provider's patient's PHI during an audit.

Comment: A few commenters believe that the requirement to audit a 3 percent sample, and, if an error is found, the requirement to audit an additional 3 percent sample that excludes any TINs/NPIs from the original sample to ensure the error is corrected creates undue burden and the sample size of NPIs and TINs and number of patients per measure required for an audit should be reduced. One commenter believes that since the nature of an error can vary widely and not all types of errors require such an intensive and resource-heavy re-sampling in order to ensure that data is error free, QCDRs should be allowed to determine the most effective and efficient manner through which they can determine the scope and root cause of any errors found in the data validation audit. Another commenter believes that either the random sample/percentage of overall users methodology or the proposal to require data validation for each submitter type be included in the data validation and audit requirements, but not both.

Response: While we understand the level of effort associated with data validation, we disagree that this causes undue burden. We believe that it is critically important that all data submitted is true, accurate and complete and all data submitted to CMS by a third party intermediary on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge (§ 414.1400(a)(5)). To help ensure that the data is true, accurate and complete we believe it is important to have data validation and as appropriate audits. Ensuring data integrity and accuracy is critical for the QPP feedback, payments and public display of the data. The sampling requirements reflect our effort to minimize the burden while ensuring a meaningful assessment of the data. We believe it is appropriate for the sampling requirements for the targeted audit to include data from the sample used for the data validation audit in order to determine the scope of the impact of the data errors on those that are choosing to use the QCDR to report. Despite the commenter's suggestion that the size of the targeted audit sample be left to the discretion of the QCDR based on the nature of the error identified in data validation, we do not believe the sample size for the targeted audit should be different from the sample size for the data validation audit. Furthermore, we do not believe it should be at the QCDR's discretion which performance categories of the data submission should be audited. If a clinician is selected for auditing through the sampling methodology, they should be audited in a manner that is objective and considerate to all performance categories in which they have submitted data. As described in the CY 2021 PFS proposed rule (85 FR 50325), the aforementioned sampling methodology has been used for many years under the legacy program, and in the first few years of the MIPS program. We do not believe a smaller sample size for the targeted audit would provide us with an understanding of the impact of the error. In addition, we disagree with the commenter who suggested that the samples used for data validation and targeting audits should not include both a minimum number of users and users of each submitter type. We believe that the samples should account for both of volume and user type in order to promote data accuracy across both these factors. We note, however, that the sample size requirements do include flexibility to reduce burden, including for example establishing that the sample size for each data validation and targeted audit does not need to include more than 50 TIN/NPIs. Therefore, we believe these sampling thresholds strike the right balance of being reliable for both large and small QCDRs and do not impose an undue burden on QCDRs.

Comment: A few commenters requested clarification regarding the calculation of sample sizes for the data validation audits and targeted data audits including: Whether ''TIN/NPI'' is referencing TIN–NPI combinations or is meant to be read as ''TIN or NPI''. Commenters also requested clarification on whether separate sample universes are required for the total number of NPIs and the total number of TINs that the QCDR submits data for; whether the sample universe can simply be based on 3 percent of the total number of TINs that a QCDR submits data for, or is the intention that the 3 percent sample size should be calculated based on the total number of unique TIN/NPI combinations, while also taking into account the minimum and maximum range requirements (for example, a minimum of 10 TIN/NPIs and a maximum of 50 TIN/NPIs); and whether the sample size of 25 percent of patients audited must be based on the total patient population for each TIN selected in the 3 percent sample or is the intention that the 25 percent of patients should be calculated based on the total number of unique TIN/NPI combinations, while also taking into account the minimum and maximum range requirements (for example, a minimum of 5 patients and a maximum of 50 patients). One commenter requested clarification and guidance on the requirement to use a 3 percent sample for targeted data audits separate from the original 3 percent sample used for data validation when an error is found.

Response: To clarify our sample sizes for data validation, the sampling methodology described in our proposal and above requires the use of at least 3 percent of the TIN/NPIs for which the QCDR will submit data to CMS, unless that 3 percent sample would result in fewer than 10 TIN/NPIs, which would require the QCDR to use at least 10 TIN/NPIs. The three percent sample size requirements is based on the QCDR's

total number of unique TIN/NPI combinations; we are not requiring two separate samples based on the number of TINs or NPIs separately. If the 3 percent sample would result in more than 50 TIN/NPIs, the QCDR may limit their sample size to 50 TIN/NPIs. For each TIN/NPI selected as a part of the auditing sample, the QCDR must audit 25 percent of the patients, with a minimum of 5 patients and a maximum of 50 patients. For example, if under a unique TIN/NPI combination a clinician has 1000 patients for a particular measure, the QCDR will only need to audit a maximum of 50 charts for this TIN/NPI for this measure. If they only have 10 patients for the given measure, the QCDR would need to review the minimum of 5 charts. In the case of 100 patients reported for a specific measure, the QCDR would need to review 25 charts.

To address what we mean by unique TIN/NPI combinations, unique combinations are how we refer the combination of identifiers used when a specific clinician (that is, NPI) is in a specific practice (that is, TIN). For example, a clinician could work under Group X for 2 days in a week and for Group Y for the remaining days in the week, this would likely result in 2 different unique TIN/NPI combinations, due to the NPI being unique to the clinician and the TIN being unique to the respective group.

The sampling methodology must be used to derive a sample for data validation. If an error was identified through the data validation audit, it would trigger the third party intermediary to conduct a targeted audit. The third party intermediary must use a sample for the targeted audit that does not include data that was used for the data validation process audit in which the error was identified. The third party intermediary must use the sampling methodology to ensure their sample size meets the requirements for the targeted audit.

Comment: One commenter stated that the proposals regarding data validation audits would be especially cumbersome and burdensome with regard to the data of anesthesiologists due to the nature of how the specialty is practiced. The commenter stated that quality measures for anesthesiologists may be derived from data from multiple sources and some practices may collect quality data on paper or practice in numerous locations. Several commenters expressed their concerns with the proposal to require auditing of the Improvement Activities and Promoting Interoperability performance categories and that meaningful validation of what constitutes compliance may vary from one group to another. The commenters suggested that CMS provide additional guidance, as well as allow flexibility to account for the difficulty in validating information often tracked outside of a clinician's EHR, varying practice conditions and constraints that may be present when completing an audit, and the large percent of clinicians who manually enter data late in the fourth quarter.

Response: We thank commenters for their feedback. We understand that data to support the performance of a quality action within a measure may rely on multiple data sources, and the need to for clinicians, such as anesthesiologists, to consistently document the clinical action during each patient encounter, to demonstrate the quality action has been completed. However, we believe that data validation is important to ensure that the quality actions have been truly completed by the clinicians. In light of this, we plan to devote one of the upcoming support conference calls to data validation for the Promoting Interoperability and Improvement Activities performance categories. We will provide guidelines and give participants the opportunity to ask questions.

While recognizing that underlying data submission for performance categories may differ among the clinicians and groups for whom the QCDRs and qualified registries submit data, compliance by a QCDR or qualified registry with its obligation to validate the data should not vary significantly from one group to another. As it relates to the validation of information potentially tracked outside of a clinician's EHR, practice conditions, or systemic constraints due to manual data entry, we believe the required parameters for data validation and targeted audits allow sufficient flexibility to account for this data variation.

Comment: One commenter expressed concern regarding the validation of electronic measures citing its belief that the process for calculating and auditing these measures is different from manually abstracted measures because electronic measures do not consider clinician notes, audio, images, videos, and other non-computable aspects of the chart in their calculation and therefore, could fail an audit if the chart review included areas of the chart not included in the eCQM specification. The commenter also requested additional clarity regarding the term ''chart review.'' The commenter stated that chart review should be defined as a review of the chart data which applies to the measure specification and is available in the manner necessary for the measure calculation process (electronic or human abstraction). The commenter also cited examples of errors (such as a clinician incorrectly documenting a case by entering conflicting information in the clinical note from the discrete, electronic data fields which make up the measure specification, or the EHR storing data in an incomprehensible manner) as areas of a chart that the commenter stated should not be considered in the chart review.

Response: We agree that the measure specification and associated data source are useful guides for implementing audits that meet the data validation requirements. The QCDR must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed. The eCQM specifications define the data elements in the measure logic and ''calculations that deviate the formulas included in the quality measure specifications undercut efforts to ensure data are consistent, reliable, and have been calculated in a uniform manner.'' We remind the commenter that QCDRs and qualified registries must perform a data validation audit to identify data errors prior to data submission to CMS, such as conflicting documentation within the medical chart. QCDRs and qualified registries must correct any deficiencies or data errors identified through targeted audits prior to the submission of data for that MIPS payment year. In addition, we would like to remind the commenter that third party intermediaries must certify that all data submitted to CMS by the third party intermediary is true, accurate, and complete to the best of their knowledge. This certification applies to all data the third party intermediary submits to CMS on behalf of a MIPS eligible clinician, group or virtual group, and does not exclude data exports directly from an EHR or other data sources. You may refer to the 2021 QCDR and Qualified Registry self-nomination fact sheets for additional information. These resources are available at *https://qpp.cms.gov/about/resource-library.*

Comment: One commenter noted that the auditing of Improvement Activities has been and will continue to be a source of validation difficulty during auditing. The commenter also noted because improvement activities are not necessarily tracked within the EHR and that these items often consist of narrative information recorded and tracked elsewhere by the provider, they

should not be considered an auditable item for the third party intermediary. One commenter requested that if these requirements are finalized in the future, CMS provide discrete data points for improvement activities that do not require collection of data points.

Response: We disagree that data regarding improvement activities should be excluded from the data validation and audit requirements for QCDRs and qualified registries. We appreciate the commenter's concern that some current clinicians and groups may have current practices for documenting and tracking improvement activities that may make validating this information more challenging. However, we do not believe these operational concerns should result in improvement activities being excluded from data validation and targeted audit requirements. Within the data validation and targeted audit requirements, QCDRs and qualified registries must submit to CMS the results of each data validation audit and targeted audit, including, among other information, how and when each deficiency or data error type was corrected. In addition, QCDRs and qualified registries must correct any deficiencies or data errors identified through targeted audits prior to the submission of data for that MIPS payment year. Regarding discrete data points for improvement activities, we interpret the commenter to be requesting future guidance on how to validate improvement activities if the activity does not require collection of data. However, we clarify that completion of each improvement activity involves some form of underlying documentation, for example, in order to complete the CDC training for IA_PSPA_23—Completion of CDC Training on Antibiotic Stewardship the module requires the MIPS eligible clinician to receive a certificate of completion and per the MIPS Data Validation Criteria document would be required to maintain this certificate for a period of up to 6 years in the event of a CMS audit. Therefore, we believe it is reasonable to require data validation for improvement activities.

Comment: A few commenters stated that while a QCDR can support eligibility verification, CMS should support this process by creating scalable and secure access to this information by either pulling data for QCDRs or having an application programming interface that communicates such information. One commenter also requested that CMS include language in the final rule emphasizing that eligibility verification is ultimately the clinician's responsibility, and not the QCDR's.

Response: As the submitter of data on behalf of the clinicians, we believe QCDR should check on clinician eligibility so that the clinician can make an informed decision regarding participation.

While we understand the commenters' recommendation may relieve some burden on the QCDRs from verifying eligibility, it is not operationally feasible to depend on CMS to conduct this verification on behalf of the QCDRs. QCDRs should verify and track the eligibility of the clinicians and groups they intend to support for purposes of MIPS reporting. This becomes particularly important for tracking purposes, in case issues arise with regard to final scores and payment adjustments, as it is necessary for the QCDR to delineate MIPS eligible clinicians from voluntary participants and opt-ins.

We provide the public, including QCDRs participating in the Quality Payment Program, with an Application Programming Interface (API) that can assist with determining eligibility for clinicians and groups which can be found at *https://cmsgov.github.io/qpp-eligibility-docs/*. Information can be obtained primarily by the Clinician type, by searching by NPI. The information contained in these endpoints includes basic enrollment information, associated organizations, information about those organizations, individual and group special status information.

Comment: One commenter stated that verifying the accuracy of TINs and NPIs is burdensome for some QCDRs and requested that CMS provide clarification regarding this verification as well as allow flexibility in how such data are verified.

Response: We continue to receive data that cannot be attributed to a specific clinician due to an inaccurate TIN, NPI, or TIN/NPI combination. While we understand there is a level of effort on the part of the QCDR that is required to verify the accuracy of TINs and NPIs, we believe this is an important requirement for QCDRs to track. We have provided suggested methods in the CY 2017 Quality Payment Program final rule of verifying the accuracy of TINs and NPIs (81 FR 77366), but we have not required QCDRs to use this approach. Any alternative process used by the QCDR should be reliable, valid, and capable of being repeated in a manner that is consistent for all verification attempts.

Comment: One commenter requested confirmation as to how random human errors should be treated under the targeted data audit requirement when identified during the randomized audit process. Specifically, the commenter requested clarification on whether a targeted audit needs to be conducted on a separate sample universe (for example, on a sample that does not include any data from the sample used for the data validation audit in which the error was identified) if, for example, the only errors identified during the randomized audit were attributed to random human error, such as a human medical coding error. The commenter also requested for clarification on whether it is sufficient to document that a detailed review was conducted as part of the randomized audit process to identify the root cause of the error (for example, that the root cause was, in fact, attributable to random human error) and to establish and implement a plan for correcting any such random human errors that were identified.

Response: We reiterate for QCDRs all policies regarding data validation audit and targeted audit requirements at § 414.1400(b)(2)(iv) and (v) must be followed. All errors, regardless of whether they are human-based or systems-based must be identified as a part of the data validation efforts. If an error is identified through data validation, regardless of whether the error is human-based or systems-based, that would then trigger the QCDR to conduct a targeted audit utilizing a sample that is unique to the sample that was used for the data validation audit. It is not sufficient to document a detailed review or root cause analysis that was done as a part of the data validation audit (previously referred to as the randomized audit). We believe that QCDRs should utilize a structured data validation methodology, inclusive or a targeted audit in instances where the data validation audit results in the discovery of errors. An audit process provides a level of structure that will lead to consistency in the type of findings discovered. Furthermore, we are concerned with allowing QCDRs discretion to conduct their root cause analysis using an undefined variety of methods may lead to arbitrary and incomplete findings. The QCDR must separately conduct the targeted audit in accordance with regulatory requirements in each instance in which data validation audit identifies one or more deficiency or data error. An alternative approach to the targeted audit will not be accepted. We will maintain our structured validation process, in which the results of the audit are shared in a manner that is standardized across all participating QCDRs and qualified registries.

Comment: A few commenters stated that this requirement of data validation audits would create additional burden and operational challenges because QCDRs have no official role, delegated authority, or guidance from CMS as a CMS auditor. Commenters also stated that if a practice disagrees with the decision of a QCDR audit, there is no clear path as to how a QCDR could respond and be supported in their decision by CMS. One commenter also stated that CMS should allow Improvement Activities submissions that QCDRs receive be sent to CMS's QPP service center so that the service center can provide guidance to QCDRs on whether each submission can be accepted/approved.

Response: While we understand data validation requires a level of effort by the QCDR, we want to note the importance of QCDRs validating the data they intend to submit to us for purposes of the MIPS program. It is our expectation that QCDRs will ensure that the data submitted is true, accurate, and complete. To be clear, QCDRs are not designated to be auditors on behalf of CMS. QCDRs are required to conduct validation to promote the accuracy of their own submissions. We encourage the QCDR to keep documentation of instances in which a clinician does not provide the data requested for validation, and suggest that the QCDR consider annotating the report with the results of their data validation audits to outline instances where clinicians refuse to cooperate. The inclusion of information of these occurrences will help bring such issues to our attention, and may lead to the non-compliant clinician's selection for auditing as described in § 414.1390. While QCDRs are required to conduct data validation regardless of the clinician type and performance category; we clarify that clinicians who fail to submit accurate data to us, regardless of whether they use a third party intermediary or submits their data directly to us, will also be held responsible. We disagree that the QPP Service Center should be involved in determining data for an improvement activity are valid. QCDRs are expected to utilize the existing improvement activity guidance that may be found in the resource library at *www.qpp.cms.gov* to validate that the clinician or group has successfully completed the activity before it is attested to.

Comment: Many commenters disagreed with the proposal to require data validation specific to performance category, submission mechanism, and submitter type. Commenters believe the proposal is duplicative of internal quality data controls and external audits already conducted; and data validation for clients who are manually entering data may be difficult to audit, as many clinicians and practices do not complete data entry until late in the fourth quarter of the performance period.

Response: We disagree with the commenters objecting to the scope of data validation. As described in the CY 2021 PFS proposed rule (85 FR 50324), the data validation requirements including validation specific to performance category, submission mechanism, and submitter type align with current practices currently utilized by QCDRs that have been in place since the 2017 performance period of the MIPS program, and therefore, pose no additional burden. We acknowledge that QCDRs in previous years of the MIPS program have performed data validation audits utilizing internal resources or hiring external contractors and have been able to share the results of their data validation with CMS. By establishing these data validation requirements in regulation, it is our intent to ensure minimum validation efforts are robust and consist across all QCDRs. We understand that some clinicians and practices may not complete data entry until late in the fourth quarter of the performance period, but we disagree that should be a deterring reason as to why QCDRs could not validate data. We encourage QCDRs to advise their participants to submit data throughout the year. By receiving data earlier in the year, not only will the QCDR be able to validate their data earlier, but they will be able to provide more timely performance feedback to their clinicians and groups in accordance with § 414.1400(b)(2)(ii), which would allow the clinician to take action on the data and improve the quality of care their patients receive—which is one of the main goals of the program.

Comment: One commenter disagreed with the proposal to apply this requirement to voluntary submitters since they would be required to agree to the audit requirements and their incentive to participate may be hampered by the additional work associated with the audit.

Response: We appreciate the commenter's concern that data validation may be a disincentive to some voluntary submitters; however, we believe this concern is outweighed by the need to promote the accuracy of the data we receive. We want to note that all data submitted may be subjected to display on Physician Compare internet website of CMS (or a successor website), and that data would be subjected to the requirements at § 414.1395. Accordingly, all data submitted to us will face the data validation audit and targeted audit requirements at § 414.1400(b)(2)(iv) and (v).

Comment: Another commenter suggested CMS may consider having QCDRs prepared to provide such documentation upon request, as it does for other audits in order to minimize burden on behalf of the vendors, practices they contract with, and CMS, while upholding the integrity of these audits. One commenter stated that the requirement to use clinical documentation may not be feasible for all QCDRs to complete. The commenter stated the QCDR may not have access to the medical record because they do not always have business associate agreements (BAAs) set up that allow for data access, and that without this access to the medical charts, the data validation and audit will be unable to occur.

Response: As described at § 414.1400(g)(2), all third party intermediaries must retain all data submitted to CMS for purposes of MIPS for 6 years from the end of the MIPS performance period. However, these documentation retention requirements are distinct from the data validation requirements. To be clear, QCDRs should have access to clinician documentation in order to complete the data validation requirements, and the access should be readily provided by clinicians who are selected through the sampling methodology. It is not sufficient to merely have this documentation available upon CMS request in meeting these data validation and targeted audit requirements since the validation and auditing must be completed prior to data submission.

Comment: One commenter requested that CMS provide a template and/or guideline for the data validation process and report.

Response: On an annual basis, we have provided QCDRs with data validation execution report templates, so they could share information about their data validation process and results with CMS. We refer readers to the Quality Payment Program resource library website at *https://qpp.cms.gov/about/resource-library* where we have published these in the past. At § 414.1400(b)(2)(iv) and (v) we are finalizing regulatory requirements for annual reports to regarding data validation and targeting audits for the 2023 MIPS payment year and beyond. We intend to publish updated report templates in the QPP Resource Library: *https://qpp.cms.gov/about/resource-library*.

Comment: One commenter requested that CMS publish minimum data accuracy requirements due to its belief that performance data is never 100 percent accurate and since QCDRs do all that is within their power to ensure data accuracy, they should not incur fines or other disciplinary action for data accuracy issues outside their control.

Response: Ensuring data is correct and suppressing inaccurate data is the responsibility of the QCDR. Accurate data is critical to calculate any payment differentials for clinicians in addition to displaying performance results on one of our compare websites. It is anticipated that the accuracy of data should improve over time and thus setting a specific reliability threshold does not allow the flexibility needed to preclude poorly performing vendors.

Comment: A few commenters noted that in order to facilitate data validation, CMS should provide a mechanism to identify and verify the clinicians that are associated with a group by TIN and NPI. The commenters believed that QCDRs could more successfully serve clinicians if this information was readily available within the QPP Portal early in the performance year rather than requiring QCDRs to access the CMS Developer or Submissions API, which is not available until the third or fourth quarter of a reporting year.

Response: For the provider eligibility, CMS provides the public, including QCDRs participating in the Quality Payment Program, with API that can assist with determining eligibility for clinicians and groups which can be found at *https://cmsgov.github.io/qpp-eligibility-docs/*. Information can be obtained primarily by the Clinician type. You can query the Clinician type by passing in an National Provider Identifier, or NPI. The information contained in these endpoints includes basic enrollment information, associated organizations, information about those organizations, individual and group special status information. QCDRs do have access to the public API. The API is updated when our eligibility data is updated for the public. Therefore, QCDRs have the availability to pull the data at the same time as clinicians to go into the QPP look up tool to check their eligibility. The final eligibility runs are not complete until the second eligibility determination period concludes, which falls on the close of the Fiscal Year. We do not allow TIN lookup, as this information is viewed as PII, but all data can be viewed by group name or NPI. In addition, we do offer third party intermediaries, excluding the CAHPS for MIPS vendors, the ability to utilize OAUTH integration to allow for more robust set of access and integration. Please refer to sections VII. and VIII. of this final rule where this process is discussed in greater detail.

After consideration of public comments, we are finalizing the proposed data validation requirements and targeted audit requirements at § 414.1400(b)(2)(iv) and (v) as proposed.

(b) QCDR Measures

We refer readers to § 414.1400(b), the CY 2017 Quality Payment Program final rule (81 FR 77374 through 77375), the CY 2018 Quality Payment Program final rule (82 FR 53813 through 53814), the CY 2019 PFS final rule (83 FR 59900 through 59906), the CY 2020 PFS final rule (84 FR 63058 through 63074), and the May 8th COVID–19 IFC (85 FR 27594 through 27595) for where we previously finalized standards and criteria for QCDR measures. In the CY 2021 PFS proposed rule (85 FR 50326), we proposed modifications to previously finalized QCDR measure requirements. While we understand the level of time and work needed to meet these requirements, we would not be grandfathering in previously approved QCDR measures.

(i) QCDR Measure Considerations and Requirements for Approval or Rejection

We refer readers to § 414.1400(b)(3), the CY 2020 PFS final rule (84 FR 63059 through 63073) for our previously finalized policies related to the QCDR measure considerations and requirements for approval or rejection. Through education and outreach, we have heard stakeholders' concerns about the complexity of reporting when there is a large inventory of QCDR measures to choose from, and we noted that we believe the proposals would help to refocus measures to those most meaningful to a clinician's scope of practice.

In the 2021 PFS proposed rule, we proposed to modify a few QCDR measure requirements: Measures in MVPs; measure testing; duplicative QCDR measures; and collection of data as discussed below.

(A) QCDR Measures in MVPs

We refer readers to section IV.A.3.a. of this final rule, where we discuss QCDR measures in MVPs. While we acknowledged the level of innovation that QCDRs have put forward as they have developed and implemented QCDR measures, we noted the differences between the QCDR measures utilized in the existing MIPS reporting method versus that of MVP reporting. In the current MIPS program, clinicians and groups may select to report on measures from a large library of what is available through the MIPS quality measure inventory and that of the QCDR measures available, if they choose to report through a QCDR. In our gradual transition to MVPs, we move to subsets of measures and activities, where clinicians may have a more focused selection of items to report on.

For that reason, it is important that the measures included in an MVP are reliable, feasible, and valid as to not inadvertently cause a clinician or group an issue with submission, calculation, and scoring of a given measure. We refer readers to our discussion below about measure testing requirements for QCDR measures in MVPs.

(B) Measure Testing Requirements

In the CMS Blueprint,[142] measure testing enables a measure developer to assess the suitability of the quality measure's technical specifications and acquire empirical evidence to help assess the strengths and weaknesses of a measure with respect to the NQF Measure Evaluation Criteria and Guidance for Evaluating Measures for Endorsement. Information gathered through measure testing is part of full measure development, and this information can be used in conjunction with expert judgment to evaluate a measure. For Blueprint purposes, measure testing refers to testing quality measures, including the components of the quality measures, such as the data elements, the instruments, and the performance score.

We refer readers to the CY 2019 PFS final rule, where we gave notice to the public that we were considering proposing to require reliability and feasibility testing as an added criterion for a QCDR measure to be considered for MIPS in future rulemaking (83 FR 59901 through 59902). After consideration of the previous public comments received, and our priority to ensure that all measures available in MIPS are reliable and valid thereby reducing reporting burden on eligible clinicians and groups, we finalized a requirement to require all QCDR measures to be fully developed and tested, with complete testing results at the clinician level, beginning with the CY 2023 payment year in the CY 2020 PFS final rule (84 FR 40816).

(aa) Measure Testing Requirements in IFC

In response to the PHE, we issued changes in the May 8th COVID–19 IFC

[142] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*.

(85 FR 27594 through 27595). We had heard from third party intermediaries, specifically QCDRs, that due to the COVID–19 pandemic they anticipated being unable to complete QCDR measure testing or collect data on QCDR measures for the 2021 MIPS performance period as specified at § 414.1400(b)(3)(v)(C) and (D). Both QCDR measure approval criteria necessitate QCDRs collecting data from clinicians in order to assess the measure. Over 50 percent of the QCDRs approved for the 2020 performance period are supported by specialty societies that represent and support clinicians on the front lines of the COVID–19 pandemic, or are hospitals that are directly impacted by the pandemic. We also anticipated that there will be a lack of available data for some QCDR measures because clinicians who work in specialties that are not primarily caring for COVID–19 patients may have their cases or elective procedures canceled or delayed so that resources can be redistributed. As a result, we anticipated that QCDRs may be unable to collect, and clinicians unable to submit, data on QCDR measures due to prioritizing the care of COVID–19 patients.

We believed that clinicians who are on the frontlines taking care of COVID–19 cases should not be burdened with having to submit data to a QCDR for purposes of QCDR measure assessment (testing and data collection). In consideration of clinicians' limited resources and in an effort to reduce burden on clinicians and health care organizations that are responding to the COVID–19 pandemic, we are amending the QCDR measure approval criteria previously finalized in the CY 2020 PFS final rule (84 FR 63065 through 63068), specifically the completion of QCDR measure testing at § 414.1400(b)(3)(v)(C) as discussed in section II.R.1. of the May 8th COVID–19 IFC (85 FR 27594 through 27595).

In the CY 2020 PFS final rule (84 FR 63065 through 63067), we finalized at § 414.1400(b)(3)(v)(C) that beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. For the reasons discussed in May 8th COVID–19 IFC (85 FR 27594 through 27595), we delayed the implementation of this policy by 1 year. Specifically, we amended § 414.1400(b)(3)(v)(C) to state that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination.

During this 1 year delay, we will continue to review QDCR measures as in past years to ensure they are valid, reliable, and align with the goals of the Meaningful Measure initiative. This process includes review by quality measure experts; QCDR policy subject matter experts; clinicians, including physicians, nurses, and PTs/OTs, who work on our support contractor team; and CMS Medical Officers. We will continue to review QCDR measures for potential risk of patient harm (for example, QCDR measures that promote clinical practices related to overuse). We also will continue to review QCDR measures for feasibility and accuracy and reliability of results. For more information, we refer readers to the 2020 QCDR Measure Development Handbook.

The following is a summary of the comments we received and our responses.

Comment: A few commenters supported the proposed delay of QCDR measure data collection requirements such that developers will have until the 2022 performance period to collect complete testing results at the clinician level prior to submitting new measures for consideration.

Response: We thank commenters for their support.

Comment: One commenter recommended that CMS gradually implement the requirements and continue to monitor the impact COVID–19 may have on QCDR testing. The commenter expressed concern that it can take a developer months to execute a QCDR testing contract with a testing vendor and that the current number of vendors available will not be able to meet the increased demand. The commenter recommended that CMS allow a grace period for the new requirements for existing measures, with an initial focus on testing measures reported by the majority of QCDR participants. For new or modified measures, the commenter recommended that CMS provide provisional approval and require testing in a future year when more data is available for testing.

Response: We refer readers to the CY 2018 Quality Payment Program proposed rule (82 FR 30160) where we described our goal and sought comment on having fully tested QCDR measures within the MIPS program. Furthermore in the CY 2019 PFS final rule, we gave notice to the public that we were considering proposing to require reliability and feasibility testing as an added criteria in order for a QCDR measure to be considered for MIPS in future rulemaking (83 FR 59901 through 59902). Furthermore, as we have signaled through previous rulemaking cycles (83 FR 59901 through 59902), we have intended to raise the bar for QCDR measures that are available for reporting within the MIPS program.

After consideration of the public comments received in the CY 2019 PFS final rule, and our priority to ensure that all measures available in MIPS are reliable and valid thereby reducing reporting burden on eligible clinicians and groups, we moved forward with our proposal in the CY 2020 PFS proposed rule. Consequently, in the CY 2020 PFS final rule (84 FR 63065 through 63067), we finalized at § 414.1400(b)(3)(v)(C) that beginning with the 2021 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. For the reasons discussed in May 8th COVID–19 IFC (85 FR 27594 through 27595), we delayed the implementation of this policy by 1 year, until the 2022 performance period. Even before the publication of the May 8th COVID–19 IFC, QCDRs should have already been preparing for this measure testing to occur as part of the finalized policies in the CY 2020 PFS final rule. We believe stakeholders have had adequate notice of this requirement in order to prepare. Furthermore, as described in section IV.A.3.g.(2)(b)(i)(B) of this final rule, we are finalizing the proposed updates to the QCDR measure testing requirement to implement the measure testing requirement in an incremental manner.

Based off experience in past performance periods of the MIPS program, there have been several situations where QCDRs have flagged for us mid performance period that they had issues collecting data on a QCDR measure, had trouble implementing the QCDR measure, or had technical issues with the measure specifications. These issues, identified mid performance period have led to QCDRs informing us that they could no longer successfully support the reporting of the impacted QCDR measure. Such issues have had downstream impacts on clinicians who have to scramble at the last minute to quickly find an alternative measure to report to satisfy the quality reporting requirements of the MIPS program. It is evident that such issues demonstrated that these measures lacked reliability, validity, and feasibility and should not have been utilized in the program. Therefore, we believe it is critical to implement measure-testing standards

that will ensure that the QCDR measures in the MIPS program are reliable, valid, and feasible. This requirement will avoid the inadvertent burden to clinicians, particularly small practices and rural practices, that is associated with issues that occur with QCDR measure during the performance period. We understand that it is difficult to determine how the PHE for COVID–19 will impact QCDRs, but believe it is imperative that QCDR measures that are available in the program are reliable because of the associated scoring calculations that are connected to payment adjustments in the MIPS program. Furthermore, as described in the CY 2020 PFS final rule (84 FR 63066), while we understand the increased time and cost burdens associated with measure testing, we believe the benefits of completed measure testing far outweigh the burdens of it. We want all measures available in the MIPS program to be reliable, feasible, valid, and implementable within the program. We want to avoid scenarios that would arise by allowing measures that do not meet these standards, which then may lead to issues with the measure mid performance period. We do not believe it is appropriate to have untested measures within the MIPS program since clinician's performance on measures have impacts on their payments. We acknowledge that not all QCDR measures currently approved would continue in the program due to business decisions by each QCDR.

After consideration of public comments, in this final rule we are finalizing the delay of this policy by 1 year, such that § 414.1400(b)(3)(v)(C) states that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. To clarify, this policy is effective from May 8, 2020 through the end of the MIPS 2022 performance period since we are finalizing further changes to this policy below as described in section A.3.g.(2)(b)(i)(B) of this final rule, where we discuss the finalization of the proposed updates to the QCDR measure testing requirement to implement the measure testing requirement in an incremental manner beginning with the 2022 performance period.

(bb) Overview

With this delay in mind and based on stakeholder feedback on the level of burden, the limited amount of time, and costs associated with measure testing after the CY 2020 PFS final rule published, in the 2021 PFS proposed rule, we proposed to both further modify our QCDR measure testing policy generally and add testing policies for QCDR measures that are being considered for inclusion in MVPs. In that rule, we noted that we continue to believe that reliable, valid measures with robust testing with empirical data should be used in quality evaluation and payment programs. However, we discussed that we want to balance those interests with stakeholders' concerns. Therefore, we proposed a gradual approach to have fully tested QCDR measures within the MIPS program. We emphasized that we still believe that all QCDR measures should be fully tested, particularly as we rely on the data from these measures to score clinicians which impact their final score and associated MIPS payment adjustments, and as we seek to utilize QCDR measures in MVPs, as summarized in section IV.A.3.a of this final rule. In the 2021 PFS proposed rule, we proposed at § 414.1400(b)(3)(v)(C)(*1*) that, generally, to be approved for the 2024 MIPS payment year, a QCDR measure must be face valid. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. Therefore, we proposed to revise § 414.1400(b)(3)(v)(C) to account for an incremental approach to require fully tested QCDR measures. We discussed requirements for QCDR measures considered for inclusion in an MVP separately. These policies are discussed in more detail further below.

(cc) Requirements for Existing QCDR Measures

In the 2021 PFS proposed rule, we proposed that QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year. Face validity is defined in the CMS Measures Blueprint [143] as the following: The extent to which a test appears to cover the concept it purports to measure ''at face value.'' It is a subjective assessment by experts of whether the measure reflects the quality of care (for example, the utilization of a current clinical guideline to frame the measure, such as using the blood pressure guideline of < 140/90 is a marker of quality).

In addition, we proposed that these measures, which were approved for the preceding MIPS performance year with face validity (that is, CY 2024 MIPS payment year), would be required to be fully tested prior to being self-nominated for any subsequent performance periods (that is, CY 2025 MIPS payment year and beyond) in order to be considered for inclusion in the MIPS program.

In the CY 2019 PFS final rule, we referred readers to the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*) for a definition of ''fully developed with completed testing results at the clinician level'' (84 FR 40817). Our Blueprint discusses both alpha and beta testing (Blueprint 15.0 September 2019 Page 207–208). To avoid any potential confusion, we clarified in the CY 2021 PFS proposed rule that for purposes of QCDR measures, we would expect QCDR measures to complete beta testing to be considered fully tested. Beta testing is defined in the CMS Measures Blueprint [144] as the following: Beta testing (that is, field testing) generally occurs after initial technical specifications have been developed and is usually larger in scope than alpha testing. In addition to gathering further information about feasibility, beta tests serve as the primary means to assess scientific acceptability and usability of a measure. For example, beta testing allows for an enhanced evaluation of a measure's importance, including evaluation of performance thresholds, disparities analysis, and outcome variation. It helps in looking for opportunities for improvement in the population, which aids in measuring the QCDR measure's importance for reasons that include evidence collection to measure variability among comparison groups, to demonstrate the measure is not topped-out where most groups achieve similarly high performance levels approaching the measure's maximum possible value. We referred readers to the CMS Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/*

[143] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

[144] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

Blueprint.pdf for additional details regarding beta testing.

The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to delay the requirement for QCDR measures to be fully tested by 1 year and only require face validity for the 2021 performance period.

Response: We thank commenters for their support. In the 2021 PFS proposed rule, we proposed that QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year. We want to clarify for commenters that this policy would affect the 2022 performance year.

Comment: A few commenters recommended that the requirement for full measure testing should be further delayed until at least 1 year after the PHE for COVID–19 ends. One commenter cited its preference for an approach where a potential measure is tested and peer reviewed by a committee for inclusion in the program.

Response: In the May 8th COVID–19 IFC (85 FR 27594 through 27595), we already delayed the requirement due to the PHE, such that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. However, in the 2021 PFS proposed rule, we proposed further changes, such that QCDR measures that were previously approved for the CY 2022 MIPS payment year, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2024 MIPS payment year. In addition, we proposed that these measures, which were approved for the preceding MIPS performance year with face validity (that is, CY 2024 MIPS payment year), would be required to be fully tested prior to being self-nominated for any subsequent performance periods (that is, CY 2025 MIPS payment year and beyond) in order to be considered for inclusion in the MIPS program. Therefore, fully tested measures are not required until the CY 2025 payment year and subsequent years (CY 2023 performance year). We believe this is a reasonable amount of time to prepare and balances the need to have fully tested, valid, and reliable measures in the MIPS program, which bases payment on quality metrics such as QCDR measures. While we do not specifically require QCDRs to utilize a process that involves peer review by a committee, we support those QCDRs that wish to do so.

Comment: A few commenters requested additional clarification on the required process and evaluation criteria for QCDR measure testing. Commenters requested detailed requirements and specific targets to enable greater understanding of how testing should be completed, as well as clarification on how CMS will evaluate the measures to determine if they ''pass'' and whether full measure testing will undergo the same, similar, or a different rigor as the National Quality Forum's measure testing. Commenters also requested clarification on the likelihood of QCDRs having their measures accepted if they are not fully tested; how the level of testing affects the measure review process in the future; who is conducting the measure review process; and what format is being used. Other commenters suggested that CMS empanel specialty specific committees of knowledgeable clinicians to evaluate self-nominated quality measures and should a QCDR measure not be approved, CMS should provide specific information on what criteria were not met and enable the QCDR to correct the deficiencies in time for the measure reconsideration meeting. One commenter provided the following recommendations regarding QCDR measure testing requirements: When assessing face validity, CMS should allow for a clear and direct association with a clinical guideline to be sufficient to fulfill face validity for a measure, especially when the guidelines are released by organizations with a strong record of high-quality clinical guideline development; if a QCDR measure has been endorsed by the NQF and is submitted to CMS, the requirement to document measure testing information for CMS should be waived, as long as the NQF measure ID is provided; and once a thoroughly tested QCDR measure has been approved by CMS, the testing requirement should be waived for subsequent years unless CMS identifies a significant substantive change to the measure that would necessitate new testing.

Response: As discussed in the proposed rule and above, in the CY 2019 PFS final rule, we referred readers to the CMS Blueprint for the CMS Measures Management System (available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*) for a definition of ''fully developed with completed testing results at the clinician level'' (84 FR 40817). Our Blueprint discusses both alpha and beta testing (Blueprint 15.0 September 2019 Page 207–208). To avoid any potential confusion, we clarified in the CY 2021 PFS proposed rule that for purposes of QCDR measures, we would expect QCDR measures to complete beta testing to be considered fully tested. Beta testing is defined in the CMS Measures Blueprint [145] as the following: Beta testing (that is, field testing) generally occurs after initial technical specifications have been developed and is usually larger in scope than alpha testing. In addition to gathering further information about feasibility, beta tests serve as the primary means to assess scientific acceptability and usability of a measure. For example, beta testing allows for an enhanced evaluation of a measure's importance, including evaluation of performance thresholds, disparities analysis, and outcome variation. It helps in looking for opportunities for improvement in the population, which aids in measuring the QCDR measure's importance for reasons that include evidence collection to measure variability among comparison groups, to demonstrate the measure is not topped-out where most groups achieve similarly high performance levels approaching the measure's maximum possible value. We referred readers to the CMS Blueprint for the CMS Measures Management System at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf* for additional details regarding beta testing.

We understand the NQF's measure testing guidelines are described at *http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx*. While our QCDR measure testing policies provide an incremental approach to measure testing while being available in the program, we believe our measure testing policies are similar. Thus, we anticipate that many measures that have received NQF endorsement would also be easily approved for this program; however, we are not waiving measure testing requirements. We note that QCDRs must self-nominate their measures each year unless the QCDR measure was approved for a 2-year period. We refer readers to the CY 2020 PFS final rule (84 FR 63073) where we discuss this process in more detail.

QCDR measures that do not meet the incremental requirements of measure testing over the 2-year period as described further above, will not be

[145] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf*.

approved for use in the program for not meeting requirements. If a QCDR measure is not fully tested by the self-nomination period, the QCDR should delay self-nomination of the QCDR measure until a future year once it has been fully tested.

Comment: Several commenters disagreed with the requirement for QCDR measures to be fully tested. Commenters expressed concerns that validity testing beyond face validity is not feasible for most quality measures and due to the time and expense involved may cause some registries to no longer invest in measure development and potentially leave the program. One commenter noted that full measure testing fails to account for the significant investments that QCDRs already make when developing measures to ensure the accuracy of their measures, including vetting by clinical subject matter experts and reliance on clinical practice guidelines, the medical literature, and preliminary data. A few commenters encouraged CMS to consider alternatives to the measure testing process such as opening the measures for public comment.

Response: We believe that measures should be reliable and valid with robust testing using empirical data prior to inclusion in a national pay-for-performance CMS program. Quality measurement should ensure measures are reliable, valid, and feasible, and this is supported by literature.[146] We disagree that validity testing beyond face validity is not feasible, since the quality measures available in the MIPS quality measure inventory are fully tested. We understand there is time, effort, and resources involved with measure testing but we believe that this must be a requirement in order to ensure we have reliable, valid, and feasible measures in a pay-for-performance program such as MIPS. We do not believe that an alternative approach such as face validity or public comment alone would meet the same rigor of validity. Furthermore, QCDRs should be held to the same standards of requirements as other measure developers. QCDRs should be developing measures utilizing measure development standards that are universally accepted by measure developers, inclusive of standardized testing procedures. The utilization of clinical experts, reliance on clinical guidelines, medical literature, and preliminary data are common practices amongst measure developers to ensure measures are developed in a relevant manner. However, these criteria that are used to develop a measure, do not replace the need for measure testing which goes beyond measure development and ensures the measure is reliable, valid, and feasible.

After consideration of public comments, we are finalizing our proposals as proposed.

(dd) Requirements for New QCDR Measures

We proposed that for a new QCDR measure to be approved for the 2024 MIPS payment year, a QCDR measure must be face valid; to be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

For example, for the CY 2026 MIPS payment year (the 2024 performance period), the self-nomination application period would open on July 1, 2023 and close on September 1, 2023. A QCDR that self-nominates a new QCDR measure by September 1, 2023 would need to complete face validity measure testing prior to submission in order for the measure to be considered for the CY 2026 MIPS payment year. If that new QCDR measure is approved for the CY 2026 MIPS payment year, it would need to be fully tested by the next self-nomination date for the CY 2027 MIPS payment year (by no later than September 1, 2024 for the 2025 performance period). QCDR measures that are not fully tested by the second year of the measure's life in MIPS (that is, second self-nomination date), would not be considered for approval for the second year.

We recognized that not all QCDR measures currently approved would continue in the program due to business decisions by each QCDR. We acknowledged that there is a cost involved with full testing of quality measures (see 84 FR 63173); however, we noted that we believe it is important that all measures used within the MIPS program are fully tested and reliable. We also noted that we believe this incremental approach in testing would allow QCDRs time to plan appropriately to complete measure testing in a timely, efficient, and effective manner. However, we encouraged QCDRs to submit fully-tested QCDR measures to the extent possible, as we have a strong preference for QCDR measures that are fully tested versus those that have only completed face validity testing.

The following is a summary of the comments we received and our responses.

Comment: A few commenters agreed with the proposal to require new QCDR measures to be face valid for the 2024 MIPS payment year and to be approved for the 2025 MIPS payment year and future years. A few commenters also agreed that a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

Response: We thank the commenters for their support.

Comment: Several commenters disagreed with the requirement that new QCDR measures must be fully tested by the subsequent performance period after initial approval due to their belief that the requirement is costly, burdensome, and arduous. A few commenters further stated that QCDR measures are created by subject matter experts; undergo significant expert vetting; are supported by literature, guidelines, and preliminary data, providing rigorous face validity for each measure; and QCDRs typically review performance data before and after implementing a measure in the registry. One commenter stated that these requirements may lead to the costs of measure development outweighing the benefit of operating QCDRs and that CMS is inherently making it impossible for small organizations to run QCDRs and develop new measures.

Response: We disagree with the commenters. While we understand the level of effort, time, and finances involved with measure testing, we believe it is important that all measures in a national pay-for-performance program such as MIPS are fully tested, as they are relied upon to make performance determinations and thereby corresponding payment adjustments. CMS is holding measures used in the QPP program to the same standards—whether they be measures generally available or measures solely submitted by QCDRs. We do acknowledge and appreciate the efforts and participation of QCDRs that are run by organizations of varying sizes, but believe it is important to hold all measures to the same standard, to ensure that we have reliable, valid, and feasible measures in the MIPS program for clinician use. We understand that measure testing requires a level of effort, resources, finances, and time in order to be completed. However, we believe that all measures should meet such rigorous standards in a pay-for-performance quality reporting program. QCDRs that require more time to test their measures,

[146] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint.pdf.*

may do so outside of the MIPS program, and can delay self-nominating a QCDR measure until the testing is appropriately completed.

Comment: A few commenters requested that CMS modify the proposed requirement that testing data for new QCDR measures must be submitted by the next self-nomination period and change it to the second self-nomination period due to its belief that many QCDRs rely on prospective data collection to generate the data needed for testing and therefore, will not have 12 months of data available and analyzed by the next self-nomination deadline (September 1). Another commenter stated that it would be impossible to explore and develop testing options and complete the testing process by the September 1, 2020 self-nomination deadline for the 2021 performance period.

Response: We refer readers to the CY 2020 PFS final rule (84 FR 63065 through 63067 and § 414.1400(b)(3)(v)(C), where we first finalized a requirement to fully test measures beginning with the 2022 performance period. Due to the PHE, we delayed this requirement in the May 8th COVID–19 IFC (85 FR 27594 through 27595), such that beginning with the 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. In this final rule, we are further changing our requirements to finalize that for a new QCDR measure to be approved for the 2024 MIPS payment year, a QCDR measure must be face valid; to be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. We believe stakeholders have had adequate advanced notice of this requirement. This incremental approach in testing would allow QCDRs time to plan appropriately to complete measure testing in a timely, efficient, and effective manner. While we understand the level of effort, time, and finances involved with measure testing, we believe it is important that all measures in a pay-for-performance quality program such as MIPS are fully tested, as they are relied upon to make performance determinations and thereby corresponding payment adjustments.

After consideration of public comments, we are finalizing our proposal as proposed.

(ee) Requirements for QCDR Measures Considered for MVP

As an additional layer, we proposed at § 414.1400(b)(3)(v)(C)(*2*) that in order for a QCDR measure to be considered for inclusion in an MVP for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested. We noted that we believe it is imperative to ensure that QCDR measures are fully tested before being included in an MVP. Unlike traditional MIPS, where clinicians and groups may choose from a large inventory of measures to report on for purposes of the quality performance category, the MVPs seek to create a focused selection of measures and activities relevant to a specific clinical topic. Since clinicians and groups who choose to report on MVPs will be reporting on a subset of measures and activities, there will be heavy reliance on the QCDR measures being reliable, valid, and feasible for reporting purposes. For a detailed discussion of MVPs, we refer readers to section IV.A.3.a. of this final rule.

The following is a summary of the comments we received and our responses.

Comment: Several commenters agreed with the proposal to require that QCDR measures that will be included in an MVP be fully tested.

Response: We thank commenters for their support.

Comment: One commenter stated that QCDR measures that are only undergoing testing should be considered for inclusion in MVPs and that Improvement Activity credit be given to practices involved in measure testing.

Response: We disagree that measures in the testing phase should be considered for MVPs; inclusion should be limited to only those that are fully tested due to this being a pay-for-performance national program. With regards to improvement activity credit, we would encourage stakeholders to submit recommendations for improvement activities during the Call for Improvement Activities that occurs on an annual basis for consideration and potential inclusion in the program for future years.

Comment: One commenter requested that CMS further delay full testing of QCDR measures and subsequently QCDR MVPs. A few commenters disagreed with the proposal to require QCDR measures to be fully tested at the clinician level prior to being considered for inclusion in an MVP due to the expense. The commenters also believe that it is inconsistent with the proposed timeline for QCDR measures under MIPS which requires face validity for performance year 2022 and full testing for performance year 2023.

Response: We disagree with commenters. We believe that in order for QCDR measures to be considered reliable metrics in a pay-for-performance program such as MIPS, the measures must be fully tested. Any delay in fully tested QCDR measures will have downstream impacts with regards to the timing in which these measures can be considered for inclusion in MVPs in future years. We also want to clarify that QCDR measures that were fully tested at the time of self-nomination (July 1, 2020 through September 1, 2020) for the 2021 performance period, would be eligible for inclusion in MVPs for the 2022 performance period. We are aware that full testing of QCDR measures was not a requirement for the 2021 performance period, but have come across instances where some QCDRs have been diligently working to test or have completed testing their QCDR measures that are currently in the program and believe those fully tested QCDR measures are potentially ready to be considered for inclusion within an MVP. QCDR measures that are not fully tested will not be considered for inclusion in an MVP.

After consideration of public comments, we are finalizing our proposal as proposed.

(C) Duplicative QCDR Measures

Throughout previous rulemaking cycles, we have communicated our desire to eliminate duplicative QCDR measures in the MIPS program, as it is counterintuitive to the Meaningful Measure Initiative (84 FR 63068). One of the methods we previously suggested to address duplicative measures is measure harmonization, as discussed in the CY 2020 PFS final rule (84 FR 63068 through 63070). We have received comments and questions from stakeholders, requesting clarification for us to define what we mean by measure harmonization.

In this rule, we intend on clarifying that measure harmonization means ''measures for which previously identified areas of duplication with other approved QCDR measures or MIPS quality measures have been addressed.'' We proposed to revise previously codified policies that refer to measure harmonization with this updated terminology.

Therefore, we proposed to revise § 414.1400(b)(3)(v)(E), to state, beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs

address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

In addition, we proposed to revise § 414.1400(b)(3)(vi) to state, beginning with the 2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

Furthermore, we proposed to remove two previously codified policies that we have identified as areas of redundancy. We proposed to remove § 414.1400(b)(3)(vii)(H), which states whether the previously identified areas of duplication have been addressed as requested, and to remove § 414.1400(b)(3)(vii)(L), which states whether the existing approved QCDR measure is no longer considered robust, in instances where new QCDR measures are considered to have a more vigorous quality actions, where CMS preference is to include the new QCDR measure rather than requesting QCDR measure harmonization. We noted that we believe the previously finalized regulatory text under § 414.1400(b)(3)(vii)(A), which states QCDR measures that are duplicative, or identical to other QCDR measures or MIPS quality measures currently in the program will address instances where areas of duplication amongst QCDR measures are not addressed or where a QCDR measure approved for a previous year is duplicative with a QCDR measure approved for the current year.

As a result of the proposed removals of two previously codified policies, we proposed technical updates to re-number the regulation text to reflect the removals. Therefore, in § 414.1400, we proposed to redesignate paragraphs (b)(3)(vii)(I), (J), (K), (M), and (N) as paragraphs (b)(3)(vii)(H), (I), (J), (K), and (L), respectively.

The following is a summary of the comments we received and our responses.

Comment: One commenter expressed its support for removing QCDR measures that reflect outdated clinical guidelines or if the QCDR that nominated the measure is no longer in good standing. A few commenters agreed with CMS' proposals to revise QCDR measure harmonization policies and remove previously codified policies that it has identified as redundant due to its belief that it supports standardization of measures across providers and settings.

Response: We agree that measures that reflect outdated clinical guidelines no longer provide accurate clinical measurement that can lead to quality improvement. In addition, we agree with commenters that a QCDR's standing in the program should impact the availability of their QCDR measures in the program. Furthermore, we thank commenters for agreeing with some of the criteria we use to retire measures from the program as well as our need to harmonize measures and the benefit it conveys to the program. Some of these benefits include fewer measures for clinicians to have to read through (burden reduction) as well as better direct comparison between providers reporting on the same measure as opposed to a similar measure.

Comment: One commenter encouraged CMS to continue to encourage measure development programs to identify commonalities and gaps in existing systems rather than create new programs to identify new measures. Another commenter urged CMS to implement adequate safeguards to ensure that measure harmonization occurs only when it is clinically appropriate to do so.

Response: We continue to encourage QCDRs and measure developers to address measurement gaps identified in the MIPS program. To clarify, we are not creating new programs to identify new measures but are utilizing our existing processes to identify measurement gaps. On an annual basis, we publish our CMS Quality Measure Development Plan (MDP) and the MDP annual report. The MDP helps us build and improve quality measures clinicians can report under the MIPS program. The MDP includes environmental scans, gap analyses, and work with stakeholders. This report is published on an annual basis to help us get expert input about the measures we need, prioritize areas of measure development, evaluate existing quality measures, to meet our goal value-based measures to support the Quality Payment Program. We refer readers to the Quality Payment Program Measure Development website where we have published the 2020 MDP Annual Report at *https://www.cms.gov/Medicare/Quality-Payment-Program/Measure-Development/Measure-development.* We encourage QCDRs to utilize the MDP as they work through the measure development-planning phase to determine which identified gaps they would like to address through measure development.

With respect to safeguards, when measures are reviewed for areas of duplication, all of the similar measures are evaluated. We would encourage QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

Comment: One commenter disagreed with the policies to remove a QCDR measure before its second year for it being topped out or duplicative of a more robust measure.

Response: We continue to believe that duplicative QCDR measures should not be in the MIPS program, as that is contradictory to the Meaningful Measure Initiative. Including duplicative or topped-out measures in the program adds to burden without meaningfully improving care or quality.

Comment: A few commenters requested CMS consider certain priorities when identifying duplicative QCDR measures and encouraging harmonization, such as: Prioritizing the original measure until subsequent measures are proven to have surpassed it, prioritizing the more scientifically rigorous measure, and identifying the measure that best advances the goals of the program. One commenter also requested that CMS consider providing measure stewards specific reasons when new measures are identified as duplicative and provide an opportunity to improve or replace the existing measure.

Response: We continue to encourage QCDRs to work collaboratively amongst each other to address areas of duplication within their QCDR measures. In this final rule, we are finalizing at § 414.1400(b)(3)(v)(E) that beginning with the 2022 MIPS payment year, we may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, we will not approve the duplicative QCDR measure. In our review of measures, we do try to identify new measures that might be duplicative and reasons why, inform QCDRs submitting duplicative measures, and encourage the QCDRs to address the duplication in a timely manner.

After consideration of the public comments, we are finalizing our proposals as proposed.

(D) Collection of Data on QCDR Measure

In the CY 2020 PFS final rule (84 FR 63067 through 63068), we finalized at § 414.1400(b)(3)(v)(D) that beginning with the 2021 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

(i) Delay of Data Collection in IFC

As mentioned previously in this section of the final rule, due to the PHE we delayed certain requirements in the May 8th COVID–19 IFC (85 FR 27594 through 27595). In the CY 2020 PFS final rule (84 FR 63067 through 63068), we finalized at § 414.1400(b)(3)(v)(D) that beginning with the 2021 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period. For the reasons discussed in section II.R.2. of the May 8th COVID–19 IFC (85 FR 27594 through 27595), we delayed the implementation of this policy by 1 year. Specifically, we amended § 414.1400(b)(3)(v)(D) to state that beginning with the 2022 performance period, QCDRs are required to collect data on a QCDR measure, appropriate to the measure type, prior to submitting the QCDR measure for CMS consideration during the self-nomination period.

During this 1-year delay, we will continue to review QDCR measures as in past years to ensure they are valid and identify performance gaps in the area of measurement. As described in the 2020 QCDR Measure Development Handbook, this process includes vetting the measures to ensure they are implementable and collectible, which includes an evaluation of the measure and coding constructs (for example, whether the measure is constructed as a ratio, proportional, or inverse measure). Additionally, we will review the evidence provided by the QCDR (for example, clinical studies and/or scientific journals) that would support the need for measurement in lieu of insufficient data collection to demonstrate that there is a measurement gap.

The following is a summary of the comments we received and our responses.

Comment: Commenters supported the delay of QCDR data collection requirements on count of concerns due to burden and likely delays in the development of new measures, problems that would only be exacerbated by the current PHE for COVID–19. Another commenter urged CMS to continue to monitor the PHE for the viability of this requirement for CY 2021.

Response: We thank commenters for their support. We are continuing to monitor the PHE.

After consideration of public comments, we are adopting our policy as finalized in the May 8th COVID–19 IFC (85 FR 27594 through 27595).

(3) Qualified Registries

We refer readers to §§ 414.1305 and 414.1400, the CY 2018 Quality Payment Program final rule (82 FR 53815 through 53818), CY 2019 PFS final rule proposed rule (83 FR 59906), and the CY 2020 PFS final rule (84 FR 40819 through 40820) for our previously finalized policies regarding qualified registries. In the CY 2021 PFS proposed rule (85 FR 50328), we proposed a technical update to the title at § 414.1400(c) to rename it from ''qualified registry approval criteria'' to ''qualified registries'', to better align the title with the content of the regulation. In addition, we proposed requirements related to data validation audits and targeted audits.

In the CY 2017 Quality Payment Program final rule, we discussed our expectation related to QCDRs and qualified registries would conduct validation on the data they intend on submitting for the MIPS performance period (81 FR 77384 through 77386) and provide the results of the data validation to CMS in the form of a data validation execution report by May 31st of the year following the performance period. Our intention was to establish our expectation that qualified registries would establish a process to assess whether the data are true, accurate, and complete prior to submitting them to CMS for purposes of the MIPS program. We believe it is important to establish a requirement that qualified registries conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. In instances where a qualified registry discovers data are inaccurate or incomplete, the entity must correct the issue prior to submitting the data to CMS in order to provide accurate certification in accordance with § 414.1400(a)(5). A qualified registry that submits a false certification submits data that is inaccurate, unusable or otherwise compromised to CMS for purposes of the MIPS program may be subject to remedial action or termination under § 414.1400(f). We believe requiring qualified registries to validate the accuracy of the data they are submitting is an important safeguard to promote accurate payments under the MIPS program. Therefore, we proposed at § 414.1400(c)(2)(iii) and (iv) requirements beginning with the 2023 MIPS payment year as condition of approval each qualified registry must conduct annual data validation audits and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits. We also proposed specific obligations for those audits as discussed below.

- We proposed to codify at § 414.1400(c)(2)(iii)(A), the qualified registry must conduct their data validation audits prior to submitting any data to CMS for purposes of the MIPS program. We noted that we believe it is important for qualified registries to conduct validation audits to identify and fix concerns regarding data accuracy prior to submitting data to us, including potential issues related to data aggregation and calculation. Conducting the data validation prior to data submission will lead to data being more reliable and promote compliance with the requirement of data being true, accurate, and complete. In the CY 2017 Quality Payment Program final rule, we described this auditing using the term randomized audit (81 FR 77384). We proposed instead to refer to this audit as the data validation audit in an effort to be abundantly clear regarding our expectations that the qualified registry will purposefully construct a sample and conduct and audit that complies with specific regulatory requirements and also to distinguish these audits from the targeted audits discussed below and proposed at § 414.1400(c)(2)(v).
- We proposed to codify at § 414.1400(c)(2)(iii)(B), the qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories. We believe that it is important that data validation be done across all performance categories for which the qualified registry submits data since qualified registries must attest that data submitted to CMS is true, accurate, and complete and data for each of these performance categories can influence score calculation and payment adjustments.
- We proposed to codify at § 414.1400(c)(2)(iii)(C), that the

qualified registry must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants. We noted that we believe it is important for the data submitted to CMS be accurate for all clinicians and groups for which the qualified registry intends on submitting data to the MIPS program, regardless of whether they are required to participate, have opted in, or have chosen to voluntarily participate. Therefore, we proposed to require that the data validation audits should account for all types of submitters that are utilizing the qualified registry to submit data to CMS for purposes of the MIPS program. We noted the importance of validating data for all submitter types regardless of its use for payment or public reporting. Even clinicians who voluntarily report to MIPS and whose data are not used for payment purposes could have their data publically posted on the Physician Compare website. We noted that we believe all data the qualified registry submits, regardless of its use for payment or public reporting, should be true, accurate, and complete.

• We proposed to codify at § 414.1400(c)(2)(iii)(D) that the qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed. If the data a qualified registry intends to submit to CMS for purposes with the MIPS program are to demonstrate that a clinician did a particular clinical activity or achieved a particular clinical outcome, we noted that we believe meaningful validation of such data requires the qualified registry to use clinical documentation to confirm that the activity occurred or was performed.

• We proposed to codify at § 414.1400(c)(2)(iii)(E), the qualified registry shall conduct each data validation audit using a sampling methodology that meets the following requirements:

++ Uses a sample size of at least 3 percent of the TIN/NPIs for which the qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the qualified registry may use a sample size of 50 TIN/NPIs.

++ Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

We believe the aforementioned sampling methodology is appropriate for multiple reasons. First, the sampling methodology criteria are consistent with the methodology established under the legacy Physician Quality Reporting System (PQRS) program and as described in the CY 2017 Quality Payment Program final rule (81 FR 77366 through 77367). As this methodology has been used for many years under the legacy program, we believe stakeholders are well versed in executing data validation audits using this sampling methodology. Second, the proposed methodology accounts for QCDRs and qualified registries of varying sizes. Data validation requires a level of effort on the part of the qualified registry to execute a data validation plan, identify a sample, and collect information for purposes of chart review; therefore, we are cognizant that requiring a larger sample size would create additional burden on qualified registries and clinicians to account for a larger volume in TIN/NPIs and medical records for review.

• We proposed to codify at § 414.1400(c)(2)(iii)(F) that each qualified registry data validation audit must include the following:

++ Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant. We believe that it is important for the qualified registry to track the eligibility status of each clinician and group that wishes to use a third party intermediary to report, because accurate information regarding eligibility is important to ensuring payment adjustments are properly applied. Furthermore, verification of eligibility status is consistent with the requirement for qualified registries to track opt-in participants, as described at § 414.1400(a)(4)(iv) and in the context of clinicians who voluntarily report to MIPS helps ensure the accuracy of data publically posted on the Physician Compare website (or a successor website) of the CMS website.

++ Verification of the accuracy of Tax Identification Numbers (TINs) or National Provider Identifiers (NPIs). Correct TINs and NPIs are critical to ensure data submitted by the qualified registry are attributed to the correct clinicians and groups. Inaccurate NPIs or TINs may lead to inadvertent downstream impacts to the way clinicians and groups are scored, and assigned a payment adjustment.

++ Calculation of reporting and performance rates (for example, formulas included in the quality measure specifications). Qualified registries must follow the measure specifications when calculating reporting and performance rates. Calculations that deviate the formulas included in the quality measure specifications undercut efforts to ensure data are consistent, reliable, and have been calculated in a uniform manner.

++ Verification that only MIPS quality measures and qualified registry measures that are relevant to the performance period will be utilized for MIPS submission. Measure specifications for the MIPS quality measures and qualified registry measures go through maintenance on an annual basis. Use of outdated measure specifications would likely result in the qualified registry submitting inaccurate or compromised data for the clinicians and groups they support. While not all measures go through substantive changes on an annual basis, there are changes to codes that do occur annually that should be accounted for when programing measures. Therefore, we believe it is important that qualified registries are utilizing the most current version of the measure specification, relevant to the performance period in which they are participating.

• We proposed to codify at § 414.1400(c)(2)(iii)(G), that in a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. We believe it is important that the results of the data validation be shared with us in order for us to understand the types of issues the qualified registries have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education. It is our belief that the report will be largely comprised of issues that were identified and resolved. However, if an issue has been identified and could not be resolved, we would want to understand what the issue is and why it could not be resolved. We emphasized that all data submitted to CMS by a qualified registry on behalf of a MIPS eligible clinician, group or virtual group must be certified by the third party intermediary as true, accurate, and complete to the best of its knowledge as described in

§ 414.1400(a)(5). If a qualified registry submits a false certification or data that are data that are inaccurate, unusable, or otherwise compromised, the qualified registry may be subject to remedial action or termination as described at § 414.1400(f).

- We proposed to codify at § 414.1400(c)(2)(iv)(A) that if a data validation audit under § 414.1400(c)(2)(iii) identifies one or more deficiency or data error, the qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year. We believe targeted audits are important to further evaluate the impact of deficiencies or data errors to the cohort of clinicians and groups that the qualified registry intends to submit data for, and for qualified registries to determine the reason the deficiency or data error occurred.
- We proposed to codify at § 414.1400(c)(2)(iv)(B), that the qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year. To promote the accuracy of the data submitted to the MIPS program for the payment year and to reduce the risk that the agency initiates payment calculations in reliance on inaccurate data, it is important for the qualified registry to conduct required targeted audits and correct any deficiencies and data errors identified through those audits prior to submitting the data to CMS.
- We proposed to codify at § 414.1400(c)(2)(iv)(C), the qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (c)(2)(iii)(E). The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified. We believe the sampling methodology we proposed for data validation audits is equally appropriate for the conduct of targeted audits. We believe that adopting the same methodology for both audit types would be less burdensome on qualified registries than requiring these entities to apply a separate sampling methodology for their targeted audits. Provided that data in the sample for the targeted audit does not overlap with the data that was reviewed in the data validation audit, we believe the targeted audit would provide the qualified registry with a reasonable perspective into impact and root cause of deficiencies and data errors across the data to be submitted without imposing the burden that would result from maintaining a separate sampling methodology for targeted audits.
- We proposed to codify at § 414.1400(c)(2)(iv)(D), in a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each error type was corrected. As is the case with the results of data validation audits, we believe it is important that the results of the targeted audits be shared with us in order for us to understand the types of issues the qualified registries have encountered and what resolutions were executed to fix the issues. The information provided will help us track frequently occurring issues which may be identified as an area to provide further education.

We requested comments on the proposals, including whether stakeholders are concerned with implementing the policies for the 2023 MIPS payment year, and if so, what barriers do they believe they would face in implementing the requirements.

The following is a summary of the comments we received and our responses. We also refer readers to the QCDR section of this final rule (section IV.A.3.g.(2)) where qualified registries can view applicable comments and responses.

Comment: A few commenters disagreed with the proposal to require qualified registries to conduct data validation due to their belief that it will unnecessarily increase burden for qualified registries who are already validating data prior to submission to CMS. One commenter disagreed with the requirement to perform data validation for each submitter type because of the low number of participants reporting via the qualified registry as individuals and stated that the randomized auditing on a small sample would result in the unintended consequence of increasing the burden of these clinicians without necessarily improving the quality of data submitted and that such a policy change would result in some practices being audited multiple times, sometimes within the same year, based on their submission category. Several commenters disagreed with the proposal to require data validation specific to performance category, submission mechanism, and submitter type due to their belief that the proposal creates unreasonable burdens for clinicians, qualified registries; would result in some individuals or groups being audited more often and less randomly in circumstances where the number of individuals/groups for a specific submitter type is lower; will impose a substantial financial burden on small, specialty society registries; is duplicative of internal quality data controls and external audits already conducted; and data validation for clients who are manually entering data may be difficult to audit, as many clinicians and practices do not complete data entry until late in the fourth quarter of the performance year.

Response: We continue to believe it is important to establish a requirement that qualified registries conduct data validation to ensure they are actively monitoring the data they submit to CMS for purposes of a pay-for-performance program. Furthermore, at § 414.1400(c)(2)(iii) and (iv) requirements beginning with the 2023 MIPS payment year as condition of approval each qualified registry must conduct annual data validation audits and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits. We understand that some qualified registries may have a small number of clients that are submitting data through their registry for purposes of MIPS reporting, but believe that data integrity is a high priority, and believe that data validation should occur regardless of the size of the clinician population the third party intermediary supports. As a point of clarification, we do not require multiple data validation audits to occur within the same year. Our data validation sampling methodology allows qualified registries to select a percentage of their clients. As noted above, correct data is vital to inform clinicians of their quality performance—let alone determining payment differentials that affect all participants in the program.

Comment: Another commenter stated that while they can perform a randomized audit requesting documentation from the EHR on Promoting Interoperability measure data to ensure accurate transposition and monitoring of errors and clinical documentation to ensure the Improvement Activities was attested to correctly, any errors discovered will be errors on the part of the practice or physician, not the registry.

Response: We appreciate the commenter's observation that in some instances the data validation conducted by a qualified registry may identify errors that stem from inaccuracies in the data supplied by the practice or

physician. Data validation requirements are intended to help ensure the qualified registry's data submissions to CMS are true, accurate, and complete. Therefore, if a qualified registry identifies errors in data on a Promoting Interoperability measure or Improvement Activity that it attributes to a practice or physician, the registry has shared responsibility to ensure the registry's submissions to CMS do not include that inaccurate data.

After consideration of the comments received, we are finalizing our proposals as proposed.

(4) Remedial Action and Termination of Third Party Intermediaries

We refer readers to § 414.1400(f), the CY 2017 Quality Payment Program final rule (81 FR 77548), CY 2019 PFS final rule (83 FR 59908 through 59910), and the CY 2020 PFS final rule (84 FR 63077 through 63080) for previously finalized policies for remedial action and termination of third party intermediaries.

As described in § 414.1400(f)(1)(i), the remedial actions CMS may take against a third party intermediary include requiring the third party intermediary to submit to CMS by a date specified by the agency a corrective action plan (CAP) to address the identified deficiencies or data issue, including that actions it will take to prevent the deficiencies or data issues from recurring. To clarify expectations and create consistency in the content of the CAPs provide by third party intermediaries, we proposed to revise and elaborate on the obligations for a CAP. Specifically, we proposed to modify § 414.1400(f)(1)(i) such that, unless different or additional information is specified by CMS, the CAP submitted by the third party intermediary must address four issues: (1) The issues that contributed to the non-compliance; (2) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (3) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved will not recur in the future and (4) the detailed timeline for achieving compliance with the applicable requirements.

We noted that we believe the four elements are generally warranted in each instance in which a CAP is required. First, any meaningful efforts at corrective action necessitate an understanding of what needs to be corrected. Therefore, we proposed at § 414.1400(f)(1)(i)(A) to require that each third party intermediary be required to articulate the issues that contributed to the non-compliance. The third party intermediary must articulate what factors cause it to fail in its obligation to meet program requirements. For example, a survey vendor subject to remedial action for not completing vendor trainings would be required to explain what factors lead to its failure to complete training. We noted that we believe this analysis will allow third party intermediary to improve their processes to better meet existing requirements and will allow CMS to better understand what operational and other challenges third party intermediaries face in meeting program requirements. Second, depending on the circumstances, non-compliance by a third party intermediary may affect an uncertain number of clinicians and groups and has the potential to implicate substantial program dollars. Accordingly, we proposed at § 414.1400(f)(1)(i)(B) to require that a third party intermediary subject to a CAP disclose to CMS the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program. We noted that we believe this information regarding the scope of harms is necessary for the agency to assess the full program impact of the non-compliance. Furthermore, we believe it is important for the CAP to include this impact information regardless of the clinician's participation status, because non-compliance may have programmatic implications even if it does not affect payment, such as for data posted on the Physician Compare website. Third, meaningful remedial action requires the identification of specific action steps both to address prior harm but to protect against future harms. Therefore, we proposed at § 414.1400(f)(1)(i)(C) that a third party intermediary subject to a CAP must address the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future. The third party intermediary will be expected to follow through with the implementation of the corrective actions and to see that the issue has been corrected permanently. It is important for us to understand in detail what actions the third party intermediary will take to resolve the issue and to evaluate the effectiveness of the proposed solution for long-term sustainability. Fourth, non-compliance must be resolved methodically and timely. Therefore, we proposed at § 414.1400(f)(1)(i)(D) that each CAP must include the detailed timeline for achieving compliance with the applicable requirements. We solicited public comments on the proposed revisions to our requirements for correction action plans.

We received one public comment on the remedial action and termination of third party intermediary proposals. The following is a summary of the comment we received and our response.

Comment: One commenter requested more information on the proposed new criteria for corrective action plans and how they would be quantified, particularly scope of clinician impact and/or harms.

Response: The new criteria in the regulation text at § 414.1400(f)(1)(i) clarify the content the CAPs provided by the third party intermediaries must include. The obligation for the CAP to identify impacts of the non-compliance on clinicians, groups and virtual groups establishes that the third party intermediary must supply information as to the volume and identity of clinicians, groups and virtual groups that are negatively impacted by the non-compliance of the third party intermediary. The appropriate method for quantifying impact will vary depending on the nature of the non-compliance. For example, if a third party intermediary submitted compromised data to CMS because it used a flawed TIN/NPI crosswalk, we would expect the CAP to include the total number and identifying information for the clinicians and groups whose data were inaccurate. The identification of impacts to clinicians would also helps us understand the volume of clinicians who may look to find a different method of reporting. Please refer to *qpp.cms.gov* for more information.

After consideration of the comment received, we are finalizing our proposal as proposed.

h. Public Reporting on Physician Compare

For previous discussions on the background of Physician Compare, we refer readers to the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final

rule (84 FR 63080 through 63083), and the Physician Compare Initiative website at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*.

(1) Definitions & Proposed Regulation Text Changes

Physician Compare (*http://www.medicare.gov/physiciancompare*) draws its operating authority from section 10331(a)(1) of the Affordable Care Act, which defines the term ''Physician Compare'' to mean the internet website developed under this section of the statute. Physician Compare has continued to pursue a phased approach to public reporting under the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015. Section 104(f)(2) of the MACRA defines the term ''Physician Compare'' to mean the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website). To more completely and accurately reference the website for which CMS will post information available for public reporting, in accordance with section 104(f)(2) of the MACRA, we proposed to define Physician Compare at § 414.1305 to mean the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website). We sought comment on the proposal. For ease of reference, we use the term ''Physician Compare'' in this final rule.

We did not receive any public comments on defining the term ''Physician Compare'' to mean the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website). Therefore, we are finalizing the ''Physician Compare'' definition at § 414.1305 as proposed.

4. APM Incentive Payment

(a) Overview

Under the Quality Payment Program, Qualifying APM Participants (QPs) receive a 5 percent APM Incentive Payment in payment years 2019 through 2024. In the CY 2017 Quality Payment Program final rule (81 FR 77480 through 77489), we finalized at § 414.1450(d) that this payment is made based on the clinician's QP status in the QP Performance Period that is 2 years prior (for example, the 2021 payment will correspond to the 2019 performance year), and at § 414.1450(b)(1) that the payment is equal to 5 percent of the estimated aggregate payments for covered professional services in the base period (the year between the QP performance and payment years). We finalized at § 414.1450(c)(1) that the APM Incentive Payment amount is made to the TIN associated with the Advanced APM Entity through which an eligible clinician becomes a QP during the QP Performance Period. Under § 414.1450(c)(3), if an eligible clinician becomes a QP through participation in multiple Advanced APMs, CMS divides the APM Incentive Payment proportionally between the TINs associated with the QP's participation in each Advanced APM based on payments for covered professional services during the QP Performance Period. In addition, under § 414.1450(c)(2), we finalized that if the QP is no longer affiliated with the TIN associated with the QP's participation in the APM Entity, the APM Incentive Payment is made to the TIN listed on the QP's CMS–588 Electronic Funds Transfer (EFT) Application form.

In our first year making the APM Incentive Payment, we experienced operational limitations that made it difficult in certain cases to distribute the payment to a current billing organization associated with the QP according to the current regulations. In particular, we encountered challenges when QPs are no longer affiliated with the TIN associated with the QP's participation in the APM Entity through which they attained QP status, and when we were unable to make the APM Incentive Payment to the TIN listed on the eligible clinician's CMS–588 EFT Application form. In certain circumstances, it has been challenging to locate accurate billing organizations for some QPs 2 years after they earned QP status. For example, we have encountered situations such as inaccurate or missing billing associations for the QP because the QP has changed their primary billing TIN between the performance and the payment year, or the billing TIN through which the QP attained QP status is not the TIN through which CMS payments are processed, and so it is not possible for CMS to know that the two are in fact connected.

(b) APM Incentive Payment Amount

In the first Quality Payment Program final rule (81 FR 77480), we finalized at § 414.1450(b)(1) through (3) how we calculate the amount of the APM Incentive Payment. Specifically, we finalized that: (1) The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the incentive payment base period (that is, the calendar year immediately preceding the payment year); (2) the estimated aggregate payment amount for covered professional services includes all such payments to the QP (NPI) via any and all of their TIN/NPI combinations; and (3) in calculating the estimated aggregate payment for a QP, CMS uses claims submitted for covered professional services with dates of service from January 1 through December 31 of the incentive payment base period.

In the CY 2021 PFS proposed rule (85 FR 50332), we are clarifying that the APM Incentive Payment amount is calculated based on the paid amount of the applicable claims for covered professional services that are subsequently aggregated to calculate the estimated aggregate payments. We proposed to amend our regulation at § 414.1450(b)(1) to reflect that clarification.

Section 1833(z)(1)(A) of the Act specifies that the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3) of the Act. Because the APM Incentive Payment is a percentage of the estimated aggregate payments made, it would not be appropriate to calculate the APM Incentive Payment based on amounts that were allowed, but not actually paid by Medicare, for such covered professional services.

We also noted that, as provided in § 414.1450(b)(4) and (5), we exclude certain payments and adjustments, including the MIPS payment adjustments, when calculating the APM Incentive Payment amount.

We sought comment on the proposal. The following is a summary of the comments we received in response to our proposal regarding the amount of the APM Incentive Payment.

Comment: One commenter recommended CMS aggregate the APM Incentive Payment on the allowed amount instead of the paid amount and the difference should be retroactive. The commenter noted that calculating on the allowed amount would produce a higher bonus for eligible clinicians.

Response: We appreciate the commenter feedback, however, as noted in the proposed rule, such an approach would be inconsistent with the plain language of the statute which requires that the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3) of the Act.

Therefore, we are finalizing our proposal to amend the language at § 414.1450(b)(1) to clarify our use of paid amounts in calculating ''payments''.

(c) APM Incentive Payment Recipient

Under our current policy as finalized at § 414.1450(c), CMS first seeks to disburse the APM Incentive Payment to the TIN associated with the QP's participation with the APM Entity in the Advanced APM through which they earned QP status. If the QP is no longer affiliated with that TIN, we seek to disburse the APM Incentive Payment to the TIN listed on the eligible clinician's CMS–588 EFT form on the date that we make the payment. And if the eligible clinician becomes a QP through participation in multiple Advanced APMs, we seek to divide the APM Incentive Payment proportionally, based on payments for covered professional services during the QP Performance Period, and to make proportional payment to each of the TINs associated with the QP's participation with the APM Entity or APM Entities in the Advanced APMs.

It is still our intention to reward achievement of QP status through participation in Advanced APMs by seeking to disburse APM Incentive Payments to TINs that are affiliated with an APM Entity through which the QP has achieved QP status, as is described in the CY 2017 Quality Payment Program final rule (81 FR 77847). However, after our first year of making APM Incentive Payments, we have learned that the amount of time between when an eligible clinician earns QP status and when APM Incentive Payments are made makes it difficult to ensure that payments can be made for these QPs in a routine and efficient manner. For example, in the space of 2 years between making QP determinations and APM Incentive Payments, eligible clinicians may change TINs, join new TINs, join new APM Entities, remain in the same APM Entity under a new billing TIN, leave Medicare altogether, or make other potential changes impacting their relationship with the Medicare program. CMS receives updated records of the changes when APM participants update their payment information through the internet based Provider Enrollment, Chain and Ownership system (PECOS) or a CMS–588 EFT Application, and subsequent updates to APM Participation Lists and Affiliated Practitioner Lists, although we note that such updates are not consistently and timely made across APM participants, as we originally believed, and therefore such lists have variable reliability. Further, on our own end, if we limit our initial search for the party or parties to which we should make the APM Incentive Payment to only the TIN or TINs through which the eligible clinician earned QP status, as is specified in our regulations at § 414.1450(c)(1) and (3), when the QP has made changes to their TIN affiliations, we might limit our opportunities to make the APM Incentive Payment to a more current TIN with which the QP is affiliated at the time we make the APM Incentive Payment. If we limit the TINs to which we will make the APM Incentive Payment to only those through which a QP was billing at the time they achieved QP status, we might be unable to identify any TIN to which we would make a payment for that QP during the payment year, or payments may be significantly delayed as a result, even in cases where a current payee TIN is available.

Therefore, we proposed to establish in our regulation at § 414.1450(c) a revised approach to identifying the TIN(s) to which we make the APM Incentive Payment. We noted that this approach would involve looking at a QP's relationship with their TIN(s) over time, as well as considering the relationship the TIN(s) have with the APM Entity or Entities through which the eligible clinician earned QP status, or other APM Entities the QP may have joined in the interim. We stated that we believe that this revised approach will enable CMS accurately identify TINs with which QPs are currently receiving other Medicare payments, and through which they would likely anticipate receiving their APM Incentive Payment. We also noted that this approach would also prioritize, when the QP is no longer affiliated with the original TIN through which they achieved QP status, identifying and paying TINs with which QPs are affiliated at the time the APM Incentive Payment is made, thereby reducing the potential burden on payee TINs to find QPs no longer affiliated with them in order to disburse the APM Incentive Payment amount, as well as reducing uncertainty and delays for the QPs themselves as they anticipate their APM Incentive Payment.

We also proposed to introduce a cutoff date of November 1 of each payment year, or 60 days from the day on which we make the initial round of APM Incentive Payments, whichever is later, as a point in time after which CMS will no longer accept new helpdesk requests from QPs or their representatives who have not received their payments. We discussed that there may be scenarios where we are unable to identify any appropriate TIN to which the APM Incentive Payment should be made, such as when the QP is no longer participating in Medicare, the QP has recently reassigned his or her billing rights, or where a payment TIN may be undergoing business transformations such that payment information changes during the payment year. In these cases, it is our goal to make correct payments for the relevant QPs as soon as feasible. To do so, it is necessary to establish a date after which we will not consider additional inquiries or additional information from QPs or their representatives for purposes of disbursing remaining APM Incentive Payments for the payment year.

To improve and expand the ways we identify the TIN(s) to which we would make the APM Incentive Payment for a QP in a timelier and efficient manner, we proposed to sequentially apply the hierarchy in the following paragraph and to amend § 414.1450(c) of our regulations to reflect such hierarchy. We proposed to begin at the first step in the hierarchy, and if we are unable to identify one or more TINs with which the QP has a current affiliation at this step, we move to the next and successive steps of the hierarchy until we do identify one or more TINs with which the QP is currently affiliated at the time we are distributing APM Incentive Payments. When we identify one or more TINs with which the QP is affiliated at a step, we would make the APM Incentive Payment to those TINs. We further proposed that if we identify more than one TIN at the applicable step in the hierarchy, we will divide the APM Incentive Payment proportionally between such TINs based on the relative paid amount for Part B covered professional services that are billed through each such TINs. We proposed the hierarchy to be:

(1) Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(2) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(3) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the eligible clinician had achieved QP status;

(4) Any TIN associated with the QP that, during the APM Incentive Payment

base period, participated in an APM Entity in an Advanced APM;

(5) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the eligible clinician achieved QP status;

(6) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;

(7) Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then

(8) If we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information. The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment must then notify CMS of their claim as directed in the public notice by November 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

We sought comment on the proposals. The following is a summary of the comments we received and our responses.

Comment: Several commenters opposed our proposed hierarchy to make the APM Incentive Payment to the QP stating the process is too complex and confusing. Those commenters stated CMS should identify a more streamlined approach where the APM Incentive Payment would be paid directly to the APM Entity.

Response: Under section 1833(z)(1)(A) of the Act, the statute provides that the APM Incentive payment is to be paid to the eligible clinician who is a QP for the year. As we explained in the CY 2017 Quality Payment Program final rule (81 FR 77487), we make the APM Incentive Payment to a TIN rather than to an individual eligible clinician. We do not believe it would be consistent with statutory intent to make the APM Incentive Payment to the APM Entity or Entities in which the QP may have participated. Rather, we believe that it would be most consistent with statutory intent to locate and make the APM Incentive Payment to the solvent TIN with the closest and most current relationship to the QP. We believe that the proposed policy provides us with the opportunity to accurately identify as many appropriate payee TINs as possible prior to making the first round of payments, and that the proposed hierarchy will allow us to identify the most appropriate TIN to which to make payment. We understand that this process is complex, but we believe that application of the hierarchy will identify an appropriate payee TIN early in the process in most cases, and therefore, be better situated to disburse APM Incentive Payments earlier in the year than was possible under our current methodology.

It has also come to our attention that there may be situations where a TIN associated with a QP may be in bankruptcy status; we would not consider this an appropriate payee TIN and would move to the next step in the hierarchy to identify another TIN to which to make the APM Incentive Payment.

Comment: Another commenter opposed our proposal that, in the event we have not identified any TIN associated with a QP to which we can make the APM Incentive Payment, we would establish a 60-day public notice process to allow QPs or other eligible clinicians who believe they are entitled to an APM Incentive Payment to notify us of their claim and provide billing information or otherwise, forfeit their claim to payment. The commenter expressed concern that because there is no official date on which future APM Incentive Payments will be made, the proposed policy is not transparent.

Response: We understand commenters' concerns about the need for CMS to complete APM Incentive Payments as quickly and predictably as possible. We proposed to introduce a cutoff date of November 1 of each payment year, or 60 days from the day on which we make the initial round of APM Incentive Payments, whichever is later; and to provide a public notice to identify the deadline by which we must receive requests from QPs or their representatives who have not received their payments. We believe establishing the cutoff date as the later of November 1 or 60 days after the initial round of payments are made creates a more predictable and finite time table for when clinicians could expect to receive their APM Incentive Payments. It is our goal to accurately make payments for all QPs as soon in the payment year as feasible. To do so, it is necessary to establish a date after which we will not consider additional inquiries or additional information from QPs or their representatives for purposes of disbursing any remaining APM Incentive Payments for the payment year.

We are finalizing without modification our proposal to adopt and use the hierarchy to identify an appropriate TIN to which to make the APM Incentive Payment for a QP. We are also finalizing our proposal that, in the event we do not identify an appropriate TIN at levels one through seven of the hierarchy, we will publish a public notice requiring the remaining QPs to come forward with their claims and provide payment information by the specified date that is the later of a 60-day deadline or November 1st of the payment year, or forfeit their claim to an APM Incentive Payment for the year.

(d) Eligible Clinicians With No Covered Professional Services in the Incentive Payment Base Period

In our experience calculating the APM Incentive Payments, it has come to our attention that there is a cohort of eligible clinicians who have been determined to be QPs for a year, and for whom an APM Incentive Payment has been calculated and in some cases paid, despite the fact that these eligible clinicians did not bill for any Part B covered professional services during the incentive payment base period. This situation arises in cases where an APM Entity is paid under the terms of the APM for supplemental services on behalf of an eligible clinician who is on their Participation List. This can occur because, for purposes of calculating the APM Incentive Payment, such supplemental service payments as described in § 414.1450(b)(7) of our regulations are considered covered professional services for purposes of calculating the APM Incentive Payment.

This scenario creates difficulty when we attempt to make the APM Incentive Payment for the QP because there are no relevant claims in our database indicating a TIN to which we should make the APM Incentive Payment. We noted in the CY 2021 PFS proposed rule (85 FR 50033 that we believe this situation is largely the result of clerical errors or delays, either in updates to the APM's Participation List that is submitted to CMS by APM participants, or through more general processes used to update an eligible clinician's Medicare enrollment information. We reminded our enrolled physicians, practitioners, group practices and other suppliers that it is their responsibility, in accordance with their APM participation and their Medicare enrollment agreement, to routinely update their APM participation lists that they submit directly to their APMs, as

well as their lists of enrolled providers assigned to their organization and associated TINs, either through the internet-based PECOS or using a CMS–855F Form. We reiterate that any payments resulting from a failure to make such updates may be considered fraud, waste, or abuse.

However, in the event that a QP's APM Incentive Payment was calculated based solely on supplemental services payments and no Medicare claims for covered professional services furnished by the QP were submitted during the incentive payment base period, we proposed to categorically assign these QPs to the list of QPs that will be given public notice requesting updated payment information within 60 day deadline or November 1st of the payment year, as described in the proposed regulation at § 414.1450(c)(8). We noted that we believe that in many if not most of these cases, such individuals have retired or otherwise ceased participation in Medicare; however, we recognized that there may be scenarios under which such individuals remain active, and noted that the proposal was meant to provide an opportunity for such clinicians to identify their current billing affiliation(s) or otherwise identify a TIN to which the APM Incentive Payment should be made.

We did not receive public comments on this provision, and therefore, we are finalizing as proposed.

d. Qualifying APM Participant (QP) and Partial QP Determinations

(1) Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77450), we finalized policies relating to QP and Partial QP determinations. In the CY 2019 PFS final rule (83 FR 59923 through 59925), we finalized additional policies relating to QP determinations and the Partial QP election to report to MIPS.

In the CY 2021 PFS proposed rule (85 FR 50333), we proposed to:

- Update the methodology for addressing prospectively aligned beneficiaries for Threshold Score calculations and QP determinations.
- Establish a Targeted Review process for QP Determinations.

Additionally, we clarified our policies on Advanced APM determinations and QP determinations in light of questions that may arise based on the effects of the PHE for COVID–19.

We solicited comment on whether to allow an APM Entity to make the Partial QP election on behalf of all of the APM Entity's participating eligible clinicians.

(2) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77440), we finalized that QP determinations would first be made at the APM Entity level, after which we would make further QP determinations at the individual level for eligible clinicians who are either: (1) Participating in multiple Advanced APM Entities, none of which meet the QP threshold as a group; or (2) on an Affiliated Practitioner List that is the list used for the QP determination when there are no eligible clinicians on a Participation List for the APM Entity (81 FR 77439 through 77443). As such, the QP determination at the APM Entity level generally applies to all the individual eligible clinicians who are on a Participation List of the Advanced APM. The QP determination Threshold Score calculations are aggregated using data for all eligible clinicians participating in the APM Entity on each snapshot date (March 31, June 30, August 31) during the QP Performance Period. If the APM Entity's Threshold Score meets the relevant QP threshold, all individual eligible clinicians in that APM Entity would receive the same QP determination, applied at the NPI level, for the relevant performance year (PY).

(3) Attribution of Prospectively Attributed Beneficiaries in QP Threshold Score Calculations

When making QP determinations, we include information for all attribution-eligible beneficiaries in the denominator of the patient count and payment amount methods used to calculate QP Threshold Scores as set forth in § 414.1435. ''Attribution-eligible beneficiary'' is a term defined in our regulation at § 414.1305, and the definition is generally based on the attribution methodology and rules for the particular Advanced APM. We have specified at § 414.1435(b)(3) that a beneficiary may be counted only once in the numerator and denominator for a single APM Entity group, and at § 414.1435(b)(4) that a beneficiary may be counted multiple times in the numerator and denominator for multiple different APM Entity groups.

When making QP determinations, at the APM Entity or individual eligible clinician level, we begin by calculating Threshold Scores, which are the ratio of the payment amounts or patient counts for ''attributed beneficiaries'' to the payment amounts or patient counts for ''attribution eligible beneficiaries.'' If this ratio (the Threshold Score) for the eligible clinician or APM Entity level, as applicable, meets or exceeds the relevant QP thresholds described at § 414.1430(a), the relevant eligible clinicians will have attained QP status for a year. It has come to our attention that under our current methodology for calculating Threshold Scores, we include attribution-eligible beneficiaries in the denominator of the calculation for some APM Entities for whom those same beneficiaries could never be included in the numerator. This may happen in a scenario where a beneficiary is attributed to an APM Entity and as a result is precluded by the applicable rules for one or more APMs from attribution to other APM Entities in certain other APMs.

For example, the Shared Savings Program offers the option for ACOs to select prospective beneficiary assignment, and prospective beneficiary alignment is used in the Direct Contracting Model and Next Generation ACO Model. When beneficiaries are prospectively attributed to an ACO in one of these APMs, under the rules of precedence within the APMs themselves, those beneficiaries are generally not available for attribution to participants in some other APMs, including other ACOs, regardless of attribution methodologies. However, the population of attribution-eligible beneficiaries for APM Entities in these other APMs still includes those prospectively aligned beneficiaries. This could have the effect of disadvantaging the APM Entities to which the beneficiaries may never be attributed, because their ratio of attributed beneficiaries to attribution-eligible beneficiaries will be lower, for reasons entirely outside the control of the relevant eligible clinicians and APM Entities.

Therefore, we proposed to amend § 414.1435(c)(1) of our regulations and add a new paragraph (c)(1)(i) to specify that beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list. We noted that the effect of the proposed policy would be to remove such prospectively attributed beneficiaries from the denominators when calculating Threshold Scores for APM Entities or individual eligible clinicians in Advanced APMs that align beneficiaries retrospectively, thereby preventing dilution of the Threshold Score for the APM Entity or individual eligible clinician in an Advanced APM that uses retrospective attribution.

We sought comment on the proposals.

We received public comments on the removal of prospectively aligned beneficiaries. The following is a summary of the comments we received and our responses.

Comment: We received several of comments in support of our proposal for the removal of prospectively attributed beneficiaries. Commenters requested that we clarify the impact of the policy where beneficiaries are attribution eligible for more than one APM Entity, but the rules of one or more of the APMs would make it so that the beneficiary could only be attributed to one of the APM Entities.

Response: We appreciate the commenters support for the proposed change. The policy as proposed at § 414.1435(c)(1)(i) would have the effect of removing those beneficiaries that are prospectively attributed to an APM entity from the attribution eligible population for all other APM entities where the beneficiary would be excluded from attribution.

For example, when calculating QP determinations for a Shared Savings Program ACO, any attribution eligible beneficiaries who are prospectively assigned to another ACO, and thus have been precluded from assignment to the ACO in question, would be removed from the attribution eligible population for the ACO in our calculation. This policy will apply to cases where beneficiaries could not be attributed to multiple APM entities in a single APM or across multiple APMs.

We are finalizing this policy as proposed.

(3) Targeted Review of QP Determinations

(i) Overview

We proposed at § 414.1455(b) to establish a targeted review process for limited circumstances surrounding QP determinations. As discussed in the CY 2021 PFS proposed rule (85 FR 50334), this targeted review process would provide a systematic opportunity for eligible clinicians to bring to our attention potential clerical errors we may have made, and for us to review and make corrections if warranted. We also proposed that, after the conclusion of the time period for targeted review, there would be no further review of our QP determination with respect to an eligible clinician for the QP Performance Period.

We noted that, consistent with section 1833(z)(4) of the Act and under § 414.1455(a) of our regulations, there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise, of the determination that an eligible clinician is a QP or Partial QP under § 414.1425, that an APM Entity is an Advanced APM Entity under § 414.1410, or of the determination of the amount of the APM Incentive Payment under § 414.1450.

(ii) Scope of Targeted Review

We proposed at § 414.1455(b)(1) that an eligible clinician or APM Entity may request targeted review of a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List used for purposes of QP determinations. We noted that if we made such a clerical error, we believe that it would be appropriate, and we proposed, to assign to the erroneously omitted eligible clinician the most favorable QP status that was determined at the APM Entity level. This would be done on any snapshot dates for the relevant QP Performance Period on which the eligible clinician participated in the APM Entity. We believe that this policy is appropriate in these circumstances because, as a result of a CMS clerical error, the eligible clinician was not provided the opportunity to become a QP based on the level of payment amounts or patient counts through an Advanced APM for an APM Entity with which they were associated.

Alternatively, if we were to recalculate an APM Entity's Threshold Scores for one or more of the snapshot dates in the relevant QP Performance Period, and the Threshold Scores no longer met the applicable QP threshold(s), that outcome could affect all of the eligible clinicians in the APM Entity group, removing their QP status. However, the affected eligible clinicians in the APM Entity group are likely to have acted in accordance with our notification of their prior QP determination, and may not have prepared for or reported to MIPS. In correcting our own clerical error with respect to some eligible clinicians, we do not believe it would be appropriate to revisit our prior QP determinations for a broader set of eligible clinicians, thereby potentially disadvantaging those eligible clinicians in MIPS scoring through no fault of their own.

We did not proposed to conduct targeted review of potential omissions from Affiliated Practitioner Lists, as QP determinations for eligible clinicians on an Affiliated Practitioner List is made at the individual eligible clinician level for each of the QP Performance Period snapshots. As such, we would not have completed a QP determination for the QP Performance Period in question for the individual eligible clinician who has been identified prior to the targeted review if that eligible clinician was indeed omitted due to CMS clerical error. We recognize that this circumstance may occur; however, we believe this to be an infrequent occurrence. Additionally, such calculations would not be operationally feasible in order to make the APM Incentive Payment in a timely manner.

We did not propose to accept targeted review requests to correct omissions from Participation Lists of Other Payer Advanced APMs, as those lists are provided to us directly by eligible clinicians and Other Payer Advanced APMs. As such, any clerical error would not be the fault of CMS.

(iii) Targeted Review Process

In general, we proposed to align this targeted review process with the MIPS targeted review process as codified at § 414.1385. We noted this alignment would reduce the likelihood of confusion and burden on eligible clinicians and APM Entities. We proposed to redesignate our regulation that reflects the statutory preclusion of administrative or judicial review under § 414.1455(a) and (b) to § 414.1455(a)(1) and (2) and to codify our targeted review policy at § 414.1455(b).

We proposed to specify at § 414.1455(b) that either an eligible clinician or APM Entity may submit a request for targeted review. We also proposed that all requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins on the day CMS makes available the MIPS payment adjustment factors for the MIPS payment year as described at § 414.1385(a)(2) of our regulations. The targeted review request submission period may be extended as specified by CMS. We also proposed that all requests for targeted review must be submitted in accordance with the form and manner specified by CMS.

We proposed that a request for targeted review may be denied if the request is duplicative of another request for a targeted review; the request for targeted review is not submitted during the targeted review request submission period; or the request is outside the scope of the targeted review, as specified in § 414.1455(b)(1). We noted that, if the targeted review request is denied, there would be no change to either the QP or Partial QP determination. If the targeted review request is approved, we will assign the most favorable Threshold Score and corresponding QP status determined for

the APM Entity in which such eligible clinician participates.

We proposed that we would respond to each timely submitted request for targeted review and determine whether a targeted review is warranted.

We proposed that a request for targeted review may include additional information in support of the request at the time it is submitted. We noted that in cases where CMS requests additional information from the eligible clinician or the APM Entity group that is the subject of a request for targeted review, the information must be provided and received by CMS within 30 days of our request. Non-responsiveness to a CMS request for additional information may result in a final decision based on the information available, although another non-duplicative request for a targeted review may be submitted before the end of the targeted review request submission period.

We proposed that if targeted review requests reveal a pattern of CMS error with impacts that extend beyond the eligible clinician or clinicians who submitted such targeted review requests, we would correct any additional errors that we identify regardless of whether a targeted review was submitted for the other eligible clinicians affected.

We proposed that decisions based on the targeted review are final, and there is no further administrative review or appeal or judicial review.

We sought comment on the proposals.

We received public comments on the proposed targeted review process for QP determinations. The following is a summary of the comments we received and our responses.

Comment: We received several of comments seeking an expanded scope of Targeted Review that would include the recalculation of individual eligible clinician QP determinations.

Response: Based on past experience, our proposed targeted review process would address the vast majority of cases where a review has been necessary. Additionally, as explained in our proposal at (85 FR 50336), performing additional individual-level QP determination calculations, under our current methodology, would not be operationally feasible given statutorily determined timelines for making the APM Incentive Payment. We may consider recalculation of individual eligible clinician QP determinations in future rulemaking.

Comment: We received a comment stating that our proposed targeted review request submission period of 60 days was too short.

Response: We recognize that participants in the Quality Payment Program must meet a number of deadlines. In an effort to maximize the efficiency of the program, we believe that the benefits of aligning with the MIPS targeted review process outweigh the potential benefit of a longer timeline for the targeted review process. Additionally, any further delay of the targeted review process could further delay the process of making timely APM incentive payments.

Comment: We received several comments in support of our proposed targeted review process for QP determinations.

Response: We appreciate the support for this proposal.

We are finalizing this policy as proposed.

(4) PHE for COVID–19 Advanced APM Determination and QP Determinations

(i) Advanced APM Determinations

In the CY 2021 PFS proposed rule (85 FR 50335), we noted that due to the PHE for COVID–19 and the urgent need to address changes to certain APMs during CY 2020 to respond to the extreme shifts in the healthcare delivery system, we are exercising its enforcement discretion in connection with Advanced APM determinations. Specifically, we will not reconsider the Advanced APM determinations of APMs which have already been evaluated and determined to meet the Advanced APM criteria for CY 2019 and CY 2020 even in the event that the APMs make changes to their governing documents or operations in such a way that, if there were a redetermination, they would no longer meet the criteria to be an Advanced APM. Furthermore, we will evaluate all APMs in future years with the understanding that any provisions of the Participation Agreement or governing regulation designed in response to the PHE for COVID–19 will not be considered to the extent they would prevent the APM from meeting the Advanced APM criteria for a year.

We noted that the following APMs are considered Advanced APMs for 2020:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Comprehensive Primary Care Plus Model;
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare Accountable Care Organization (ACO) Track 1+ Model;
- Next Generation ACO Model;
- Oncology Care Model (Two-Sided Risk Arrangements);
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We note that the following APMs are considered Advanced APMs for 2019:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track);
- Comprehensive Primary Care Plus Model;
- Comprehensive ESRD Care Model (LDO arrangement and Non LDO Two Sided Risk Arrangement);
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare Accountable Care Organization (ACO) Track 1+ Model;
- Next Generation ACO Model;
- Oncology Care Model (Two-Sided Risk Arrangements);
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

(ii) QP Determinations

As discussed in the CY 2021 PFS proposed rule (85 FR 50336), we also understand that the PHE for COVID–19 may lead to the adoption of an earlier end date for certain APMs based on amendments to the APM's governing documentation, such as a Participation Agreement. For example, an Advanced APM governed by a Participation Agreement was originally scheduled to end on December 31, 2020, and the amended Participation Agreement may revise the ending date to July 1, 2020. In the event that such changes are made to a Participation Agreement to modify the end date of an Advanced APM in response to the PHE for COVID–19, we would not consider this to be a termination from an Advanced APM under § 414.1425(c)(5) or (6) of our regulations. As such, we would not revoke the QP status of eligible clinician participants in the Advanced APM on that basis.

We noted that we are aware that circumstances resulting from the PHE for COVID–19 could affect the results of QP and Partial QP determinations for the 2020 QP Performance Period, as compared to what those determinations would otherwise be in absence of the PHE for COVID–19.

However, after considering whether changes in our methodology to address the PHE for COVID–19 were warranted, we determined that any change to the QP determination methodology could have unintended negative consequences for Advanced APM participants as practice patterns have shifted even in areas with a low volume of COVID–19 cases. We noted that with the duration, scope, and severity of the PHE for COVID–19 being unknown, it is impossible to predict the potential impact both in terms of scale and which providers may be most likely to be affected. As such, we noted that we are concerned that making changes to the QP determination methodology would be more likely to inadvertently pick winners (those who would benefit from the change in methodology by achieving higher scores) and losers (those who would score better under our normal methodology than under a changed one) than it would be to generate relief from the PHE for COVID–19 across the board. We also noted that we anticipate that there would be significant challenges resulting from modifying QP calculations with so many unknown variables at play, and are concerned that any changes to our methodology could result in delays in the timing of our announcing QP status.

We discussed our belief that Advanced APM participants benefit from timely and predictable QP determinations. With all of these considerations in mind, we clarified that, apart from the exercise of enforcement discretion explained above, we would continue to perform QP determinations as established in our regulations at §§ 414.1305, 414.1425, 414.1430, 414.1435, and 414.1440 for the 2020 QP Performance Period, without modifications to address the PHE for COVID–19.

V. Physician Self-Referral Law: Annual Update to the List of CPT/HCPCS Codes

A. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless the financial relationship satisfies all requirements of an applicable exception. Section 1877 of the Act also prohibits the entity from submitting claims to Medicare or billing the beneficiary or any other individual or entity for designated health services that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following items and services are designated health services:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

B. Annual Update to the Code List

1. Background

In § 411.351, we specify that the entire scope of four categories of designated health services is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibitions:

- EPO and other dialysis-related drugs (§ 411.355(g)).
- Preventive screening tests, immunizations, and vaccines (§ 411.355(h)).

The definition of ''designated health services'' at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically included in the statutory or regulatory lists of items and services that are designated health services and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not designated health services and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

ESRD-related oral-only drugs, which are drugs or biologicals with no injectable equivalents or other forms of administration other than an oral form, were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. On December 19, 2014, section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these oral-only drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and, thus, are designated health services.

The United States is responding to an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named ''severe acute respiratory syndrome coronavirus 2'' (''SARS–CoV–2'') and the disease it causes has been named ''coronavirus disease 2019'' (''COVID–19''). In response to the COVID–19 outbreak, the American Medical Association (AMA) has established and published new CPT codes on its website to identify currently available SARS–CoV–2 tests (see *https://www.ama-assn.org/practice-management/cpt/covid-19-cpt-coding-and-guidance*). As of the effective date of this rule, tests for COVID–19 are designated health services, as they fall within the category of ''clinical laboratory services.''

The AMA has also established and published two new CPT codes to identify each of two COVID–19 vaccines under development, both of which are included on the Code List as qualifying for the exception at § 411.355(h). There are additional COVID–19 vaccines still under development, and we anticipate that new CPT or HCPCS codes will be established to identify those vaccines as they become available. As noted above, in order to qualify for the exception at § 411.355(h), a vaccine must be included on the Code List. Therefore, in order to ensure that any COVID–19 vaccine to which a CPT or HCPCS code applies prior to the publication of the CY 2022 Code List qualifies for the exception at § 411.355(h), we are including language in the CY 2021 Code List to address such vaccines. Under

this final regulation, the physician self-referral prohibitions do not apply to CPT code 90749 (unlisted vaccine/toxoid) *when it is used to identify a COVID–19 vaccine* or to any future CPT or HCPCS code designated for a COVID–19 vaccine. This is in addition to the other codes listed on the Code List that relate to the application of § 411.355(h). The inclusion of CPT code 90749 on the Code List is not intended and should not be considered to direct or approve the use of CPT code 90749 for the identification and billing of any COVID–19 vaccine. Coding and billing guidance is expected as COVID–19 vaccines become available and coverage and billing policies are developed. We are making this revision to the Code List to ensure that the physician self-referral law does not impede the availability of COVID–19 vaccines, when they are available, for Medicare (and other) patients. CPT and HCPCS codes assigned to any COVID–19 vaccine(s) will be posted on *CMS.gov* as they become available.

The Code List was last updated in Tables 67 and 68 of the CY 2020 PFS final rule (84 FR 63100).

2. Response to Comments

We received no comments relating to the Code List that became effective January 1, 2020.

3. Revisions Effective for CY 2021

The updated, comprehensive Code List effective January 1, 2021, is available on our website at *https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes*.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II and to changes in Medicare coverage policy and payment status.

Tables 58 and 59 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2021. Tables 58 and 59 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis–related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

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TABLE 58: Additions to the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
0016M Onc bladder mrna 209 gen alg
0153U Onc breast mrna 101 genes
0154U Onc urthl ca rna fgfr3 gene
0155U Onc brst ca dna pik3ca gene
0172U Onc sld tum alys brca1 brca2
0174U Onc solid tumor 30 prtn trgt
0177U Onc brst ca dna pik3ca 11
0179U Onc nonsm cll lng ca alys 23
0202U Nfct ds 22 trgt sars-cov-2
0204U Onc thyr mrna xprsn alys 593
0208U Onc mtc mrna xprsn alys 108
0223U Nfct ds 22 trgt sars-cov-2
0224U Antibody sars-cov-2 titer(s)
0225U Nfct ds dna&rna 21 sarscov2
0226U Svnt sarscov2 elisa plsm srm
0240U Nfct ds vir resp rna 3 trgt
0241U Nfct ds vir resp rna 4 trgt
C9803 Hopd covid-19 spec collect
G2023 Specimen collect covid-19
G2024 Spec coll snf/lab covid-19
U0001 2019-ncov diagnostic p
U0002 Covid-19 lab test non-cdc
U0003 Cov-19 amp prb hgh thruput
U0004 Cov-19 test non-cdc hgh thru
U0005 Infec agen detec ampli probe
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No additions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
0633T Ct breast w/3d uni c-
0634T Ct breast w/3d uni c+
0635T Ct breast w/3d uni c-/c+
0636T Ct breast w/3d bi c-
0637T Ct breast w/3d bi c+
0638T Ct breast w/3d bi c-/c+
71271 Ct thorax lung cancer scr c-
92229 Img rta detc/mntr ds poc aly
A9591 Fluoroestradiol f 18
C9067 Gallium ga-68 dotatoc
C9068 Copper cu-64, dotatate, dx
C9762 Cardiac mri seg dys strain
C9763 Cardiac mri seg dys stress
RADIATION THERAPY SERVICES AND SUPPLIES
{No additions}
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90689 Vacc iiv4 no prsrv 0.25ml im
90694 Vacc aiiv4 no prsrv 0.5ml im
90749 Unlisted vaccine/toxoid [only when used to identify a COVID-19 vaccine]
91300 Sarscov2 vac 30mcg/0.3ml im
91301 Sarscov2 vac 100mcg/0.5ml im
Any future CPT or HCPCS code designated for a COVID-19 vaccine

[1]CPT codes and descriptions only are copyright 2020 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 59: Deletions from the Physician Self-Referral List of CPT[1]/HCPCS Codes

CLINICAL LABORATORY SERVICES
0058T Cryopreservation ovary tiss
0111T Rbc membranes fatty acids
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No deletions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
76970 Ultrasound exam follow-up
78135 Red cell survival kinetics
RADIATION THERAPY SERVICES AND SUPPLIES
{No deletions}
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
{No deletions}

[1]CPT codes and descriptions only are copyright 2020 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

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VI. Waiver of Delay in Effective Date for This Final Rule

We are committed to ensuring that we fulfill our statutory obligation to update the PFS as required by law and have worked diligently in that regard. We ordinarily provide a 60-day delay in the effective date of final rules after the date they are issued in accordance with the Congressional Review Act (CRA) (5 U.S.C. 801(a)(3)). However, 5 U.S.C. 808(2) provides that, if an agency finds good cause that notice and public procedures are impracticable, unnecessary, or contrary to the public interest, the rule shall take effect at such time as the agency determines.

As discussed in the CY 2021 PFS proposed rule (85 FR 50074, 50336), the United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named ''SARS CoV 2'' and the disease it causes has been named ''coronavirus disease 2019'' (abbreviated ''COVID 19'').

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a ''Public Health Emergency of International Concern'' (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the WHO publicly characterized COVID–19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID–19 outbreak a national emergency.

The PFS payment rule is necessary to annually review and update the payment systems, and it is critical to ensure that the payment policies for these systems are effective on the first day of the year to which they are intended to apply. Due to CMS prioritizing efforts in support of containing and combatting the PHE for COVID–19, and devoting significant resources to that end, we announced in the proposed rule that this CY 2021 PFS final rule would not be completed in accordance with our usual schedule for this rulemaking, which aims for a publication date of at least 60 days before the start of the year to which it applies. We announced that we may need up to an additional 30 days to complete the work needed on this final rule.

Therefore, in light of the PHE for COVID–19, and the resulting strain on CMS's resources to that end, it was impracticable for CMS to publish this final rule 60 days prior to the beginning of the upcoming year, and CMS has determined that, for good cause, it would be contrary to the public interest to delay the effective date of this final rule beyond January 1, 2021; and we are waiving the 60-day delay in effective date, pursuant to 5 U.S.C. 808(2), and this CY 2021 PFS final rule will be effective 30 days after publication. Accordingly, we are providing a 30-day delay in the effective date of the final rule in accordance with the Administrative Procedure Act (5 U.S.C. 553(d)), which ordinarily requires a 30-day delay in the effective date of a final rule from the date of its public availability in the **Federal Register**, and section 1871(e)(1)(B)(i) of the Act, which generally prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date of its public availability.

VII. Collection of Information Requirements

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

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

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

We solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). In this regard, Table 60 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 60: National Occupational Employment and Wage Estimates

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Anesthesiologists	29-1211	125.83	125.83	251.66
Billing and Posting Clerks	43-3021	19.53	19.53	39.06
Computer Systems Analyst	15-1211	46.23	46.23	92.46
Family Medicine Physicians	29-1215	102.53	102.53	205.06
General Internal Medicine Physicians	29-1216	96.85	96.85	193.70
Health Diagnosing and Treating Practitioners	29-1000	49.26	49.26	98.52
Licensed Practical Nurse (LPN)	29-2061	23.32	23.32	46.64
Medical and Health Services Managers	11-9111	55.37	55.37	110.74
Medical Secretary	43-6013	18.31	18.31	36.62
Obstetricians and Gynecologists	29-1218	112.31	112.31	224.62
Pediatricians, General	29-1221	88.66	88.66	177.32
Physicians, All Other; and Ophthalmologists, Except Pediatric	29-1228	97.81	97.81	195.62
Psychiatrists	29-1223	105.98	105.98	211.96
Surgeons, Except Ophthalmologists	29-1248	121.17	121.17	242.34

As indicated, we adjusted our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

For the CY 2019 and CY 2020 PFS final rules, we used the BLS wage rate for ''Physicians and Surgeons'' (occupation code 29–1060) to estimate the burden for Physicians. In BLS' most recent set of occupational wage rates dated May 2019, they have discontinued this occupation in their wage data. As a result, in order to estimate the burden for Physicians, we are using a rate of $212.78/hr which is the average of the mean wage rates for Anesthesiologists; Family Medicine Physicians; General Internal Medicine Physicians; Obstetricians and Gynecologists; Pediatricians, General; Physicians, All Other; and Ophthalmologists, Except Pediatric; Psychiatrists; and Surgeons, Except Ophthalmologists [($251.66/hr + $205.06/hr + $193.70/hr + $224.62/hr + $177.32/hr + $195.62/hr + $211.96/hr + $242.34/hr) ÷ 8].

B. Information Collection Requirements (ICRs)

1. ICRs Regarding Modifications to OTP Enrollment Process (§ 424.67)

The following requirement and burden changes will be submitted to OMB for approval under control numbers 0938–0685 and 0938–1377 (respectively, CMS–855A and CMS–855B).

a. Form CMS–855B Completion—Estimates in November 15, 2019 Final Rule

In the aforementioned November 15, 2019 final rule (84 FR 62568), we prepared estimates of the hour and cost burdens to OTPs in completing the Form CMS–855B (Medicare Enrollment Application Clinics/Group Practices and Certain Other Suppliers). We are restating them in the current rule to help stakeholders better understand the burdens associated with our changes to § 424.67.

Based on SAMHSA statistics and our internal data, we estimated in the November 15, 2019 final rule that: (1) About 1,700 certified and accredited OTPs were eligible for Medicare enrollment; and (2) 200 OTPs would become certified by SAMHSA in the next 3 years (or roughly 67 per year). This brought the total number of OTPs eligible to enroll during this 3-year period to approximately 1,900.

We projected that it would take each OTP an average of 3 hours to obtain and furnish the required information on the Form CMS–855B and a new supplement thereto designed to capture data unique to OTPs. Per our experience, we believed that the OTP's medical secretary would secure and report the data on the Form CMS–855B and supplement. We estimated that this task

would take approximately 2.5 hours, of which about 30 minutes would involve completion of the supplement. In addition, a health diagnosing and treating practitioner of the OTP would review and sign the form, a process we estimated would take 30 minutes.

Using BLS' May 2018 wage estimates, we consequently projected a first-year burden of 5,301 hours (1,767 entities × 3 hr) at a cost of $244,146 [1,767 entities ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr))]; a second-year burden of 201 hours (67 entities × 3 hr) at a cost of $9,257 [67 entities × ((2.5 hr × $35.66/hr) + (0.5 hr $98.04/hr))]; and a third-year burden of 198 hours [66 entities × 3 hr) at a cost of $9,119 (66 entities × ((2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr))]. In aggregate, we estimated a total 3-year burden of 5,700 hours (5,301 hr + 201 hr + 198 hr) at a cost of $262,522 ($244,146 + $9,257 + $9,119). When averaged over the typical 3-year OMB approval period, we estimated an annual burden of 1,900 hours (5,700 hr/3) at a cost of $87,507 ($262,522/3).

b. Revisions to § 424.67

(1) Completion of Form CMS–855A

We foresee three main implications associated with our changes to § 424.67. First, newly enrolling OTPs would be able to complete and submit a Form CMS–855A (Medicare Enrollment Application—Institutional Providers) instead of a Form CMS–855B. Second, we anticipate that numerous OTPs that are currently enrolled via the Form CMS–855B would terminate the latter enrollments and complete/submit a Form CMS–855A application in order to bill for OTP services via the 837I. (As stated in revised § 424.67(c), an OTP cannot be enrolled via both the Form CMS–855A and Form CMS–855B; it must choose one of these two enrollment mechanisms.) Third, it is possible that some OTPs that enroll using the Form CMS–855A (pursuant to revised § 424.67(b)) would later change their enrollment to a Form CMS–855B.

In preparing the following OTP enrollment estimates, we: (1) Reviewed internal PECOS and billing data concerning existing OTP Form CMS–855 enrollments and claim submissions; and (2) considered feedback recently received from the OTP community regarding potential billing and enrollment options. Based on this, we project that over the first 3 years of our changes to § 424.67:

- Roughly one-half (or 33) of the previously estimated 67 annually enrolling OTPs (that is, in Years 2 and 3 and beyond) would elect to complete a Form CMS–855A rather than a Form CMS–855B.
- Approximately 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A.
- About 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B.

(a) New OTPs Enrolling Via the Form CMS–855A

We estimate that it would take each OTP approximately 4 hours to secure and provide the relevant data on the Form CMS–855A and the new supplement thereto (which would capture OTP-specific information). Consistent with our experience, the OTP's medical secretary would obtain and report information on the Form CMS–855A and supplement, a task that would take roughly 3.5 hours (about 30 minutes of which would involve completion of the supplement). A health diagnosing and treating practitioner of the OTP would spend 30 minutes reviewing and signing the form.

Given the preceding data, we project an annual burden for new OTPs seeking to complete a Form CMS–855A of 132 hours (4 hr × 33 OTPs) at a cost of $5,855 (33 OTPs × ((3.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). Since these OTPs would not be completing the Form CMS–855B as originally anticipated in the November 15, 2019 final rule and approved by OMB in that rule's collection of information request, we must revise the Form CMS–855B estimates identified therein. Using the hour and wage burdens from that rule, we project a Form CMS–855B annual burden reduction of 99 hours (33 OTPs × 3 hr) at a cost of $4,560 (33 OTPs × (2.5 hr × $35.66/hr) + (0.5 hr × $98.04/hr)).

(b) Enrolled OTPs Transitioning to Form CMS–855A or Form CMS–855B Enrollment

As already mentioned, we believe that roughly:

++ 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A.

++ 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B.

This would involve the OTP's completion of a Form CMS–855A or Form CMS–855B application as a new enrollment. We note that in our proposed estimates, we had stated that these OTPs would also need to report the voluntary termination of their existing Form CMS–855 enrollment via the latter form (that is, if the OTP is ceasing its Form CMS–855B enrollment, it would report this via a Form CMS–855B voluntary termination submission). Upon further analysis and reflection, this step will not be necessary; termination of the prior enrollment will done by the Medicare contractor systematically. Accordingly, we are not finalizing our estimates of the burden associated with completing a Form CMS–855 voluntary termination application.

(i) Transition to Form CMS–855A Enrollment

Under our previously mentioned Form CMS–855A hour and wage estimates, we project a total burden for new Form CMS–855A enrollments pursuant to revised § 424.67(b) of 1,200 hours (300 OTPs × 4 hr) at a cost of $53,229 (300 OTPs × ((3.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). We believe this burden would be incurred exclusively in the first year following our changes; it is very likely these OTPs would wish to pursue Form CMS–855A enrollment as soon as possible in order to bill via the 837I. Over the first 3 years, the average annual burden would be 400 hours (1,200 hr/3) at a cost of $17,743 ($53,229/3).

(ii) Transition to Form CMS–855B Enrollment

In line with our hour and wage estimates previously referenced in this section VII.B.1. of this final rule, we project a total burden for new Form CMS–855B enrollments under § 424.67(c)(2) of 30 hours (10 OTPs × 3 hr) at a cost of $1,480 (10 OTPs × ((2.5 hr × $36.62/hr) + (0.5 hr × $98.52/hr)). We anticipate that changes to a Form CMS–855B enrollment would occur in the second and third years following the effective date of our revisions. This is because Year 1 would mostly involve these new OTPs enrolling for the first time via the Form-855A; only in the succeeding 2 years would they switch to a Form CMS–855B enrollment. We thus project that the average annual burden in the first 3 years would be 10 hours (30 hr/3) at a cost of $469 ($1,408/3).

(2) Total Annual Burden

In light of foregoing estimates, and when averaged over the typical 3-year OMB approval period, we estimate the following:

- Form CMS–855A—The total annual increased burden would be 532 hours (132 hr + 400 hr) at a cost of $23,598 ($5,855 + $17,743).
- Form CMS–855B—We project a reduction in annual burden of −89 hours (−99 hr−10 hr) and $4,091 (−$4,560−$469).

(3) Application Fee

Under § 424.67(b)(2), an enrolling OTP must comply with the application fee requirements in § 424.514. This means, in short, that an OTP must pay the required application fee as part of the enrollment process. The application fee does not meet the definition of a ''collection of information'' and, as such, is not subject to the requirements of the PRA. Although we did not set out such burden under this section of the preamble, the cost is included under the Regulatory Impact Analysis section.

(4) Fingerprinting

We discussed in section III.B. of this final rule that certain OTPs are subject to the high-risk level of categorical screening under § 424.518. Said screening includes the submission of a set of fingerprints (via FBI Applicant Fingerprint Card FD–258) for a national background check from all individuals who maintain a 5 percent or greater direct or indirect ownership interest in the provider or supplier. In the November 15, 2019 final rule, we calculated the hour and cost burden associated with this activity, basing our estimates on an anticipated 1,900 total OTP enrollees over the 3-year period following publication of that rule.

We do not believe our revisions to § 424.67 would involve any additional or reduced fingerprinting burden for two reasons. First, we specify in revised § 424.67(b)(3)(ii) that, in effect, Form CMS–855B-enrolled OTPs that are changing to a Form CMS–855A enrollment need only undergo the limited level of categorical screening (§ 424.518) if they have (as part of their Form CMS–855 enrollment) already successfully completed the moderate or high level of categorical screening under that same regulatory section. Since completion of moderate or high level screening (as applicable) would have been required for Form CMS–855B OTP enrollment, these OTPs (previously estimated at 300 total) would not have to again undergo fingerprinting as part of their Form CMS–855A enrollment. Second, and with the exception of the 300 new enrollments mentioned in the previous sentence, we do not foresee additional enrolling OTPs beyond: (1) The 1,900 which we estimated in the November 15, 2019 final rule; and (2) the roughly 67 newly enrolling OTPs in Year 2 and Year 3 and annually thereafter. In other words, the only change we project would be in the type of Form CMS–855 application these OTPs may complete, not the number of anticipated enrollees. As such, the total fingerprinting burden would not change.

We received no comments regarding our ICR estimates pertaining to OTP provider enrollment.

2. ICRs Regarding the Medicare Shared Savings Program (42 CFR Part 425)

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out burden under the authority of the PRA. Please refer to sections VIII.H.7.a., VIII.H.7.b., VIII.H.7.c., and VIII.H.8. of this final rule for a discussion of the impacts associated with this rule's changes to the Shared Savings Program's quality reporting requirements, beneficiary assignment methodology, and repayment mechanism requirements, and section VIII.H.7.c. of this final rule for a discussion of the impacts associated with finalization of Shared Savings Program policies established in the May 8th COVID–19 IFC.

3. ICRs Regarding the Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan § 423.160(a)

When ready, the following changes will be submitted to OMB through the standard PRA process for approval under control number 0938–TBD (CMS–10755). The standard PRA process includes the publication of 60- and 30-day **Federal Register** notices, which we expect to publish shortly after the publication of this final rule. Please note that the proposed rule indicated (85 FR 50340) that the changes would be submitted under control number 0938–0763 (CMS–R–262). However, based on internal review we have since determined that the changes should be set out under a new collection of information request. Importantly, the new collection of information request (0938–TBD; CMS–10755) has no effect on our proposed and final requirements and burden estimates. Rather, we are simply changing the location of those requirements and burden estimates. Please note that OMB will issue the new control number when ready. In the meantime it is to be determined (or ''TBD''). The new collection of information request's CMS identification number (CMS–10755) is not subject to change.

We are implementing section 2003 of the SUPPORT for Patients and Communities Act, which requires that the prescribing of a Schedule II, III, IV, or V controlled substance under Medicare Part D be done electronically in accordance with an electronic prescription drug program beginning January 1, 2021, subject to any exceptions, which HHS may specify. We are requiring prescribers to use the NCPDP SCRIPT 2017071 standard for Electronic Prescription for Controlled Substances (EPCS) prescription transmissions beginning January 1, 2021.

In the first year of implementation, we expect that prescribers would have to revise their policies and procedures and-train staff on this new requirement. Based on our conversations with providers, EHR vendors, and Part D plans, we understand that because electronic prescribing is so widespread and vendors train the staff directly and set-up their systems, we estimate that this transition could be completed with a one-time burden of 5 hours at $36.62/hr by an Administrative Assistant or Medical Secretary. We solicited comments on this assumption and, we received several public comments related to the numbers used for this burden estimate assumption for the Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan.

Comment: Several commenters expressed concerns that CMS' proposal assumes these functionalities to be successful, when in actuality they still require significant fixes and delayed implementation timelines. Perhaps the biggest challenge clinicians will face, commenters stated, is incorporating EPCS into their EHRs, and most clinician practices are not in a position to cover the costs and acquire the necessary resources for technical or system upgrades required by EHR vendors—especially rural and small practices. Commenters stated that due to the PHE for COVID–19, many practices have been forced to delay or cancel implementation altogether of EHRs that support EPCS due to the implementation cost. Commenters expressed concern that practices that do not currently even have the capability to prescribe electronically would be forced to purchase such a software. A commenter supported the intent to facilitate efficiency, convenience, and better security with the implementation of EPCS, but encourages CMS to avoid unreasonable burden imposed upon clinicians and delay compliance until at least January 1, 2023.

Response: We are aware of the difficulties that many clinicians may face when implementing EPCS. Given that the mandate is statutory with potentially broad public health

implications, we believe a January 1, 2021 effective date complies with the statutory intent and would enable the safety and other benefits previously discussed to be put in place during the current pandemic. However, to help ensure that the burden on prescribers is not unreasonable, we will be finalizing a compliance date of January 1, 2022 such that prescribers who do not implement the NCPDP SCRIPT 2017071 standard for electronic prescribing of Schedule II, III, IV, and V controlled substances until January 1, 2022 will still be considered compliant with the requirement. We have also adjusted the estimate of the provider burden to accurately reflect fixing any issues that may arise.

Comment: One commenter expressed concern with the health care provider burden associated with reporting EPCS transactions to CMS.

Response: Based on internal CMS data, there are 425,000 Part D prescribing practices. Based on the increasing rate of doctors conducting e-prescribing thus far in light of the current social distancing guidelines, currently, 61 percent of Part D prescribers have electronic prescribing capabilities absent the requirement. Therefore, the one-time burden to implement this provision is 828,750 hours (165,750 prescribers * 5 hr) at a cost of $30,348,825 (828,750 hr * $36.62/hr). Based on the modeling that we have seen, we have found that EHR companies provide the initial set-up of e-prescribing software free of charge, provided the prescribers pay the per transaction cost of $1.88 mentioned previously. Based on the comments received, we understand that implementing EPCS can lead to technological glitches, and then fixing those issues. We understand that the EHR companies remedy the issues free of charge. However, we understand that such fixes take time away from the medical office staff. We estimate that such fixes would take the staff approximately 1 extra hour when averaged across all prescribers. As a result, we have changed our one-time burden estimate from 5 hours to 6 hours per provider, which means a total of 994,500 hours (165,750 * 6 hr) at a cost of $36,418,590 (994,500 hr * 36.62).

4. ICRs Regarding the Medicare Diabetes Prevention Program (MDPP) Expanded Model

In section III.P. of this final rule, we finalize policies necessary to allow certain flexibilities for Medicare enrolled MDPP suppliers and eligible beneficiaries in the MDPP Expanded Model during a PHE. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the MDPP expanded model, from the provisions of the PRA.

5. The Quality Payment Program (42 CFR Part 414 and Section IV. of This Final Rule)

The following QPP-specific ICRs reflect this rule's finalized policy changes and policies that have been finalized in our CY 2017 and 2018 Quality Payment Program final rules (81 FR 77008 and 82 FR 53568, respectively), and our CY 2019 and CY 2020 PFS final rules (83 FR 59452 and 84 FR 62568, respectively).

a. Background

(1) ICRs Associated With MIPS and Advanced APMs

The Quality Payment Program is comprised of a series of ICRs associated with MIPS and Advanced APMs. The MIPS ICRs consist of: Registration for virtual groups (see section VII.B.5.b of this final rule); QCDR self-nomination applications and other requirements (see section VII.B.5.c.(2) of this final rule); qualified registry self-nomination applications and other requirements (see section VII.B.5.c.(3) of this final rule); CAHPS survey vendor applications (see section VII.B.5.c.(4) of this final rule); Open Authorization credentialing and token request process (see section VII.B.5.d of this final rule); Quality Payment Program Identity Management Application Process (see section VII.B.5.e.(3) of this final rule); quality performance category data submission by Medicare Part B claims collection type (see section VII.B.5.e.(4) of this final rule), QCDR and MIPS CQM collection type (see section VII.B.5.e.(5) of this final rule), eCQM collection type (see section VII.B.5.e.(6) of this final rule), and CMS Web Interface collection type (see section VII.B.5.e.(7) of this final rule); CAHPS for MIPS survey beneficiary participation (see section VII.B.5.e.(8) of this final rule); group registration for CMS Web Interface (see section VII.B.5.e.(9) of this final rule); group registration for CAHPS for MIPS survey (see section VII.B.5.e.(10) of this final rule); call for quality measures (see section VII.B.5.f of this final rule); reweighting applications for Promoting Interoperability and other performance categories (see section VII.B.5.g.(2) of this final rule); Promoting Interoperability performance category data submission (see section VII.B.5.g.(3) of this final rule); call for Promoting Interoperability measures (see section VII.B.5.h of this final rule); improvement activities performance category data submission (see section VII.B.5.i of this final rule); nomination of improvement activities (see section VII.B.5.j of this final rule); nomination of MVPs (see section VII.B.5.k of this final rule); and opt-out of Physician Compare for voluntary participants (see section VII.B.5.o of this final rule).

The ICRs for Advanced APMs consist of: Partial Qualifying APM Participant (QP) election (section VII.B.5.m of this final rule); Other Payer Advanced APM identification: Payer Initiated and Eligible Clinician Initiated Processes (sections VII.B.5.n.(1) and (2) of this final rule); and submission of data for QP determinations under the All-Payer Combination Option (section VII.B.5.n.(3) of this final rule).

(2) Summary of Quality Payment Program Changes: MIPS

Nine MIPS ICRs [(1) QCDR self-nomination applications, (2) Qualified Registry self-nomination applications, (3) quality performance category data submission by QCDR and MIPS CQM collection type, (4) quality performance category data submission by eCQM collection type, (5) quality performance category data submission by CMS Web Interface collection type, (6) group registration for the CMS Web Interface, (7) CAHPS for MIPS survey beneficiary participation, (8) nomination of improvement activities, and (9) reweighting applications for Promoting Interoperability and other performance categories] show changes in burden due to finalized policies. In aggregate, we estimate the policies will result in a net increase in burden of +1,163 hours and +$120,391 for the 2021 MIPS performance period and −4,763 hours and −$421,117 for the 2022 MIPS performance period. The provisions discussed in section VII.A.3.g. to require QCDRs and qualified registries to conduct targeted audits if one or more deficiencies or data errors are identified in an annual data validation audit will increase the annual burden hours for both QCDRs and qualified registries by a range of 5 to 10 hours per audit. The provision discussed in section IV.A.3.c.(1)(c) of this final rule to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period will result in removal of the quality performance category data submission by CMS Web Interface collection type and group registration for the CMS Web Interface ICRs beginning with the 2022 MIPS performance period. The same provision will increase the number of respondents for both the MIPS CQM and QCDR and eCQM collection types for

the quality performance category beginning with the 2022 MIPS performance period as we assume respondents who previously submitted via the CMS Web Interface collection type will alternatively utilize one of these collection types to submit quality data in the 2022 MIPS performance period. The provision discussed in section IV.A.3.c.(1)(f)(i) of this final rule to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the CAHPS for MIPS Survey will increase the time required for beneficiaries to respond to the survey by 0.2 minutes (0.0033 hours) per beneficiary. The provision discussed in section IV.A.3.c.(3)(b)(i)(B)(bb) of this final rule to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible will increase the time by 1 hour per improvement activity nominated. Finally, the provision discussed in section IV.A.3.c.(5)(e) of this final rule to allow APM Entities the ability to submit an extreme and uncontrollable circumstances exception application will increase our estimated number of respondents by 7 APM Entities. The remaining changes to our currently approved burden estimates are adjustments due to the use of updated data sources available at the time of publication of this final rule.

We have also added two new ICRs (Open Authorization (OAuth) Credentialing and Token Request Process (see section VII.B.5.d of this final rule) and the Nomination of MVPs (see section VII.B.5.k of this final rule). The Open Authorization (OAuth) Credentialing and Token Request Process ICR reflects the burden associated with the availability of a new process for all submitter types to request approval to submit data via direct upload to CMS. The Nomination of MVPs reflects the burden associated with a new process available for all stakeholders to nominate MVPs for inclusion in the Quality Payment Program.

We are not making any changes or adjustments to the following ICRs: Registration for virtual groups, CAHPS survey vendor applications, Quality Payment Program Identity Management Application Process, group registration for CAHPS for MIPS survey; call for MIPS quality measures; and call for Promoting Interoperability measures. See section VII.B.5. of this final rule for a summary of the ICRs, the overall burden estimates, and a summary of the assumption and data changes affecting each ICR.

The accuracy of our estimates of the total burden for data submission under the quality, Promoting Interoperability, and improvement activities performance categories may be impacted due to two primary reasons. First, we are unable to predict with 100 percent certainty who will be a QP. New eligible clinician participants in Advanced APMs who become QPs would be excluded from MIPS reporting requirements and payment adjustments, and as such, unlikely to report under MIPS; while some current Advanced APM participants may end participation such that the APM Entity's eligible clinicians would not be QPs for a year based on § 414.1425(c)(5), and thus be required to report under MIPS. Second, it is difficult to predict what Partial QPs, who can elect whether to report to MIPS, will do in the 2021 MIPS performance period compared to the 2019 MIPS performance period, and therefore, the actual number of Advanced APM participants and how they elect to submit data may be different than our estimates. However, we believe our estimates are the most appropriate given the available data.

(3) Summary of Quality Payment Program Changes: Advanced APMs

For these ICRs (identified above under, ''ICRs Associated with MIPS and Advanced APMs''), the changes to currently approved burden estimates are adjustments based on updated projections for the 2021 MIPS performance period. We are not making any changes to the Other Payer Advanced APM identification: Eligible Clinician Initiated Process and submission of Data for QP determinations under the All-Payer Combination Option ICRs.

(4) Framework for Understanding the Burden of MIPS Data Submission

Because of the wide range of information collection requirements under MIPS, Table 61 presents a framework for understanding how the organizations permitted or required to submit data on behalf of clinicians vary across the types of data, and whether the clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, MIPS APM participant, or an Advanced APM participant. As shown in the first row of Table 61, MIPS eligible clinicians that are not in MIPS APMs and other clinicians voluntarily submitting data will submit data either as individuals, groups, or virtual groups for the quality, Promoting Interoperability, and improvement activities performance categories. Note that virtual groups are subject to the same data submission requirements as groups, and therefore, we will refer only to groups for the remainder of this section unless otherwise noted. Because MIPS eligible clinicians are not required to submit any additional information for assessment under the cost performance category, the administrative claims data used for the cost performance category is not represented in Table 61.

For MIPS eligible clinicians participating in MIPS APMs, the organizations submitting data on behalf of MIPS eligible clinicians will vary between performance categories and, in some instances, between MIPS APMs. As discussed in section IV.A.3.b. of this final rule, for clinicians in APM Entities, the APM Performance Pathway is available for both ACO and non ACOs to submit quality data. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway, using the CMS Web Interface option, and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity.

For the Promoting Interoperability performance category, group TINs may submit data on behalf of eligible clinicians in MIPS APMs, or eligible clinicians in MIPS APMs may submit data individually. For the improvement activities performance category, we will assume no reporting burden for MIPS APM participants. In the CY 2017 Quality Payment Program final rule, we described that for MIPS APMs, we compare the requirements of the specific MIPS APM with the list of activities in the Improvement Activities Inventory and score those activities in the same manner that they are otherwise scored for MIPS eligible clinicians (81 FR 77185). Although the policy allows for the submission of additional improvement activities if a MIPS APM receives less than the maximum improvement activities performance category score, to date all MIPS APM have qualified for the maximum improvement activities score. Therefore, we assume that no additional submission will be needed.

Eligible clinicians who attain Partial QP status may incur additional burden if they elect to participate in MIPS, which is discussed in more detail in the CY 2018 Quality Payment Program final rule (82 FR 53841 through 53844).

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TABLE 61: Clinicians or Organizations Submitting MIPS Data on Behalf of Clinicians, by Type of Data and Category of Clinician*

Category of Clinician	Type of Data Submitted			
	Quality Performance Category	Promoting Interoperability Performance Category	Improvement Activities Performance Category	Other Data Submitted on Behalf of MIPS Eligible Clinicians
MIPS Eligible Clinicians and Other Eligible Clinicians Voluntarily Submitting MIPS Data, Participating in Shared Savings Program, and other MIPS APMs that use the APM Performance Pathway for model measures	As virtual group, group, individual clinicians, or APM Entity.[a]	As virtual group, group, individual clinicians, or APM Entity. Certain types of MIPS eligible clinicians are automatically eligible for a zero percent weighting for the Promoting Interoperability performance category. Clinicians who submit an application and are approved for significant hardship or other exceptions are also eligible for a zero percent weighting. Each MIPS eligible clinician in the APM Entity reports data for the Promoting Interoperability performance category through either group TIN or individual reporting. [The burden estimates for this final rule assume group TIN-level reporting].[b]	As virtual group, group, or individual clinicians. MIPS APMs do not submit information. CMS will assign the same improvement activities performance category score to each APM Entity based on the activities involved in participation in the MIPS APM.[c]	Groups electing to use a CMS-approved survey vendor to administer CAHPS must register. Groups electing to submit via CMS Web Interface for the first time must register. MIPS APMs electing the APM Performance Pathway. APM Entities will make Partial QP election for participating eligible clinicians. Virtual groups must register via email.[d]

* Because the cost performance category relies on administrative claims data, MIPS eligible clinicians are not required to provide any additional information, and therefore, the cost performance category is not represented in this table.

[a] Submissions by the ACO are not included in burden estimates for this final rule because quality data submissions to fulfill requirements of the Shared Savings Program and for purposes of testing and evaluating the Next Generation ACO Model are not subject to the PRA. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA.

[b] Both group TIN and individual clinician Promoting Interoperability data will be accepted. If both group TIN and individual scores are available for the same APM Entity, CMS will use the higher score for each TIN/NPI. The TIN/NPI scores are then aggregated for purposes of calculating the APM Entity score.

[c] The burden estimates for this final rule assume no improvement activities performance category reporting burden for APM participants because we assume the MIPS APM model provides a maximum improvement activity score. APM Entities participating in MIPS APMs receive an improvement activities performance category score of at least 50 percent (§ 414.1380) and do not need to submit improvement activities data unless the CMS-assigned improvement activities scores are below the maximum improvement activities score.

[d] Virtual group participation is limited to MIPS eligible clinicians, specifically, solo practitioners and groups consisting of 10 eligible clinicians or fewer.

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The policies finalized in the CY 2017 and CY 2018 Quality Payment Program final rules, the CY 2019 and CY 2020 PFS final rules, and continued in this

final rule create some additional data collection requirements not listed in Table 61. These additional data collections, some of which are currently approved by OMB under the control numbers 0938–1314 (Quality Payment Program, CMS–10621) and 0938–1222 (CAHPS for MIPS, CMS–10450), are as follows:

Additional ICRs Related to MIPS Third-Party Intermediaries (See Section VII.B.5.c)

- Self-nomination of new and returning QCDRs (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59998 through 60000) (OMB 0938–1314).
- Self-nomination of new and returning registries (81 FR 77507 through 77508, 82 FR 53906 through 53908, and 83 FR 59997 through 59998) (OMB 0938–1314).
- Approval process for new and returning CAHPS for MIPS survey vendors (82 FR 53908) (OMB 0938–1222).
- Open Authorization Credentialing and Token Request Process (New) (OMB 0938–1314) (see section VII.B.5.d).

Additional ICRs Related to the Data Submission and the Quality Performance Category (See Section VII.B.5.e)

- CAHPS for MIPS survey completion by beneficiaries (81 FR 77509, 82 FR 53916 through 53917, and 83 FR 60008 through 60009) (OMB 0938–1222).
- Quality Payment Program Identity Management Application Process (82 FR 53914 and 83 FR 60003 through 60004) (OMB 0938–1314).

Additional ICRs Related to the Promoting Interoperability Performance Category (See Section VII.B.5.g)

- Reweighting Applications for Promoting Interoperability and other performance categories (82 FR 53918 and 83 FR 60011 through 60012) (OMB 0938–1314).

Additional ICRs Related To Call for New MIPS Measures and Activities (See Sections VII.B.5.f, VII.B.5.h, VII.B.5.j. and VII.B.5.k)

- Nomination of improvement activities (82 FR 53922 and 83 FR 60017 through 60018) (OMB 0938–1314).
- Call for new Promoting Interoperability measures (83 FR 60014 through 60015) (OMB 0938–1314).
- Call for MIPS quality measures (83 FR 60010 through 60011) (OMB 0938–1314).
- Nomination of MVPs (OMB 0938–1314).

Additional ICRs Related to MIPS (See Section VII.B.5.o)

- Opt out of performance data display on Physician Compare for voluntary reporters under MIPS (82 FR 53924 through 53925 and 83 FR 60022) (OMB 0938–1314).

Additional ICRs Related to APMs (See Sections VII.B.5.m and VII.B.5.n)

- Partial QP Election (81 FR 77512 through 77513, 82 FR 53922 through 53923, and 83 FR 60018 through 60019) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Payer Initiated Process (82 FR 53923 through 53924 and 83 FR 60019 through 60020) (OMB 0938–1314).
- Other Payer Advanced APM determinations: Eligible Clinician Initiated Process (82 FR 53924 and 83 FR 60020) (OMB 0938–1314).
- Submission of Data for All-Payer QP Determinations (83 FR 60021) (OMB 0938–1314).

b. ICRs Regarding the Virtual Group Election (§ 414.1315)

This rule is not implementing any new or revised collection of information requirements or burden related to the virtual group election. The virtual group election requirements and burden are currently approved by OMB under control number 0938–1343 (CMS–10652). Consequently, we are not making any virtual group election changes under that control number.

c. ICRs Regarding Third-Party Intermediaries (§ 414.1400)

In section IV.A.3.g. of this rule, we discuss multiple changes to the third party intermediary regulations at § 414.1400. Specifically, we are: (1) Amending current requirements for approval of third party intermediaries to take into account past performance and provision of inaccurate information regarding MIPS program requirements to eligible clinicians; (2) requiring attendance by all third party intermediaries for training and support sessions; (3) requiring that QCDRs and qualified registries must conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits; (4) incrementally increasing requirements for QCDR measure testing and clarify what is meant by full testing; and (5) requiring third party intermediaries to submit a CAP to address identified deficiencies and data issues, as well as actions to prevent recurrence. The collection of information burdens associated with each of these topics are discussed separately below for qualified registries, QCDRs, and survey vendors.

(1) Background

Under MIPS, the quality, Promoting Interoperability, and improvement activities performance category data may be submitted via relevant third-party intermediaries, such as qualified registries, QCDRs, and health IT vendors. Data on the CAHPS for MIPS survey, which counts as either one quality performance category measure, or towards an improvement activity, can be submitted via CMS-approved survey vendors. Entities seeking approval to submit data on behalf of clinicians as a qualified registry, QCDR, or survey vendor must complete a self-nominate process annually.[147] The processes for self-nomination for entities seeking approval as qualified registries and QCDRs are similar with the exception that QCDRs have the option to nominate QCDR measures for approval for the reporting of quality performance category data. Therefore, differences between QCDRs and qualified registry self-nomination are associated with the preparation of QCDR measures for approval.

(2) QCDR Self-Nomination Applications

The requirements and burden associated with this rule's data submission changes related to QCDRs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). For simplicity and due to limitations in data available, the changes in burden for QCDRs and qualified registries associated with the finalized policies regarding CAPs have been incorporated into the discussion of burden for qualified registries.

(a) Self-Nomination Process and Other Requirements

We refer readers to § 414.1400(a)(4) which states that QCDRs interested in submitting MIPS data to us on behalf of a MIPS eligible clinician, group, or virtual group will need to complete a self-nomination process to be considered for approval to do so. We also refer readers to § 414.1400(b) and the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59998 through 60000), and the CY 2020 PFS final rule (84 FR 63116 through 63121) for our previously finalized requirements and burden for self-

[147] As stated in the CY 2019 PFS final rule (83 FR 53998), health IT vendors are not included in the burden estimates for MIPS.

nomination of QCDRs and nomination of QCDR measures.

In section VII.A.3.g.(2)(a) of this rule, we are codifying that beginning with the 2023 payment year as a condition of approval each QCDR must conduct annual data validation audits that conform to the requirements in § 414.1400(b)(2)(iv), including specific obligations discussed in detail in those sections, and if one or more deficiencies or data errors are identified the QCDR must also conduct targeted audits that conform to the § 414.1400(b)(2)(v) including specific obligations discussed in detail in those sections. In particular, we are codifying at § 414.1400(b)(2)(iv)(G), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. In addition, we are codifying at § 414.1400(b)(2)(v)(D), that in a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected. We are not revising our burden estimates as a result of the provision to codify that QCDRs must conduct particular data validation audits and report data validation results because we believe the burdens of the data validation requirements are not greater than existing expectations for which we have already accounted the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and previously submitted to OMB for approval under control number 0938–1314 (CMS–10621).

With regard to the provision to require QCDRs to conduct targeted audits if one or more data errors are identified during data validation audits, we solicited comment on the burdens associated with the requirements for data validation audits and targeted audits, including expected frequency of targeted audits and the anticipated scope of effort related to submitting results to assist in estimating the burden associated with this provision, but received no comments. However, we are including burden estimates associated with this finalized requirement based on our best available analysis. Due to the unknown scope of patient records that may need to be audited, we estimate a range of effort to complete a targeted data audit from a minimum of 5 hours to a maximum of 10 hours at a cost ranging from $462.30 ($92.46/hr × 5 hrs) to $924.60 ($92.46/hr × 10 hrs) per targeted audit. In the 2019 MIPS performance period, 23 of the 77 QCDRs (30%) that submitted 2019 MIPS quality data were required to complete a targeted audit. Based on the results of the 2020 self-nomination period, 58 QCDRs have been approved for the 2021 MIPS performance period; assuming the same percentage, we estimate 17 QCDRs (58 × 30%) will be required to complete targeted audits. Therefore we estimate the total impact associated with QCDRs completing targeted audits will range from 85 hours (17 audits × 5 hrs/audit) at a cost of $7,859 (17 audits × $462.30/audit) to 170 hours (17 audits × 10 hrs/audit) at a cost of $15,718 (17 audits × $924.60/audit). We also discuss additional impacts of this provision in section VIII.H.15.e.(4)(d) of the Regulatory Impact Analysis.

In section VII.A.3.g.(1)(b)(iii) of this rule, we are codifying that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner and at the times, specified by CMS. Due to the nature of the information provided during these calls and because the training requirements as applied to qualified registries and QDCRs are similar to existing expectations for these entities, we are not revising our burden estimates as a result of the provisions. However, we refer readers to section VIII.H.15.e.(4)(d) of this final rule for discussion of our estimates of overall impact.

In section VII.A.3.g.(1)(b)(ii) of this rule, we discussed that the determination of whether to approve as entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with requirements of third party intermediaries for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician. Because this provision does not require any additional effort for affected entities but instead allows CMS to utilize already available information to make approval decisions, collection of information burden is unaffected for all entities. In addition, we do not anticipate this provision will result in any QCDRs electing not to self-nominate during the 2021 MIPS performance period, but believe it is possible this may occur. However, we have neither any data nor knowledge of intent from previously approved QCDRs with which to support making any changes to our burden estimates as a result of this policy. We solicited public feedback to help us determine if there are any burden implications. We did not receive comments related to this provision.

For this rule, we are adjusting the number of QCDRs we assume will self-nominate for the CY 2022 performance period from the currently approved estimate of 76 to 82, an increase of 6 from the currently approved estimate based on the number of self-nominations received during the CY 2020 nomination period which was ongoing at the time the CY 2021 PFS proposed rule was published. As discussed in section IV.A.3.g, some commenters expressed their opinion that specific requirements as well as the totality of requirements imposed on QCDRs may result in some QCDRs electing to no longer participate in QPP. Without specific information regarding the intent of each QCDR, we are unable to determine if a future decrease in QCDR participation will occur. We note that additional requirements for QCDRs were finalized in the CY 2020 PFS final rule and there was an increase in QCDRs self-nominating during the subsequent CY 2020 self-nomination period. We continue to update our burden estimates annually as we receive updated data; if QCDRs elect to end their participation in the future, we will adjust our burden estimates when the corresponding data is available.

(b) QCDR Measure Requirements

Previously, we finalized a requirement to require all QCDR measures to be fully developed and tested, with complete testing results at the clinician level, beginning with the CY 2021 performance period in the CY 2020 PFS final rule (84 FR 40816). In the May 8th COVID–19 IFC–2 (85 FR 27594 through 27595), we delayed this requirement such that beginning with the CY 2022 performance period, all QCDR measures must be fully developed and tested, with complete testing results at the clinician level, prior to submitting the QCDR measure at the time of self-nomination. In section VII.A.3.g.(2)(b)(i)(B) of this rule, we discussed an incremental approach to require fully tested QCDR measures. Specifically, at § 414.1400(b)(3)(v)(C)(*1*)we are finalizing that QCDR measures that were previously approved for the CY 2020

performance period, would be required to, at a minimum, be face valid prior to being self-nominated for the CY 2022 performance period/CY 2024 payment year. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved. In order for the QCDR measure to be considered for approval, testing must be completed at the clinician level by the time the measure is self-nominated. However, to be included in an MVP for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested. QCDR measures that were previously approved for the 2020 performance period, will be required to, at a minimum, be face valid prior to being self-nominated for the CY 2022 performance period, and would be required to be fully tested prior to being self-nominated for any subsequent performance periods in order to be considered for inclusion in the MIPS program. Because these provisions are not modifying the final testing requirements for QCDR measures but are instead are making modifications to the phasing and timeline for implementation of previously finalized requirements for QCDR measures other than those which will be included in an MVP, we are not making any changes to our currently approved burden estimates; however, we refer readers to section VIII.H.15.e.(4)(d) of this final rule for discussion of impacts associated with this provision. Such burden estimates and requirements are currently approved by OMB under control number 0938–1314 (CMS–10621). We solicited comment on our burden estimates and assumptions associated with these provisions regarding the testing of QCDR measures including those which will be included in an MVP. We did not receive comments related to our burden estimates and assumptions regarding the testing of QCDR measures.

We assume that the staff involved in the QCDR self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $92.46/hr. Considering that the time per QCDR associated with the self-nomination process range from a minimum of 5.5 hours to a maximum of 8 hours, we estimate that the annual burden will range from 451 hours (82 QCDRs × 5.5 hr) to 656 hours (82 QCDRs × 8 hr) at a cost ranging from $41,699 (451 hr × $92.46/hr) and $60,654 (656 hr × $92.46/hr), respectively. Combined with our estimate of annual burden for targeted audits, the total burden estimate ranging from 536 hours (451 + 85) at a cost of $49,559 ($41,699 + 7,859) to 826 hours (656 +170) at a cost of $76,372 ($60,654 + $15,718) (see Table 62).

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a QCDR self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 62: Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

	Minimum	Maximum
# of QCDR Simplified Self-Nomination Applications submitted (a)	82	0
# of QCDR Full Self-Nomination Applications submitted (b)	0	82
Total Applications	**82**	**82**
Total Annual Hours Per QCDR for Simplified Process (c)	5.5	5.5
Total Annual Hours Per QCDR for Full Process (d)	8	8
Total Annual Hours (e) = (a)*(c) + (b)*(d)	**451**	**656**
Cost Per Simplified Process Per QCDR (@ computer systems analyst's labor rate of $92.46/hr) (f)	$508.53	$508.53
Cost Per Full Process Per QCDR (@ computer systems analyst's labor rate of $92.46/hr) (g)	$739.68	$739.68
Total Annual Cost (h) = (a)*(f)+(b)*(g)	**$41,699**	**$60,654**

As shown in Table 63, using the unchanged currently approved per respondent burden estimate, the increase in respondents from 76 to 82 results in an increase of between +33 (+6 respondents × 5.5 hr/respondent) and +48 hours (+6 respondents × 8 hr/respondent) at a cost of between +$3,051 (6 respondents × $508.53/respondent) and +$4,438 (6 respondents × $739.68/respondent). The finalized policy to require targeted audits as necessary results in an increase of between +85 (17 audits × 5hrs/audit) and +170 (17 audits × 10 hrs/audit) at a cost of between $7,859 (17 audits × $462.30/audit) and $15,718 (17 audits × $924.60/audit). In aggregate, we estimate a total increase in burden of between +118 hours (33 + 85) at a cost $10,911 ($3,051 + $7,859) and +218 hours (48 + 170) at a cost of $20,156 ($4,438 + $15,718).

TABLE 63: Change in Estimated Burden for QCDR Self-Nomination and QCDR Measure Submission

	Minimum Burden Estimate	Maximum Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	418	608
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	536	826
Difference (c) = (b)-(a)	**+118**	**+218**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$38,648	$56,216
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$49,559	$76,372
Difference (f) = (e)-(d)	**+$10,911**	**+20,156**

(3) Qualified Registry Self-Nomination Process and Other Requirements

The requirements and burden associated with this rule's data submission changes related to qualified registries and QCDRs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to § 414.1400(a)(4) which states that qualified registries interested in submitting MIPS data to us on behalf of MIPS eligible clinicians, groups, or virtual groups need to complete a self-nomination process to be considered for approval to do so. We also refer readers to § 414.1400 (c) and the CY 2017 Quality Payment Program final rule (81 FR 77507 through 77508), CY 2018 Quality Payment Program final rule (82 FR 53906 through 53908), CY 2019 PFS final rule (83 FR 59997 through 59998), and the CY 2020 PFS final rule (84 FR 63114 through 63116) for our previously finalized requirements and burden for self-nomination of qualified registries.

In section IV.A.3.g.(3) of this rule, we are codifying that beginning with the 2023 payment year as a condition of approval each qualified registry must conduct annual data validation audits that conform to the requirements in § 414.1400(b)(2)(iv), including specific obligations discussed in detail in those sections and if one or more deficiencies or data errors are identified the qualified registry must also conduct targeted audits that conform to the § 414.1400(b)(2)(v) including specific obligations discussed in detail in those sections. In particular, we are codifying at § 414.1400(c)(2)(iii)(G), that in a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, and how and when each deficiency or data error type was corrected. In addition, we are codifying at § 414.1400(c)(2)(iv)(D), in a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each error type was corrected. We are not revising our burden estimates as a result of the provision to codify that qualified registries must conduct particular data validation audits and report data validation results because we believe the burdens of the data validation requirements are not greater than existing expectations for which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999) and previously submitted to OMB for approval under control number 0938–1314 (CMS–10621).

With regard to the provision to require qualified registries conduct targeted audits if one or more data errors are identified during data validation audits, we solicited comment on the burdens associated with the requirements for data validation audits and targeted audits, including expected frequency of targeted audits and the anticipated scope of effort related to submitting results to assist in estimating the burden associated with this provision, but did not receive any. However, we are including burden estimates associated with this finalized requirement based on our best available analysis. Due to the unknown scope of patient records that may need to be audited, we estimate a range of effort to complete a targeted data audit from a minimum of 5 hours to a maximum of 10 hours at a cost ranging from $462.30 ($92.46/hr × 5 hrs) to $924.60 ($92.46/hr × 10 hrs) per targeted audit. In the 2019 MIPS performance period, 37 of the 84 QCDRs (44%) that submitted 2019 MIPS quality data were required to complete a targeted audit. Based on the results of the 2020 self-nomination period, 127 qualified registries have been approved for the 2021 MIPS performance period; assuming the same percentage, we estimate 56 qualified registries (127 × 44%) will be required to complete targeted audits. Therefore we estimate the total impact associated with qualified registries completing targeted audits will range from 280 hours (56 audits × 5 hrs/audit) at a cost of $25,889 (56 audits × $462.30/audit) to 560 hours (56 audits × 10 hrs/audit) at a cost of $51,778 (56 audits × $924.60/audit). We also discuss additional impacts of this provision in section VIII.H.15.e.(4)(d) of the Regulatory Impact Analysis.

In sections VII.A.3.g.(1)(b)(iii) of this rule, we are codifying that beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times specified, by CMS. Due to the nature of the information provided during these calls and because the training requirements as applied to qualified registries and QDCRs are similar to existing expectations for these entities, we are not revising our burden estimates as a result of these provisions. However, we do refer readers to section VIII.H.15.e.(4)(d) of this final rule for discussion of our estimates of the overall impact of this provision for all third party intermediaries.

In section VII.A.3.g.(1)(b)(ii) of this rule, we discussed that the determination of whether to approve an entity as a third party intermediary for a MIPS performance period may take into account: (1) Whether the entity failed to comply with requirements of third party intermediaries for any prior MIPS payment year for which it was approved as third party intermediary; and (2) whether the entity provided inaccurate information regarding the requirements of the subpart to any eligible clinician. Because this provision does not require any additional effort for

affected entities but instead allows CMS to utilize already available information to make approval decisions, collection of information burden is unaffected for all entities. We also do not anticipate this provision will result in any qualified registries or other third party intermediaries electing not to self-nominate during the 2021 MIPS performance period, but believe it is possible this may occur. However, we have neither any data nor knowledge of intent from previously approved qualified registries or other third party intermediaries with which to support making any changes to our burden estimates as a result of this provision. We are solicited public feedback to help us determine if there are any burden implications. We did not receive comments related to burden implications of this provision.

In section VII.A.3.g.(4) of this final rule, we are modifying the existing requirement at § 1400(f)(1)(i) requiring third party intermediaries to submit to CMS by a date specified by the agency a Corrective Action Plan (CAP) to address the identified deficiencies or data issue, including the actions it will take to prevent the deficiencies or data issues from recurring. While the requirement for third party intermediaries to submit a CAP was finalized in our CY 2017 Quality Payment Program final rule (81 FR 77389), we did not specify the information that must be included to be included in the CAP and neglected to identify the burden associated with the required information. We are correcting that oversight in this final rule. In addition, to clarify expectations and create consistency in the content of the CAPs provide by third party intermediaries, we are revising and elaborating on the obligations for a CAP in this final rule. Specifically, we are modifying § 414.1400(f)(1)(i) such that, unless different or additional information is specified by CMS, the CAP submitted by the third party intermediary must address four issues: (1) The issues that contributed to the non-compliance; (2) the impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program; (3) the corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved will not recur in the future and (4) the detailed timeline for achieving compliance with the applicable requirements. We have historically received a total of 34 CAPs over the 3-year period of CY 2017–2019 (an average of 11.3 per year). As third party intermediaries become increasingly effective at identifying data issues and discrepancies prior to submitting data to CMS and accounting for the estimated decrease in number of QCDRs and qualified registries self-nominating in the 2020 MIPS performance period compared to the 2019 MIPS performance period (from 350 to 229), we anticipate the annual number of CAPs received to decrease to fewer than 10 per year (83 FR 59997 through 60000 and 84 FR 63114 through 63121). The effort involved in developing a CAP including the detail specified in this final rule and submitting it to CMS is likely to be no more than 3 hours for a computer systems analyst at a rate of $92.46/hr. In aggregate we estimate an annual burden of no more than 30 hours (3 hr × 10 CAPs) at a cost of $2,774 (30 hr × $92.46/hr) for third party intermediaries to develop and submit a CAP. Because we are unable to predict how many of the estimated 10 third party intermediaries submitting CAPs will be qualified registries, QCDRs, survey vendors, or health IT vendors; for simplicity we are adding the burden to the currently approved burden for qualified registries.

For this final rule, we are adjusting the number of qualified registries we assume will self-nominate for the CY 2022 performance period from the currently approved estimate of 153 to 183, an increase of 30 from the currently approved estimate and CY 2021 PFS proposed rule (85 FR 50347) based on the number of self-nominations received during the CY 2020 nomination period which was ongoing at the time the CY 2021 PFS proposed rule was published.

As discussed in section IV.A.3.g, some commenters expressed their opinion that specific requirements as well as the totality of requirements imposed on qualified registries may result in some qualified registries electing to no longer participate in QPP. Without specific information regarding the intent of each qualified registry, we are unable to determine if a future decrease in qualified registry participation will occur. We note that additional requirements for qualified registries were finalized in the CY 2020 PFS final rule and there was an increase in qualified registries self-nominating during the subsequent CY 2020 self-nomination period. We continue to update our burden estimates annually as we receive updated data; if qualified registries elect to end their participation in the future, we will adjust our burden estimates when the corresponding data is available.

We assume that the staff involved in the qualified registry self-nomination process will continue to be computer systems analysts or their equivalent, who have an average labor rate of $92.46/hr. Considering that the time per qualified registry associated with the self-nomination process range from a minimum of 0.5 hours to a maximum of 3 hours, we estimate that the annual burden will range from 91.5 hours (183 qualified registries × 0.5 hr) to 549 hours (183 qualified registries × 3 hr) at a cost ranging from $8,460 (91.5 hr × $92.46/hr) and $50,760 (549 hr × $92.46/hr), respectively (see Table 64). Combined with our estimates of burden associated with completing targeted audits and developing and submitting a CAP, our total burden estimate ranges from 401.5 hours (91.5 + 30 + 280) to 1,139 (549 + 30 + 560) at a cost between $37,123 ($8,460 + $2,774 + $25,889) and $105,312 ($50,760 + $2,774 + $51,778).

Based on the assumptions discussed in this section, we provide an estimate of the total annual burden associated with a qualified registry self-nominating to be considered ''qualified'' to submit quality measures results and numerator and denominator data on MIPS eligible clinicians.

TABLE 64: Estimated Burden for Qualified Registry Self-Nomination

	Minimum	Maximum
# of Qualified Registry Simplified Self-Nomination Applications submitted (a)	183	0
# of Qualified Registry Full Self-Nomination Applications submitted (b)	0	183
Total Applications	**183**	**183**
Total Annual Hours Per Qualified Registry for Simplified Process (c)	0.5	0.5
Total Annual Hours Per Qualified Registry for Full Process (d)	3	3
Total Annual Hours for Self-Nomination (e) = (a)*(c) + (b)*(d)	**91.5**	**549**
Total Annual Hours for Completion of 56 Targeted Audits (f)	**280**	**560**
Total Annual Hours for development and submittal of 30 CAPs (g)	**30**	**30**
Cost Per Simplified Process Per Qualified Registry (@ computer systems analyst's labor rate of $92.46/hr) (h)	$46.23	$46.23
Cost Per Full Process Per Qualified Registry (@ computer systems analyst's labor rate of $92.46/hr) (i)	$277.38	$277.38
Cost Per Targeted Audit (@ computer systems analyst's labor rate of $92.46/hr) (j)	$462.30	$924.60
Cost Per CAP (@ computer systems analyst's labor rate of $92.46/hr) (k)	$277.38	$277.38
Total Annual Cost (j) = (a)*(f)+(b)*(g)+(j)*56+(k)*10	**$37,123**	**$105,312**

As shown in Table 65, using the unchanged currently approved per respondent burden estimate, the increase in respondents from 153 to 183 results in an increase of between +15 hours (+30 respondents × 0.5 hr/respondent) and +90 hours (+30 respondents × 3 hr/respondent) at a cost of between +$1,387 (+30 respondents × $46.23/respondent) and +$8,321 (+30 respondents × $277.38/respondent). The finalized policy to require targeted audits as necessary results in an increase of between +280 (56 audits × 5 hrs/audit) and +560 (56 audits × 10 hrs/audit) at a cost of between $25,889 (56 audits × $462.30/audit) and $51,778 (56 audits × $924.60/audit). When combined with our estimate of +30 hours at a cost of +$2,774 for developing and submitting CAPs, the total aggregate change ranges from +325 hours (15 + 30 + 280) to +680 hours (90 + 30 + 560) at a cost ranging from +$30,050 ($1,387 + $2,774 + $25,889) to +$62,873 ($8,321 + $2,774 + $51,778).

TABLE 65: Change in Estimated Burden for Qualified Registry Self-Nomination

	Minimum Burden Estimate	Maximum Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	76.5	459
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	401.5	1,139
Difference (c) = (b)-(a)	**+325**	**+680**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$7,073	$42,439
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$37,123	$105,312
Difference (f) = (e)-(d)	**+$30,050**	**+$62,873**

(4) Survey Vendor Requirements

This rule is not implementing any new or revised collection of information requirements or burden related to CMS-approved CAHPS for MIPS survey vendors. The requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any MIPS survey vendor changes under that control number.

(5) Health IT Vendors

This rule is not implementing any new or revised collection of information requirements or burden related to health IT vendors and we do not anticipate any changes to the CEHRT process as a result of provisions promulgated in this final rule. Consequently, we are not setting out burden or making any changes under the 0938–1314 (CMS–10621) control number.

d. Open Authorization (OAuth) Credentialing and Token Request Process

In the CY 2017 Quality Payment Program final rule (81 FR 77035), we finalized the initial MIPS data submission terminology at § 414.1305 and requirements at § 414.1325, as well as the associated burden estimates. As discussed in the CY 2019 PFS final rule (83 FR 59747 through 59748), it subsequently came to our attention that the way we had previously described data submission did not precisely reflect the experience users have when submitting data to us. To ensure clarity and precision for all users, we amended the terminology at § 414.1305 to more precisely reflect this experience and made conforming amendments to § 414.1325 and other MIPS regulations. Among the newly defined terms was ''submission type'', which we defined at § 414.1305 as the mechanism by which a submitter type submits data to CMS, including, as applicable: Direct, log in and upload, log in and attest, Medicare Part B claims and the CMS Web

Interface. We stated in the CY 2019 PFS final rule that the direct submission type allows users to transmit data through a computer-to-computer interaction, such as an Application Programming Interface (API).

Beginning in the 2021 MIPS performance period, CMS will offer the Open Authorization (OAuth) Credentialing and Token Request Process. This process utilizes an API to allow users to transmit data through a computer-to-computer interaction. As such, it is an alternate means of operationalizing the previously established direct submission type. The process first requires software developers to apply for production OAuth credentials to the submissions API by registering their application so that it can interact with the system providing OAuth capabilities. Next, the developer must request a meeting with the Quality Payment Program development team. During this meeting, the requesting organization will demonstrate their application's use of OAuth to successfully submit data in the Submissions API test environment. The requesting organization will also provide documentation about their terms of service, privacy policy, and related information for review by the Quality Payment Program team. If further clarification is required about any of the documentation or application, the Quality Payment Program team will follow up with the requesting organization. Once approved, the Quality Payment Program development team will issue production OAuth credentials to the requesting organization's point of contact. Detailed instructions for the authentication process and application for organizations to request OAuth credentials are available at *https://cmsgov.github.io/qpp-submissions-docs/*.

The following burden estimates are associated with the first year of data collection for the OAuth Credentialing and Token Request Process. This process is available to all submitter types to be approved to submit data via the direct submission type. However, we assume the only parties that will elect to undergo the process will be health IT vendors or other third party intermediaries, as we believe these are the most likely parties to be developing applications. The burden associated with this ICR belongs only to the application developer; QPP participants will not be required to do anything additional to submit their data. For third party intermediaries, OAuth Credentialing will allow QPP participants to use their own QPP credentials to login through the third party intermediary's application to submit their data and view performance feedback from QPP. The burden associated with the OAuth Credentialing and Token Request Process will be submitted to OMB for approval under control number 0938–1314 (CMS–10621). We refer readers to § 414.1400(a)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77363 through 77364) and as further revised in the CY 2019 and CY 2020 PFS final rules at § 414.1400(a)(2) (83 FR 60088 and 84 FR 63052) for our current policy regarding the types of MIPS data third party intermediaries may submit.

As stated in the CY 2020 PFS final rule (84 FR 63049) we are aware of stakeholders' desire to have a more cohesive participation experience across all performance categories under MIPS. We are offering this process in support of our current requirements for QCDRs and qualified registries to be able to submit data for all MIPS performance categories and health IT vendors to be able to submit data for at least one MIPS performance category (84 FR 63052 and 84 FR 63076) as well as our desire to further reduce administrative burden for clinicians to participate in MIPS. As we discuss in sections VII.B.5.e.(5), VII.B.5.e.(6), VII.B.5.(e).7, VII.B.5.g, and VII.B.5.i of this final rule individual clinicians or groups may submit their quality measures using the direct submission type via the MIPS CQM and QCDR, eCQM, or CMS Web Interface (only for the 2021 MIPS performance period) collection types as well as their Promoting Interoperability measures and improvement activities through the same direct submission type. Entities that receive approval for their applications through this process will be able to provide QPP participants a more comprehensive and less administratively burdensome experience using the direct submission type.

We estimate it would take approximately 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to provide documentation and any follow-up communication via email. We estimate that for during the 2021 MIPS performance period, 15 submitter types, consisting of third party intermediaries will complete this process to be approved for the CY 2022 submission period. We expect health IT vendors to adopt this method initially, with limited further adoption by QCDRs and Qualified Registries in future years. As shown in Table 66, we estimate it would take 1 hour at $92.46/hr for a computer systems analyst (or their equivalent) to complete the process. We estimate an annual burden of 15 hours (15 vendors × 1 hr) at a cost of $1,387 (15 hr × $92.46/hr) or $92.46 per organization ($1,387/15 vendors).

TABLE 66: Estimated Burden for the OAuth Credentialing and Token Request Process

	Burden Estimate
# of Organizations (a)	15
Total Annual Hours Per Organization to Submit (b)	1
Total Annual Hours (c) = (a)*(b)	**15**
Cost Per Organization (@ computer systems analyst's labor rate of $92.46/hr.) (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	$1,387

e. ICRs Regarding Quality Data Submission (§§ 414.1325 and 414.1335)

(1) Background

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77502 through 77503), CY 2018 Quality Payment Program final rule (82 FR 53908 through 53912), CY 2019 PFS final rule (83 FR 60000 through 60003), and the CY 2020 PFS final rule (84 FR 63121 through 63124) for our previously finalized requirements for data submission for the quality performance category.

Under our current policies, two groups of clinicians must submit quality data under MIPS: Those who submit as

MIPS eligible clinicians and those who opt to submit data voluntarily but are not subject to MIPS payment adjustments. Clinicians are ineligible for MIPS payment adjustments if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group.

(2) Changes and Adjustments to Quality Performance Category Respondents

To determine which QPs should be excluded from MIPS, we used the first snapshot of the QP List for CY 2020 that contains participation in Advanced APMs as of March 31, 2020, that could be connected into our respondent data and are the best estimate of future expected QPs. From this data, we calculated the QP determinations as described in the Qualifying APM Participant (QP) definition at § 414.1305 for the 2021 QP Performance Period. We assumed that all Partial QPs will participate in MIPS data collections. Due to data limitations, we could not identify specific clinicians who have not yet enrolled in APMs, but who may become QPs in the future 2021 QP Performance Period (and therefore will no longer need to submit data to MIPS); hence, our model may underestimate or overestimate the number of respondents.

In the CY 2019 PFS final rule, we finalized limiting the Medicare Part B claims collection type to small practices beginning with the 2021 MIPS payment year and allowing clinicians in small practices to report Medicare Part B claims as a group or as individuals (83 FR 59752). In the CY 2020 PFS final rule, we provided a set of assumptions and an approach to account for the clinicians not in small practices for whom the Medicare Part B claims collection type will no longer be available as an option for collecting and reporting quality data (84 FR 63121 through 63122). Because we continued to use 2018 MIPS performance period data to estimate the number of respondents in the CY 2021 PFS proposed rule, we used the same methodology. For this final rule, we are using 2019 MIPS performance period respondent data which inherently includes the impacts of the aforementioned policies finalized in the CY 2019 PFS final rule; therefore, we no longer need to make any further adjustments to account for them.

There may be an undercount in submissions because of the extreme and uncontrollable circumstances policy due to the PHE for COVID–19, that allowed clinicians to elect not to submit during the submission period for the 2019 MIPS performance period that we are using to inform our burden estimates. Despite this limitation, we believe the data from the 2019 MIPS performance period is still the best data source available as it most accurately reflects the impacts of policies finalized in previous rules and trend toward increased group reporting.

In section IV.A.3.c.(1)(c) of this rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 performance period. As a result, groups of 25 or more clinicians that previously submitted quality performance data via the CMS Web Interface will be required to use an alternate collection type beginning with the 2022 performance period, which will have to be either the MIPS CQM and QCDR or eCQM collection type. While we know that 111 groups submitted quality performance data via the CMS Web Interface in the 2019 MIPS performance period, we are not able to ascertain what alternative collection type(s) the groups would elect. In order to estimate the number of groups that will select each of these collection types, we first clustered the number of groups which submitted data via the CMS Web Interface collection type during the 2019 MIPS performance period by practice size (between 25 and 49 clinicians, between 50 and 99 clinicians, etc.). Then, for each cluster, we allocated these groups to each of the MIPS CQM and QCDR and eCQM collection types based on the percent of TINs that submitted MIPS data via these two collection types. For example, of the 1,638 TINs with a practice size of 25 to 49 clinicians which submitted data for the 2019 MIPS performance period, 1,086 (66 percent) submitted data via the MIPS CQM and QCDR collection type and 552 (34 percent) submitted data via the eCQM collection type. We applied these percentages to the 11 TINs with a practice size of 25 to 49 clinicians which submitted data via the CMS Web Interface collection type for the 2019 MIPS performance period to estimate that 7 (11 TINs $\times$ 0.73) would elect to submit data via the MIPS CQM and QCDR collection type and the remaining 4 (11 TINs $\times$ 0.27) would elect to submit data via the eCQM collection type. In total, beginning with the 2022 performance period, we estimate that 45 of the 111 groups that submitted data via the CMS Web Interface collection type for the 2019 MIPS performance period will submit quality data via the MIPS CQM and QCDR collection type and 66 groups will now submit quality data via the eCQM collection type. Note that the 111 groups is an increase of 7 from our currently approved estimate of 104 groups due to updated data (84 FR 63123) (111 groups − 104 groups). We also performed this analysis to determine the number of clinicians that would be affected and would need to submit quality data via an alternate collection type beginning with the 2022 performance period. In total, of the estimated 45,599 individual clinicians affected by this provision, we estimate that 11,432 would submit quality data as part of a group via the MIPS CQM and QCDR collection type and 34,167 would submit quality data as part of a group via the eCQM collection type. These estimates are reflected in Tables 66 and 68 and the associated changes in burden are reflected in Tables 72, 74, and 76. In aggregate, as discussed in sections VII.B.5.e.(5), (6), (7), and (9) of this final rule, we estimate the provision to sunset the CMS Web Interface measures as a collection type/submission type will result in a net decrease in quality performance data reporting burden while acknowledging the additional financial impacts on clinicians as discussed in section VIII.H.15.e.(4)(b)(i) of the Regulatory Impact Analysis.

We assume that 100 percent of ACO APM Entities will submit quality data to CMS as required under their models. While we do not believe there is additional reporting for ACO APM entities, consistent with assumptions used in the CY 2019 and CY 2020 PFS final rules (83 FR 60000 through 60001 and 84 FR 63122), we include all quality data voluntarily submitted by MIPS APM participants made at the individual or TIN-level in our respondent estimates. As stated in section VII.5.a.(4) of this final rule, we assume non-ACO APM Entities will participate through traditional MIPS and submit as an individual or group rather than as an entity. To estimate who will be a MIPS APM participant in the 2021 MIPS performance period, we used the latest QP List for the first snapshot data of the 2020 QP performance period and supplemented with clinicians who are in an APM in 2020 but not in the 2020 snapshot. This file was selected to better reflect the expected increase in the number of MIPS APMs in future years compared to previous APM eligibility files. Based on this information, if we determine that a MIPS eligible clinician will not be scored as a MIPS APM, then their reporting assumption is based on their

reporting as a group or individual for the CY 2019 MIPS performance period.

Our burden estimates for the quality performance category do not include the burden for the quality data that APM Entities submit to fulfill the requirements of their APMs. The burden is excluded as sections 1899(e) and 1115A(d)(3) of the Act (42 U.S.C. 1395jjj(e) and 1315a(d)(3), respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models tested under section 1115A of the Act (or section 3021 of the Affordable Care Act) are not subject to the PRA.[148] Tables 66, 67, and 68 explain our revised estimates of the number of organizations (including groups, virtual groups, and individual MIPS eligible clinicians) submitting data on behalf of clinicians segregated by collection type.

Table 66 provides our estimated counts of clinicians that will submit quality performance category data as MIPS individual clinicians or groups in the 2021 and 2022 MIPS performance periods based on data from the 2019 MIPS performance period.

For the 2021 MIPS performance period, respondents will have the option to submit quality performance category data via Medicare Part B claims, direct, and log in and upload submission types, and Web Interface. For the 2022 MIPS performance period, respondents will no longer have the option to submit quality performance category data via the Web Interface. We estimate the burden for collecting data via collection type: Medicare Part B claims, QCDR and MIPS CQMs, eCQMs, and the CMS Web Interface. We believe that, while estimating burden by submission type may be better aligned with the way clinicians participate with the Quality Payment Program, it is more important to reduce confusion and enable greater transparency by maintain consistency with previous rulemaking.

As shown in Table 66, using participation data from the 2019 MIPS performance period combined with the estimate of QPs for the 2021 performance period, we estimate a total of 651,514 clinicians will submit quality data as individuals or groups in each of the 2021 and 2022 MIPS performance periods, a decrease of 129,091 clinicians when compared to our estimate of 780,605 clinicians in the CY 2020 PFS final rule (84 FR 63122) and a decrease of 140,547 from the estimate of 792,061 in the CY 2021 PFS proposed rule due to availability of updated data from the 2019 MIPS performance period (85 FR 50350). For the 2021 performance period, we estimate 29,273 clinicians will submit data as individuals for the Medicare Part B claims collection type; 284,509 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; 292,133 clinicians will submit data as individuals or as part of groups via eCQM collection types; and 45,599 clinicians will submit as part of groups via the CMS Web Interface. Compared to the CY 2021 PFS proposed rule (85 FR 50350), these are decreases from the estimates of 94,587 and 410,518 for Medicare Part B claims and MIPS CQM and QCDR collection types, respectively; and increases from the estimates of 286,956 and 0 for the eCQM and CMS Web Interface collection types, respectively. These adjustments are due to the availability of updated data from the 2019 MIPS performance period and the delay in sunsetting the CMS Web Interface from the 2021 performance period to the 2022 performance period. For the 2022 performance period, we estimate 29,273 clinicians will submit data as individuals for the Medicare Part B claims collection type; 295,941 clinicians will submit data as individuals or as part of groups for the MIPS CQM and QCDR collection type; 326,300 clinicians will submit data as individuals or as part of groups via the eCQM collection type.

Table 67 provides estimates of the number of clinicians to collect quality measures data via each collection type, regardless of whether they decide to submit as individual clinicians or as part of groups. Because our burden estimates for quality data submission assume that burden is reduced when clinicians elect to submit as part of a group, we also separately estimate the expected number of clinicians to submit as individuals or part of groups.

TABLE 67: Estimated Number of Clinicians Submitting Quality Performance Category Data by Collection Type (as Individual Clinicians or as Part of Groups)

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2021 MIPS performance period (excludes QPs) (a)	29,273	284,509	292,133	45,599	651,514
* 2020 MIPS performance period (excludes QPs) (b)	94,846	391,430	247,856	46,473	780,605
Difference (c)=(a)-(b)	-65,573	-106,921	+44,277	-874	-129,091
2022 MIPS performance period (excludes QPs) (d)	29,273	295,941	326,300	0	651,514
* 2020 MIPS performance period (excludes QPs) (e)	94,846	391,430	247,856	46,473	780,605
Difference (f)=(d)-(e)	-65,573	-95,489	+78,444	-46,473	-129,091

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Because MIPS eligible clinicians may submit data for multiple collection types for a single performance category, the estimated numbers of individual clinicians and groups to collect via the various collection types are not mutually exclusive and reflect the occurrence of individual clinicians or groups that collected data via multiple collection types during the 2019 MIPS performance period. We captured the burden of any eligible clinician that may have historically collected via multiple collection types, as we assume they will continue to collect via multiple collection types and that our MIPS scoring methodology will take the highest score where the same measure is submitted via multiple collection types.

Table 68 uses methods similar to those described to estimate the number of clinicians that will submit data as

[148] Our estimates do reflect the burden on MIPS APM participants of submitting Promoting Interoperability performance category data, which is outside the requirements of their APMs.

individual clinicians via each collection type in the 2021 and 2022 MIPS performance periods. For both the 2021 and 2022 performance periods, we estimate that approximately 29,273 clinicians will submit data as individuals using the Medicare Part B claims collection type; approximately 41,340 clinicians will submit data as individuals using MIPS CQM and QCDR collection type; and approximately 42,255 clinicians will submit data as individuals using eCQMs collection type. Based on availability of updated data from the 2019 MIPS performance period, these are decreases from the currently approved estimates of 94,846 and 100,269 for the Medicare Part B claims and MIPS CQM and QCDR collection types, respectively; and an increase from the currently approved estimate of 38,935 for the eCQM collection type.

TABLE 68: Estimated Number of Clinicians Submitting Quality Performance Category Data as Individuals by Collection Type

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2021 MIPS Performance Period (excludes QPs) (a)	29,273	41,340	42,255	0	112,868
* 2020 MIPS Performance Period (excludes QPs) (b)	94,846	100,269	38,935	0	234,050
Difference (c)=(a)-(b)	-65,573	-58,929	+3,320	0	-121,182
2022 MIPS Performance Period (excludes QPs) (d)	29,273	41,340	42,255	0	112,868
* 2020 MIPS Performance Period (excludes QPs) (e)	94,846	100,269	38,935	0	234,050
Difference (f)=(d)-(e)	-65,573	-58,929	+3,320	0	-121,182

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM, eCQM, or QCDR collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table 68 are not mutually exclusive.

Table 69 provides our estimated counts of groups or virtual groups that will submit quality data on behalf of clinicians for each collection type in the 2021 and 2022 MIPS performance periods. We assume that groups that submitted quality data as groups in the 2019 MIPS performance period will continue to submit quality data either as groups or virtual groups for the same collection types as they did as a group or TIN within a virtual group for the 2021 and 2022 MIPS performance periods. Specifically, for the 2021 performance period we estimate that 11,559 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 243,169 clinicians; 8,154 groups and virtual groups will submit for eCQM collection types on behalf of 249,878 eligible clinicians; and 111 groups will submit data via the CMS Web Interface on behalf of 45,599 clinicians. These are increases from the currently approved estimates of 10,949, 4,398, and 104 groups and virtual groups for the MIPS CQM and QCDR, eCQM, and CMS Web Interface collection types, respectively; due to the availability of updated data from the 2019 MIPS performance period. For the 2022 performance period we estimate that 11,604 groups and virtual groups will submit data for the MIPS CQM and QCDR collection type on behalf of 254,601 clinicians and 8,220 groups and virtual groups will submit for eCQM collection types on behalf of 284,045 eligible clinicians. In section IV.A.3.(b) of this rule, we discuss the APM Performance Pathway for clinicians in APM Entities. The APM Performance Pathway is available for APM entities and as discussed in section IV.A.3.(b).(3)(a) we are finalizing an alternate measure set consisting of the CMS Web Interface measures for the 2021 MIPS performance period. However, as the data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM entities, we assume non-ACO APM Entities would participate through traditional MIPS and base our estimates on submissions received in the 2019 MIPS performance period.

TABLE 69: Estimated Number of Groups and Virtual Groups Submitting Quality Performance Category Data by Collection Type on Behalf of Clinicians

	Medicare Part B Claims	QCDR/ MIPS CQM	eCQM	CMS Web Interface	Total
2021 MIPS performance period (excludes QPs) (a)	0	11,559	8,154	111	19,824
*2020 MIPS performance period (b)	0	10,949	4,398	104	15,451
Difference (c)=(a)-(b)	0	+610	+3,756	+7	+4,373
2022 MIPS performance period (excludes QPs) (d)	0	11,604	8,220	0	19,824
*2020 MIPS performance period (e)	0	10,949	4,398	104	15,451
Difference (f)=(d)-(e)	0	+655	+3,822	-104	+4,373

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

The burden associated with the submission of quality performance category data have some limitations. We believe it is difficult to quantify the burden accurately because clinicians and groups may have different processes for integrating quality data submission into their practices' workflows. Moreover, the time needed for a clinician to review quality measures and other information, select measures applicable to their patients and the services they furnish, and incorporate the use of quality measures into the practice workflows is expected to vary along with the number of measures that are potentially applicable to a given clinician's practice and by the collection type. For example, clinicians submitting data via the Medicare Part B claims collection type need to integrate the capture of quality data codes for each encounter whereas clinicians submitting via the eCQM collection types may have quality measures automated as part of their EHR implementation.

We believe the burden associated with submitting quality measures data will vary depending on the collection type selected by the clinician, group, or third-party. As such, we separately estimated the burden for clinicians, groups, and third parties to submit quality measures data by the collection type used. For the purposes of our burden estimates for the Medicare Part B claims, MIPS CQM and QCDR, and eCQM collection types, we also assume that, on average, each clinician or group will submit 6 quality measures. In terms of the quality measures available for clinicians and groups to report for the 2021 MIPS performance period, the total number of quality measures will be 209. The new MIPS quality measures finalized for inclusion in MIPS for the 2021 MIPS performance period and future years are found in Table Group A of Appendix 1; MIPS quality measures with finalized substantive changes can be found in Table Group D of Appendix 1; and MIPS quality measures finalized for removal can be found in Table Group C of Appendix 1. These measures are stratified by collection type in Table 70, as well as counts of new, removed, and substantively changed measures.

TABLE 70: Summary of Quality Measures for the 2021 MIPS Performance Period

Collection Type	# Measures Finalized as New	# Measures Finalized for Removal	# Measures Finalized with a Substantive Change	# Measures Remaining for CY 2021*
Medicare Part B Claims Specifications	0	-9	+24	+46
MIPS CQMs Specifications	0	-11	+101	+185
eCQM Specifications	0	0	+36	+47
Survey – CSV	0	0	0	+1
CMS Web Interface Measure Specifications	0	0	+10	+10
Administrative Claims	+2	-1	0	+2
Total	+2	-14	+113	209

*A measure may be specified under multiple collection types but will only be counted once in the total.

For the 2021 MIPS performance period, there is a net reduction of 9 quality measures across all collection types compared to the 218 measures finalized for the 2020 MIPS performance period (84 FR 63124). Specifically, as discussed in section IV.A.3.c.(1)(d), we are adding 2 new administrative claims outcome measures, removing 14 quality measures, and make substantive updates to 113 quality measures. We do not anticipate that removing these measures will increase or decrease the reporting burden on clinicians and groups as respondents generally are still required to submit quality data for 6 measures.

(3) Quality Payment Program Identity Management Application Process

This rule is not implementing any new or revised collection of information requirements or burden related to the identity management application process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not

making any identity management application process changes under that control number.

(4) Quality Data Submission by Clinicians: Medicare Part B Claims-Based Collection Type

This rule is not implementing any new or revised collection of information requirements related to the submission of Medicare Part B claims data for the quality performance category. However, we are adjusting our currently approved burden estimates based on more recent data. The following burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77501 through 77504), CY 2018 Quality Payment Program final rule (82 FR 53912), CY 2019 PFS final rule (83 FR 60004 through 60005), and the CY 2020 PFS final rule (84 FR 63124 through 63126) for our previously finalized requirements and burden for quality data submission via the Medicare Part B claims collection type.

As noted in Table 67, based on 2019 MIPS performance period data, we assume that 29,273 individual clinicians will collect and submit quality data via the Medicare Part B claims collection type. This rule is adjusting the number of Medicare Part B claims respondents from the currently approved estimate of 94,846 to 29,273 (a decrease of 65,573) based on more recent data. This is an increase/decrease of 65,314 from the estimate of 94,587 provided in the CY 2021 PFS proposed rule (85 FR 50352).

As shown in Table 71, consistent with our currently approved per response time figures, we estimate that the burden of quality data submission using Medicare Part B claims will range from 0.15 hours (9 minutes) at a cost of $13.87 (0.15 hr × $92.46/hr) to 7.2 hours at a cost of $665.71 (7.2 hr × $92.46/hr). The burden will involve becoming familiar with MIPS quality measure specifications. We believe that the start-up cost for a clinician's practice to review measure specifications is 7 hours, consisting of 3 hours at $110.74/hr for a medical and health services manager, 1 hour at $212.78/hr for a physician, 1 hour at $46.64/hr for an LPN, 1 hour at $92.46/hr for a computer systems analyst, and 1 hour at $39.06/hr for a billing and posting clerk. We are not revising our currently approved per response time estimates.

Considering both data submission and start-up requirements, the estimated time (per clinician) ranges from a minimum of 7.15 hours (0.15 hr + 7 hr) to a maximum of 14.2 hours (7.2 hr + 7 hr). In this regard the total annual time ranges from 209,302 hours (7.15 hr × 29,273 clinicians) to 415,677 hours (14.2 hr × 29,273 clinicians). The estimated annual cost (per clinician) ranges from $737.03 [(0.15 hr × $92.46/hr) + (3 hr × $110.74/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (1 hr × $212.78/hr)] to a maximum of $1,388.87 [(7.2 hr × $92.46/hr) + (3 hr × $110.74/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (1 hr × $212.78/hr)]. The total annual cost ranges from a minimum of $21,575,050 (29,273 clinicians × $737.03) to a maximum of $40,656,450 (29,273 clinicians × $1,388.87).

Table 71 summarizes the range of total annual burden associated with clinicians submitting quality data via Medicare Part B claims.

TABLE 71: Estimated Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden
# of Clinicians (a)	29,273	29,273	29,273
Hours Per Clinician to Submit Quality Data (b)	0.15	1.05	7.2
# of Hours Medical and Health Services Manager Review Measure Specifications (c)	3	3	3
# of Hours Computer Systems Analyst Review Measure Specifications (d)	1	1	1
# of Hours LPN Review Measure Specifications (e)	1	1	1
# of Hours Billing Clerk Review Measure Specifications (f)	1	1	1
# of Hours Physician Review Measure Specifications (g)	1	1	1
Annual Hours per Clinician (h) = (b)+(c)+(d)+(e)+(f)+(g)	7.15	8.05	14.2
Total Annual Hours (i) = (a)*(h)	**209,302**	**235,648**	**415,677**
Cost to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr @ varying times) (j)	$13.87	$97.08	$665.71
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr @ 3 hr) (k)	$332.22	$332.22	$332.22
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr @ 1 hr) (l)	$92.46	$92.46	$92.46
Cost to Review Measure Specifications (@ LPN's labor rate of $46.64/hr @1 hr) (m)	$46.64	$46.64	$46.64
Cost to Review Measure Specifications (@ billing clerk's labor rate of $39.06/hr @ 1 hr) (n)	$39.06	$39.06	$39.06
Cost to Review Measure Specifications (@ physician's labor rate of $212.78/hr @ 1 hr) (o)	$212.78	$212.78	$212.78
Total Annual Cost Per Clinician (p) = (j)+(k)+(l)+(m)+(n)+(o)	$737.03	$820.24	$1,388.87
Total Annual Cost (q) = (a)*(p)	**$21,575,050**	**$24,010,973**	**$40,656,450**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 72, using the unchanged currently approved per respondent burden estimates which range from $737.03 to $1,388.87, the decrease in number of respondents from 94,846 to 29,273 results in a total adjustment of between −468,847 hours (−65,573 respondents × 7.15 hr/respondent) at a cost of −$48,329,203 (−65,573 respondents × $737.03/respondent) and −931,136 hours (−65,573 respondents × 14.2 hr/respondent) at a cost of −$91,072,504 (−65,573 respondents × $1,388.87/respondent). For purposes of calculating total burden associated with the final rule as shown in Tables 100, 101, and 103, only the maximum burden is used.

TABLE 72: Adjusted Burden for Quality Performance Category: Clinicians Using the Medicare Part B Claims Collection Type

	Minimum Burden	Median Burden	Maximum Burden
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	678,149	763,510	1,346,813
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	209,302	235,648	415,677
Difference (c) = (b)-(a)	**-468,847**	**-527,862**	**-931,136**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$69,904,253	$77,796,768	$131,728,954
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$21,575,050	$24,010,973	$40,656,450
Difference (f) = (e)-(d)	**-$48,329,203**	**-$53,785,795**	**-$91,072,504**

(5) Quality Data Submission by Individuals and Groups Using MIPS CQM and QCDR Collection Types

The following requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77504 through 77505), CY 2018 Quality Payment Program final rule (82 FR 53912 through 53914), CY 2019 PFS final rule (83 FR 60005 through 60006), and the CY 2020 PFS final rule (84 FR 63127 through 63128) for our previously finalized requirements and burden for quality data submission via the MIPS CQM and QCDR collection types.

In the CY 2021 PFS proposed rule (85 FR 50290), we proposed to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 MIPS performance period. As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period. Using the methodology discussed in section VII.B.5.e.(1) of this final rule, for the 2022 MIPS performance period, we estimate 45 additional groups will submit quality data via the MIPS CQM and QCDR collection type due to the sunsetting of the CMS Web Interface measures as a collection type/submission type after the 2021 MIPS performance period.

As noted in Tables 67, 68, and 69, and based on 2019 MIPS performance period data, for the 2021 performance period, we assume that 284,509 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types; 41,340 clinicians will submit as individuals and the remaining 243,169 clinicians will submit as members of 11,559 groups and virtual groups. This is a decrease of 63,496 individuals and increase of 488 groups from the estimates of 104,836 individuals and 11,071 groups provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50353). For the 2022 performance period, we assume that 295,957 clinicians will submit quality data as individuals or groups using MIPS CQM or QCDR collection types; 41,340 clinicians will submit as individuals and the remaining 254,601 clinicians will submit as members of 11,604 groups and virtual groups. Given that the number of measures required is the same for clinicians and groups, we expect the burden to be the same for each respondent collecting data via MIPS CQM or QCDR, whether the clinician is participating in MIPS as an individual or group.

Under the MIPS CQM and QCDR collection types, the individual clinician or group may either submit the quality measures data directly to us, log in and upload a file, or utilize a third-party intermediary to submit the data to us on the clinician's or group's behalf.

We estimate that the burden associated with the QCDR collection type is similar to the burden associated with the MIPS CQM collection type; therefore, we discuss the burden for both together below. For MIPS CQM and QCDR collection types, we estimate an additional time for respondents (individual clinicians and groups) to become familiar with MIPS quality measure specifications and, in some cases, specialty measure sets and QCDR measures. Therefore, we believe that the burden for an individual clinician or group to review measure specifications and submit quality data total 9.083 hours at $891.13. This consists of 3 hours at $92.46/hr for a computer systems analyst (or their equivalent) to submit quality data along with 2 hours at $110.74/hr for a medical and health services manager, 1 hour at $92.46/hr for a computer systems analyst, 1 hour at $46.64/hr for a LPN, 1 hour at $39.06/hr for a billing clerk, and 1 hour at $212.78/hr for a physician to review measure specifications. Additionally, clinicians and groups who do not submit data directly will need to authorize or instruct the qualified registry or QCDR to submit quality measures' results and numerator and denominator data on quality measures to us on their behalf. We estimate that the time and effort associated with authorizing or instructing the quality registry or QCDR to submit this data will be approximately 5 minutes (0.083 hours) at $92.46/hr for a computer systems analyst at a cost of $7.70 (0.083 hr × $92.46/hr). Overall we estimate a cost of $897.47/response [(3 hr × $92.46/hr) + (2 hr × $110.74/hr) + (1 hr × $212.78/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr) + (0.083 hr × $92.46/hr)].

In aggregate, we estimate a burden of 480,482 hours [9.083 hr/response × (41,340 clinicians submitting as individuals + 11,559 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 52,899 responses)] at a cost of $47,475,487 (52,899 responses × $897.47/response) for the 2021 performance period. For the 2022 performance period, we estimate a burden of 480,890 hours [9.083 hr/response × (41,340 clinicians submitting as individuals + 11,604 groups submitting via QCDR or MIPS CQM on behalf of individual clinicians or 52,944 responses)] at a cost of $47,515,873 (52,944 responses × $897.47/response). Based on these assumptions, we have estimated in Table 73 the burden for these submissions.

TABLE 73: Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
# of clinicians submitting as individuals (a)	41,340	41,340
# of groups submitting via QCDR or MIPS CQM on behalf of individual clinicians (b)	11,559	11,604
# of Respondents (groups plus clinicians submitting as individuals) (c)=(a)+(b)	52,899	52,944
Hours Per Respondent to Report Quality Data (d)	3	3
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1	1
# of Hours LPN Review Measure Specifications (g)	1	1
# of Hours Billing Clerk Review Measure Specifications (h)	1	1
# of Hours Physician Review Measure Specifications (i)	1	1
# of Hours Per Respondent to Authorize Qualified Registry to Report on Respondent's Behalf (j)	0.083	0.083
Annual Hours Per Respondent (k)= (d)+(e)+(f)+(g)+(h)+(i)+(j)	9.083	9.083
Total Annual Hours (l) = (c)*(k)	**480,482**	**480,890**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr) (m)	$277.38	$277.38
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr) (n)	$221.48	$221.48
Cost Computer System's Analyst Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr) (o)	$92.46	$92.46
Cost LPN Review Measure Specifications (@ LPN's labor rate of $46.64/hr) (p)	$46.64	$46.64
Cost Billing Clerk Review Measure Specifications (@ clerk's labor rate of $39.06/hr) (q)	$39.06	$39.06
Cost Physician Review Measure Specifications (@ physician's labor rate of $212.78/hr) (r)	$212.78	$212.78
Cost for Respondent to Authorize Qualified Registry/QCDR to Report on Respondent's Behalf (@ computer systems analyst's labor rate of $92.46/hr) (s)	$7.70	$7.70
Total Annual Cost Per Respondent (t) = (m)+(n)+(o)+(p)+(q)+(r)+(s)	$897.47	$897.47
Total Annual Cost (u) = (c)*(t)	**$47,475,487**	**$47,515,873**

*Due to burden for certain activities being estimated in fractions of hours, totals may not reflect the sum of individual rows due to rounding.

As shown in Table 74, using the unchanged currently approved per respondent burden estimate, the decrease of 58,319 respondents from 111,218 to 52,899 for the 2021 performance period results in a decrease of −529,711 hours (−58,319 respondents × 9.083 hr/respondent) and −$52,339,796 (−58,319 respondents × $897.47/respondent). For the 2022 performance period, the decrease of 58,274 respondents from 111,218 to 52,944 results in a decrease of −529,303 hours (−58,264 respondents × 9.083 hr/respondent) and −$52,299,410 (−58,274 respondents × $897.47/respondent).

TABLE 74: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the MIPS CQM and QCDR Collection Type

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	1,010,193	1,010,193
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	480,482	480,890
Difference (c) = (b)-(a)	**-529,711**	**-529,303**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$99,815,283	$99,815,283
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$47,475,487	$47,515,873
Difference (f) = (e)-(d)	**-$52,339,796**	**-$52,299,410**

(6) Quality Data Submission by Clinicians and Groups: eCQM Collection Type

The following requirement and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77505 through 77506), CY 2018 Quality Payment Program final rule (82 FR 53914 through 53915), CY 2019 PFS final rule (83 FR 60006 through 60007), and the CY 2020 PFS final rule (84 FR 63128 through 63130) for our previously finalized requirements and burden for quality data submission via the eCQM collection types.

In the CY 2021 PFS proposed rule (85 FR 50290), we proposed to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 MIPS performance period. As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period. Using the methodology discussed in section VII.B.5.e.(1) of this final rule, for the 2022 MIPS performance period, we estimate 66 additional groups will submit quality data via the eCQM collection type due to the sunsetting of the CMS Web Interface measures as a collection type/submission type after the 2021 MIPS performance period.

Based on 2019 MIPS performance period data, for the 2021 performance period, we assume that 292,133 clinicians will elect to use the eCQM collection type; 42,255 clinicians are expected to submit eCQMs as individuals; and 8,154 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 249,878 clinicians. This is an increase of 778 individuals and 3,680 groups from the estimates of 41,477 individuals and 4,474 groups provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50355). For the 2022 performance period, we assume that 320,003 clinicians will elect to use the eCQM collection type; 42,255 clinicians are expected to submit eCQMs as individuals; and 8,220 groups and virtual groups are expected to submit eCQMs on behalf of the remaining 284,045 clinicians. We expect the burden to be the same for each respondent using the eCQM collection type, whether the clinician is participating in MIPS as an individual or group.

Under the eCQM collection type, the individual clinician or group may either submit the quality measures data directly to us from their eCQM, log in and upload a file, or utilize a third-party intermediary to derive data from their CEHRT and submit it to us on the clinician's or group's behalf.

To prepare for the eCQM collection type, the clinician or group must review the quality measures on which we will be accepting MIPS data extracted from eCQMs, select the appropriate quality measures, extract the necessary clinical data from their CEHRT, and submit the necessary data to a QCDR/qualified registry or use a health IT vendor to submit the data on behalf of the clinician or group. We assume the burden for collecting quality measures data via eCQM is similar for clinicians and groups who submit their data directly to us from their CEHRT and clinicians and groups who use a health IT vendor to submit the data on their behalf. This includes extracting the necessary clinical data from their CEHRT and submitting the necessary data to a QCDR/qualified registry.

We estimate that it will take no more than 2 hours at $92.46/hr for a computer systems analyst to submit the actual data file. The burden will also involve becoming familiar with MIPS quality measure specifications. In this regard, we estimate it will take 6 hours for a clinician or group to review measure specifications. Of that time, we estimate 2 hours at $110.74/hr for a medical and health services manager, 1 hour at $212.78/hr for a physician, 1 hour at $92.46/hr for a computer systems analyst, 1 hour at $46.64/hr for an LPN, and 1 hour at $39.06/hr for a billing clerk. Overall we estimate a cost of $797.34/response [(2 hr × $92.46/hr) + (2 hr × $110.74/hr) + (1 hr × $212.78/hr) + (1 hr × $92.46/hr) + (1 hr × $46.64/hr) + (1 hr × $39.06/hr)].

In aggregate, for the 2021 performance period, we estimate a burden of 403,272 hours (8 hr × 50,409 groups and clinicians submitting as individuals) at a cost of $40,193,112 (50,409 responses × $797.34/response). For the 2022 performance period, we estimate a burden of 403,800 hours (8 hr × 50,475 groups and clinicians submitting as individuals) at a cost of $40,245,737 (50,475 responses × $797.34/response). Based on these assumptions, we have estimated in Table 75 the burden for these submissions.

TABLE 75: Estimated Burden for Quality Performance Category: Clinicians (Submitting Individually or as Part of a Group) Using the eCQM Collection Type

	2021 Performance Period Burden estimate	2022 Performance Period Burden estimate
# of clinicians submitting as individuals (a)	42,255	42,255
# of Groups submitting via EHR on behalf of individual clinicians (b)	8,154	8,220
# of Respondents (groups and clinicians submitting as individuals) (c)=(a)+(b)	50,409	50,475
Hours Per Respondent to Submit MIPS Quality Data File to CMS (d)	2	2
# of Hours Medical and Health Services Manager Review Measure Specifications (e)	2	2
# of Hours Computer Systems Analyst Review Measure Specifications (f)	1	1
# of Hours LPN Review Measure Specifications (g)	1	1
# of Hours Billing Clerk Review Measure Specifications (h)	1	1
# of Hours Physicians Review Measure Specifications (i)	1	1
Annual Hours Per Respondent (j)=(d)+(e)+(f)+(g)+(h)+(i)	8	8
Total Annual Hours (k)=(c)*(j)	**403,272**	**403,800**
Cost Per Respondent to Submit Quality Data (@ computer systems analyst's labor rate of $92.46/hr) (l)	$184.92	$184.92
Cost to Review Measure Specifications (@ medical and health services manager's labor rate of $110.74/hr) (m)	$221.48	$221.48
Cost to Review Measure Specifications (@ computer systems analyst's labor rate of $92.46/hr) (n)	$92.46	$92.46
Cost to Review Measure Specifications (@ LPN's labor rate of $46.64/hr) (o)	$46.64	$46.64
Cost to Review Measure Specifications (@ clerk's labor rate of $39.06/hr) (p)	$39.06	$39.06
Cost to D21Review Measure Specifications (@ physician's labor rate of $212.78/hr) (q)	$212.78	$212.78
Total Cost Per Respondent (r)=(l)+(m)+(n)+(o)+(p)+(q)	$797.34	$797.34
Total Annual Cost (s) = (c)*(r)	**$40,193,112**	**$40,245,737**

As shown in Table 76, using the unchanged currently approved per respondent burden estimate, the increase of 7,076 respondents from 43,333 to 50,409 for the 2021 performance period results in a total difference of +56,608 hours (+7,076 respondents × 8 hr/respondent) at a cost of +$5,641,978 (+7,076 respondents × $797.34/respondent). For the 2022 performance period, the increase of 7,142 respondents from 43,333 to 50,475 results in a total difference of +57,136 hours (+7,142 respondents × 8 hr/respondent) at a cost of +$5,694,603 (+7,142 respondents × $797.34/respondent).

TABLE 76: Change in Estimated Burden for Quality Performance Category: Clinicians (Participating Individually or as Part of a Group) Using the eCQM Collection Type

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	346,664	346,664
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	403,272	403,800
Difference (c) = (b)-(a)	**+56,608**	**+57,136**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$34,551,134	$34,551,134
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$40,193,112	$40,245,737
Difference (f) = (e)-(d)	**+$5,641,978**	**+$5,694,603**

(7) Quality Data Submission via CMS Web Interface

The requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2021 PFS proposed rule, we proposed to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 MIPS performance period (85 FR 50290). As a result, we did not provide a burden estimate for quality data submission via the CMS Web Interface for the 2021 performance period. As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period; therefore, we are now providing a burden estimate for the 2021 MIPS performance period.

We assume that 111 groups will submit quality data via the CMS Web Interface based on the number of groups who completed 100 percent of reporting quality data via the Web Interface in the 2019 MIPS performance period. This is an increase of 7 groups from the currently approved number of 104 groups provided in the CY 2020 PFS final rule (84 FR 63130) due to receipt of more current data. We estimate that 45,599 clinicians will submit as part of groups via this method, a decrease of 874 from our currently approved estimate of 46,473 clinicians.

The burden associated with the group submission requirements is the time and effort associated with submitting data on a sample of the organization's beneficiaries that is prepopulated in the CMS Web Interface. Our burden estimate for submission includes the time (61.67 hours) needed for each group to populate data fields in the web interface with information on approximately 248 eligible assigned Medicare beneficiaries and submit the data (we will partially pre-populate the CMS Web Interface with claims data from their Medicare Part A and B beneficiaries). The patient data either can be manually entered, uploaded into the CMS Web Interface via a standard file format, which can be populated by CEHRT, or submitted directly. Each group must provide data on 248 eligible assigned Medicare beneficiaries (or all eligible assigned Medicare beneficiaries if the pool of eligible assigned beneficiaries is less than 248) for each measure. In aggregate, we estimate a burden for the 2021 performance period of 6,845 hours (111 groups × 61.67 hr) at a cost of $632,923 (6,845 hr × $92.46/hr). For the 2022 performance period, we estimate a burden of zero due to our assumption that all Web Interface respondents will alternately utilize either the MIPS CQM and QCDR or eCQM collection types. Based on the assumptions discussed in this section, Table 77 summarizes the burden for groups submitting to MIPS via the CMS Web Interface.

TABLE 77: Estimated Burden for Quality Data Submission via the CMS Web Interface

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
# of Eligible Group Practices (a)	111	0
Total Annual Hours Per Group to Submit (b)	61.67	61.67
Total Annual Hours (c) = (a)*(b)	6,845	0
Cost Per Group to Report (@ computer systems analyst's labor rate of $90.02/hr.) (d)	$5,701.70	$5,701.70
Total Annual Cost (e) = (a)*(d)	$632,923	$0

As shown in Table 78, using our unchanged currently approved per respondent burden estimate, the increase in number of respondents results in a total adjustment of +432 hours (+7 respondents × 61.67 hr) at $39,914 (+431.7 hr × $92.46/hr) for the 2021 MIPS Performance Period. For the 2022 MIPS performance period, our burden estimate is 0 hours and $0.

TABLE 78: Change in Estimated Burden for Quality Data Submission via the CMS Web Interface

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	6,413	6,413
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	6,845	0
Difference (c) = (b)-(a)	**+432**	**-6,413**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$593,009	$592,977
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$632,923	$0
Difference (f) = (e)-(d)	**+$39,914**	**-$592,977**

(8) Beneficiary Responses to CAHPS for MIPS Survey

In this final rule, we are revising the requirements for the CAHPS for MIPS survey which will result in updates to the CAHPS for MIPS survey instrument which is currently approved by OMB under control number 0938–1222 (CMS–10450). The survey instrument is not ready at this time, therefore we will make the updated survey instrument and burden available for public review through a stand-alone non-rule **Federal Register** notice that is expected to publish in early CY 2021.

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77509), CY 2018 Quality Payment Program final rule (82 FR 53916 through 53917), and CY 2019 PFS final rule (83 FR 60009 through 60010 for our previously finalized requirements and burden for beneficiary responses to the CAHPS for MIPS survey.

In section IV.A.3.c.(1)(f)(ii), we are: (1) Revising and codifying at § 414.1305 the definition of primary care services used in the MIPS assignment methodology to include virtual primary care visits and telehealth visits to determine patient assignment to groups starting in the 2021 CAHPS for MIPS survey; and (2) revising the CAHPS for MIPS Survey cover page to include a reference to care received in telehealth settings. We do not believe any of these provisions will impact the number of groups electing to have the CAHPS for MIPS survey administered on their behalf, the number of beneficiaries who complete the survey, or the time required for a beneficiary to complete the survey. In the future, if additional data becomes available, we may revise our assumptions at that time.

Additionally, in IV.A.2.c.(1)(e)(i), we are adding a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the performance year 2021 CAHPS for MIPS Survey. Currently, the CAHPS for MIPS survey instrument contains 58 questions and we estimate it requires a beneficiary 12.9 minutes on average to complete it, or approximately 0.2 minutes per question. We assume this provision will result in 1 additional question being added to the survey which would result in the total time to complete the survey increasing from 12.9 minutes (0.215 hr) to 13.1 minutes (0.2183 hr) per beneficiary, or an increase of 0.2 minutes (0.0033 hr).

Based on the number of beneficiaries who completely or partially responded to the survey in the 2019 MIPS performance period, we assume that 29,952 beneficiaries will respond to the survey during the 2021 MIPS performance period. This is a decrease of 9,087 from our currently approved estimate of 39,039 beneficiaries and a decrease of 37 beneficiaries from the CY 2020 PFS proposed rule due to updated data. Using this updated number of respondents and our revised estimate of burden per respondent, we estimate an annual burden of 6,540 hours (29,952 respondents × 0.2183 hr/respondent) at a cost of $168,196 (6,540 hr × $25.72/hr). Table 79 shows the estimated annual burden for beneficiaries to participate in the CAHPS for MIPS Survey.

TABLE 79: Estimated Burden for Beneficiary Responses to CAHPS for MIPS Survey

	Burden Estimate
Number of beneficiaries who will respond to the survey (a)	29,952
Number of hours per beneficiary respondent (b)	0.2183
Total Annual Hours (c) = (a)*(b)	**6,540**
Labor rate for a beneficiary (d)	$25.72/hr
Total Annual Cost (e) = (a)*(d)	**$168,196**

*Due to burden being estimated in fractions of minutes and hours, totals may reflect impact of rounding.

Independent of the change in burden per respondent, the decrease of −9,087 respondents from 39,039 to 29,952 results in a difference of −1,954 hours (−9,087 respondents × 0.215 hr/respondent) at a cost of −$50,250 (−9,087 hrs × $25.72/hr). Accounting for the change in number of respondents, the increase in burden per respondent from 0.215 hours to 0.2183 hours results in a difference of +100 hours (29,952 respondents × 0.0033 hr/respondent) at a cost of $2,568 (100 hrs × $25.72/hr). As shown in Table 80, the aggregate change in burden is −1,854 hours (100 hours–1,954 hours) at a cost of −$47,682 ($2,568 − $50,250).

TABLE 80: Change in Estimated Burden for Beneficiary Responses to CAHPS for MIPS Survey

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	8,393
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	6,540
Difference (c) = (b)-(a)	**-1,854**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$215,878
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$168,196
Difference (f) = (e)-(d)	**-$47,682**

The revised survey and burden will be released to the public via the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices.

(9) Group Registration for CMS Web Interface

The requirements and burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

In the CY 2021 PFS proposed rule, we proposed to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2021 MIPS performance period (85 FR 50290). As a result, we did not provide a burden estimate for group registration for the CMS Web Interface for the 2021 performance period. As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type/submission type starting with the 2022 MIPS performance period; therefore, are now providing a burden estimate for both the 2021 and 2022 MIPS performance period.

Groups interested in participating in MIPS using the CMS Web Interface for the first time must complete an online registration process. After first time registration, groups will only need to opt out if they are not going to continue to submit via the CMS Web Interface. In Table 81, we estimate that the registration process for groups under MIPS involves approximately 0.25 hours at $92.46/hr for a computer systems analyst (or their equivalent) to register the group.

In this rule, we are adjusting the number of respondents from 69 to 90 based on more recent data; an increase of 21 from the 69 groups currently approved by OMB and our estimate in the CY 2021 PFS proposed rule (85 FR 50358). Because we are finalizing to sunset the CMS Web Interface beginning with the 2022 MIPS performance period, it is possible that fewer groups will elect to register to submit quality data for the first time in the performance year prior to the collection type/submission type no longer being available; however, we currently have no data with which to estimate what the associated reduction may be. Therefore, we continue to assume that approximately 90 groups will elect to use the CMS Web Interface for the first time during the 2020 MIPS performance period based on the number of new registrations received during the CY 2020 registration period. As shown in Table 81, we estimate a burden of 22.5 hours (90 new registrations × 0.25 hr/registration) at a cost of $2,080 (22.5 hr × $92.46/hr).

TABLE 81: Estimated Burden for Group Registration for CMS Web Interface

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Number of New Groups Registering for CMS Web Interface (a)	90	0
Annual Hours Per Group (b)	0.25	0.25
Total Annual Hours (c) = (a)*(b)	22.5	0
Labor rate for a computer systems analyst (d)	$92.46/hr	$92.46/hr
Total Annual Cost (e) = (a)*(d)	$2,080	$0

As shown in Table 82 using our unchanged currently approved per respondent burden estimates, the increase in the number of groups registering to submit MIPS data via the CMS Web Interface results in an adjustment to the total time burden of +5.25 hours (+21 respondents × 0.25 hours/respondent) at a cost of $485 (+21 groups × 0.25 hr × $92.46/hr) for the 2021 MIPS performance period. For the 2022 MIPS performance period, our burden estimate is 0 hours and $0.

TABLE 82: Change in Estimated Burden for Group Registrations for the CMS Web Interface

	2021 Performance Period Burden Estimate	2022 Performance Period Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	17.25	17.25
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	22.5	0
Difference (c) = (b)-(a)	**+5.25**	**-17.25**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$1,595	$1,595
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$2,080	$0
Difference (f) = (e)-(d)	**+$485**	**-$1,595**

(10) Group Registration for CAHPS for MIPS Survey

This rule is not implementing any new or revised collection of information requirements or burden related to the group registration for the CAHPS for MIPS Survey. The CAHPS for MIPS survey requirements and burden are currently approved by OMB under control number 0938–1222 (CMS–10450). Consequently, we are not making any changes to burden for CAHPS for MIPS survey group registration under that control number.

f. ICRs Regarding the Call for MIPS Quality Measures

This rule is not implementing any new or revised collection of information requirements or burden related to the call for MIPS quality measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any call for MIPS quality measure changes under that control number.

g. ICRs Regarding Promoting Interoperability Data (§§ 414.1375 and 414.1380)

(1) Background

For the 2021 MIPS performance period, clinicians and groups can submit Promoting Interoperability data through direct, log in and upload, or log in and attest submission types. With the exception of submitters who elect to use the log in and attest submission type for the Promoting Interoperability performance category, which is not available for the quality performance category, we anticipate that individuals and groups will use the same data submission type for the both of these performance categories and that the clinicians, practice managers, and computer systems analysts involved in supporting the quality data submission will also support the Promoting Interoperability data submission process. The following burden estimates show only incremental hours required above and beyond the time already accounted for in the quality data submission process. Although this analysis assesses burden by performance category and submission type, we emphasize that MIPS is a consolidated program and submission analysis and decisions are expected to be made for the program as a whole.

(2) Reweighting Applications for Promoting Interoperability and Other Performance Categories

The requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53918 through 53919), CY 2019 PFS final rule (83 FR 60011 through 60012), and the CY 2020 PFS final rule (84 FR 63134 through 63135) for our previously finalized requirements and burden for reweighting applications for Promoting Interoperability and other performance categories.

As established in the CY 2017 and CY 2018 Quality Payment Program final rules, MIPS eligible clinicians who meet the criteria for a significant hardship or other type of exception may submit an application requesting a zero percent weighting for the Promoting Interoperability, quality, cost, and/or improvement activities performance categories under specific circumstances (81 FR 77240 through 77243, 82 FR 53680 through 53686, and 82 FR 53783 through 53785). Respondents who apply for a reweighting for the quality, cost, and/or improvement activities performance categories have the option of applying for reweighting for the Promoting Interoperability performance category on the same online form. We assume that respondents applying for a reweighting of the Promoting Interoperability performance category due to extreme and uncontrollable circumstances will also request a reweighting of at least one of the other performance categories simultaneously and not submit multiple reweighting applications.

Table 83 summarizes the burden for clinicians to apply for reweighting the Promoting Interoperability performance category to zero percent due to a significant hardship exception (including a significant hardship exception for small practices) or as a result of a decertification of an EHR. Based on the number of reweighting applications received by December 31, 2019 for the 2019 MIPS performance period, we assume 51,098 respondents (eligible clinicians or groups) will submit a request to reweight the Promoting Interoperability performance category to zero percent due to a significant hardship (including clinicians in small practices) or EHR decertification and an additional 994 respondents will submit a request to reweight one or more of the quality, cost, Promoting Interoperability, or improvement activity performance categories due to an extreme or uncontrollable circumstance, for a total of 52,092 reweighting applications submitted. This is an increase of 21,472 respondents compared to our currently approved estimate of 30,620 respondents (84 FR 63134). Similar to the data used to estimate the number of respondents in the CY 2020 PFS final rule, our respondent estimate includes a significant number of applications submitted as a result of a data issue CMS was made aware of and is specific to a single third-party intermediary. While we do not anticipate similar data issues to occur in each performance period, we do believe future similar incidents may occur and are electing to use this data without adjustment to reflect this belief. Our respondent estimate is also based on data that does not include applications submitted during the extended period ending April 30, 2020 due to the PHE for COVID–19, as we do not believe it would be an accurate basis for future estimates of application submissions. Of our total respondent estimate of 52,092, we estimate that 35,986 respondents (eligible clinicians or groups) will submit a request for reweighting the Promoting Interoperability performance category to zero percent due to extreme and uncontrollable circumstances, insufficient internet connectivity, lack of control over the availability of CEHRT, or as a result of a decertification of an EHR. An additional 16,106 respondents will submit a request for reweighting the Promoting Interoperability performance category to zero percent as a small practice experiencing a significant hardship.

In section IV.A.3.c.(5)(e), we discussed that, beginning with the 2022 MIPS payment year (2020 performance year), APM Entities may submit an extreme and uncontrollable circumstances exception application for all four performance categories and applicable to all MIPS eligible clinicians in the APM Entity group. As previously discussed in section VII.B.5.a.(4) of this final rule, due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, we assume ACO APM Entities will submit data through the APM Performance Pathway and non-ACO APM Entities would participate through traditional MIPS, thereby submitting as an individual or group rather than as an entity. Therefore, we limited our analysis to ACOs that were eligible for an exception due to extreme and uncontrollable circumstances during the 2019 MIPS performance period and elected not to report quality data. Based on this data, we estimate 7 APM Entities will submit an extreme and uncontrollable circumstances exception application for the 2021 MIPS performance period. Combined with our aforementioned estimate of 52,092 eligible clinicians and groups, the total estimated number of respondents for the 2021 MIPS performance period is 52,099.

The application to request a reweighting to zero percent only for the Promoting Interoperability performance category is a short online form that requires identifying the type of hardship experienced or whether decertification of an EHR has occurred and a description of how the circumstances

impair the clinician or group's ability to submit Promoting Interoperability data, as well as some proof of circumstances beyond the clinician's control. The application for reweighting of the quality, cost, Promoting Interoperability, and/or improvement activities performance categories due to extreme and uncontrollable circumstances requires the same information with the exception of there being only one option for the type of hardship experienced. We continue to estimate it will take 0.25 hours at $92.46/hr for a computer system analyst to complete and submit the application. As shown in Table 83, we estimate an annual burden of 13,025 hours (52,099 applications × 0.25 hr/application) and $1,204,268 (13,025 hr × $92.46/hr).

TABLE 83: Estimated Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden estimate
# of Eligible Clinicians or Groups Applying Due to Significant Hardship and Other Exceptions or Extreme and Uncontrollable Circumstances (a)	35,986
# of Eligible Clinicians or Groups Applying Due to Significant Hardship for Small Practice (b)	16,106
# APM Entities requesting Extreme and Uncontrollable Circumstances exception	7
Total Applications Submitted (c)	52,099
Hours Per Applicant per Application Submission (d)	0.25
Total Annual Hours (e)=(a)*(c)	**13,025**
Labor Rate for a computer systems analyst (f)	$92.46/hr
Total Annual Cost (g)=(a)*(f)	**$1,204,268**

As shown in Table 84, using our unchanged currently approved per respondent burden estimate, the increased number of respondents results in a total adjustment of 5,370 hours (21,479 respondents × 0.25 hr/respondent) and $496,487 (5,370 hr × $92.46/hr).

TABLE 84: Adjusted Burden for Reweighting Applications for Promoting Interoperability and Other Performance Categories

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	7,655
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	13,025
Difference (c) = (b)-(a)	**+5,370**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$707,781
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$1,204,268
Difference (f) = (e)-(d)	**+$496,487**

(3) Submitting Promoting Interoperability Data

We did not propose any new or revised collection of information requirements related to the submission of data for the Promoting Interoperability performance category. However, we are adjusting our currently approved burden estimates based on more recent data. The burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77509 through 77511), CY 2018 Quality Payment Program final rule (82 FR 53919 through 53920), CY 2019 PFS final rule (83 FR 60013 through 60014), and the CY 2020 PFS final rule (84 FR 63135 through 63137) for our previously finalized requirements and burden for submission of data for the Promoting Interoperability performance category.

In this final rule, we did not propose any changes to our current criteria for automatic reweighting of the Promoting Interoperability performance category for certain MIPS eligible clinicians or MIPS eligible clinicians who have experienced a significant hardship or decertification of an EHR.

In section IV.A.3.c.(4)(b) of this rule, we are adding § 414.1320(g)(1), which would establish a performance period for the Promoting Interoperability performance category of a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. Because this does not change the number of required Promoting Interoperability measures that must be reported, we are not making any changes to our burden assumptions.

In section IV.3.c.(4)(c)(ii)(b) we are adding the HIE bi-directional exchange measure for the 2021 performance period and subsequent years as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information

measure. This provision provides clinicians the option of either reporting the new measure or the two existing measures. Because the new HIE measure is an optional alternative instead of a new requirement and the provision does not change the number of required Promoting Interoperability measures that must be reported, we are not making any changes to our burden assumptions.

A variety of organizations will submit Promoting Interoperability data on behalf of clinicians. Clinicians not participating in a MIPS APM may submit data as individuals or as part of a group. In the CY 2017 Quality Payment Program final rule (81 FR 77258 through 77260, 77262 through 77264) and CY 2019 PFS final rule (83 FR 59822–59823), we established that eligible clinicians in MIPS APMs (including the Shared Savings Program) may report for the Promoting Interoperability performance category as an APM Entity group, individuals, or a group. Because we are not making changes at § 414.1375 to the scoring for APM entities as a result of our provision in section IV.A.3.(b) of this final rule to establish an APM Performance Pathway, our reporting assumptions for clinician in MIPS APMs remains unchanged.

As shown in Table 85, based on data from the 2019 MIPS performance period, we estimate that a total of 53,636 respondents consisting of 42,110 individual MIPS eligible clinicians and 11,526 groups and virtual groups will submit Promoting Interoperability data. Since our CY 2020 PFS final rule estimated 74,281 respondents, this represents a decrease of 20,645 respondents (53,636 respondents − 74,281 active respondents). This is a decrease of 20,636 individuals and 3,227 groups from the estimates of 62,746 individuals and 14,753 groups provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50360).

We assume that MIPS eligible clinicians previously scored under the APM scoring standard, as described in the CY 2020 PFS final rule, will continue to submit Promoting Interoperability data (84 FR 63006) in a similar way through the APM Performance Pathway. As a result, we do not anticipate any change in burden. Each MIPS eligible clinician in an APM Entity reports data for the Promoting Interoperability performance category through either their group TIN or individual reporting. Sections 1899 and 1115A of the Act (42 U.S.C. 1395jjj and 42 U.S.C. 1315a, respectively) state that the Shared Savings Program and the testing, evaluation, and expansion of Innovation Center models are not subject to the PRA. However, in the CY 2019 PFS final rule, we established that MIPS eligible clinicians who participate in the Shared Savings Program are no longer limited to reporting for the Promoting Interoperability performance category through their ACO participant TIN (83 FR 59822 through 59823). Burden estimates for this final rule assume group TIN-level reporting as we believe this is the most reasonable assumption for the Shared Savings Program, which requires that ACOs include full TINs as ACO participants. As we receive updated information which reflects the actual number of Promoting Interoperability data submissions submitted by Shared Savings Program ACO participants, we will update our burden estimates accordingly.

TABLE 85: Estimated Number of Respondents to Submit Promoting Interoperability Performance Data on Behalf of Clinicians

	# of Respondents
Number of individual clinicians to submit Promoting Interoperability (a)	42,110
Number of groups to submit Promoting Interoperability (b)	11,526
Total Respondents in 2021 MIPS performance period (CY 2021 Final Rule) (c) = (a) + (b)	53,636
*Total Respondents in 2020 MIPS performance period (CY 2020 Final Rule) (d)	74,281
Difference (e) = (c) – (d)	-20,645

We continue to estimate the time required for an individual or group to submit Promoting Interoperability data to be 2.67 hours. As shown in Table 86, the total burden estimate for submitting data on the specified Promoting Interoperability objectives and measures is estimated to be 143,029 hours (53,636 respondents × 2.67 incremental hours for a computer analyst's time above and beyond the physician, medical and health services manager, and computer system's analyst time required to submit quality data) and $13,224,492 (143,029 hr × $92.46/hr)).

TABLE 86: Estimated Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate
Number of individual clinicians to submit Promoting Interoperability (a)	42,110
Number of groups to submit Promoting Interoperability (b)	11,526
Total (c) = (a) + (b)	53,636
Total Annual Hours Per Respondent (b)	2.67
Total Annual Hours (c) = (a)*(b)	**143,029**
Labor rate for a computer systems analyst to submit Promoting Interoperability data (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	**$13,224,492**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 87, using our unchanged currently approved per respondent burden estimate, the decrease in number of respondents results in a total adjustment of −55,054 hours (−20,645 respondents × 2.67 hr/respondent) at a cost of −$5,090,231 (−55,054 hr × $92.46/hr).

TABLE 87: Adjusted Burden for Promoting Interoperability Performance Category Data Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	198,083
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	143,029
Difference (c) = (b)-(a)	**-55,054**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$18,314,723
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$13,224,492
Difference (f) = (e)-(d)	**-$5,090,231**

h. ICRs Regarding the Nomination of Promoting Interoperability (PI) Measures

This rule is not implementing any new or revised collection of information requirements or burden related to the nomination of Promoting Interoperability measures. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes under that control number.

i. ICRs Regarding Improvement Activities Submission (§§ 414.1305, 414.1355, 414.1360, and 414.1365)

We are adjusting our currently approved burden estimates based on more recent data. The adjusted burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77511 through 77512), CY 2018 Quality Payment Program final rule (82 FR 53920 through 53922), CY 2019 PFS final rule (83 FR 60015 through 60017), and the CY 2020 PFS final rule (84 FR 63138 through 63140) for our previously finalized requirements and burden for submission of data for the Improvement Activities performance category.

In this final rule, we did not make any changes to our requirements associated with criteria for attesting to specific improvement activities.

As discussed in section IV.A.3.c.(3)(b)(iii) of this rule, we are finalizing the removal of one obsolete improvement activity, modification of two existing improvement activities, and adoption of the COVID–19 improvement activity added via IFC. We refer readers to Appendix 2 of this final rule for further details. Because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform, we do not expect these provisions to affect our currently approved information collection burden estimates.

In section IV.A.3.b.(3)(c) of this rule, we outline how we would assign a score for the Improvement Activities performance category for MIPS APMs. We will assign Improvement Activities scores to APM participants in the APP based on the requirements of participation in APMs. To develop the Improvement Activities score for MIPS APMs, we will compare requirements of the APM with the list of Improvement Activities measures for the applicable year, and score those measures as they would otherwise be scored according to § 414.1355. In the event a MIPS APM participant does not actually perform an activity for which Improvement Activities credit would otherwise be assigned under this provision, the MIPS APM participant would not receive credit for the associated Improvement Activity. In the event that the assigned score does not represent the maximum improvement activities score, we specify that MIPS eligible clinicians reporting through the APP would have the opportunity to report additional improvement activities that then would be applied towards their scores. Our burden estimates assume there will be no improvement activities burden for MIPS APM participants electing the APP. We will assign the improvement

activities performance category score at the APM Entity level.

A variety of organizations and in some cases, individual clinicians, will submit improvement activity performance category data. For clinicians who are not part of APMs, we assume that clinicians submitting quality data as part of a group through direct, log in and upload submission types, and CMS Web Interface will also submit improvement activities data. In the 2020 and prior MIPS performance periods, individuals and groups submitting data for the quality performance category through a MIPS CQM or QCDR that did not also support reporting of data for the Promoting Interoperability or improvement activity performance categories would be required to submit data for these performance categories using an alternate submission type, the policies requiring qualified registries and QCDRs to be able to submit data for all three of the MIPS performance categories identified in § 414.1400(a)(2) will help to alleviate this issue. As finalized in the CY 2017 Quality Payment Program final rule (81 FR 77264), APM Entities only need to report improvement activities data if the CMS-assigned improvement activities score is below the maximum improvement activities score. Similar to our assumption in the CY 2018 Quality Payment Program final rule, our burden estimates assume that the MIPS APM models for the 2021 MIPS performance period will qualify for the maximum improvement activities performance category score and, as such, APM Entities will not submit any additional improvement activities. (82 FR 53921 through 53922).

As represented in Table 88, based on 2019 MIPS performance period data, we estimate that a total of 79,927 respondents consisting of 62,603 individual clinicians and 17,324 groups will submit improvement activities during the 2021 MIPS performance period. Since our currently approved burden sets out 103,813 respondents, this represents a decrease of − 23,886 respondents (79,927 respondents—103,813 active respondents). This is a decrease of 23,157 individuals and an increase of 610 groups from the estimates of 85,760 individuals and 16,714 groups provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50362).

As discussed in sections VII.B.5.e.(2) and VII.B.5.g.(3) of this final rule regarding our estimate of clinicians and groups submitting data for the quality and Promoting Interoperability performance categories, we have updated our estimates for the number of clinicians and groups that will submit improvement activities data based on projections of the number of eligible clinicians that were not QPs or members of an ACO in the 2019 MIPS performance period but will be in the 2021 MIPS performance period, and will therefore not be required to submit improvement activities data.

TABLE 88: Estimated Number of Organizations Submitting Improvement Activities Performance Category Data on Behalf of Clinicians

	Count
# of clinicians to participate in improvement activities data submission as individuals during the 2021 MIPS performance period (a)	62,603
# of Groups to submit improvement activities on behalf of clinicians during the 2021 MIPS performance period (b)	17,324
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2020 MIPS performance period (CY 2021 Final Rule) (c) = (a) + (b)	79,927
*Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (CY 2020 Final Rule) (d)	103,813
Difference (e)=(c)-(d)	**-23,886**

*Currently approved by OMB under control number 0938-1314 (CMS-10621).

Consistent with the CY 2020 PFS final rule, we continue to estimate that the per response time required per individual or group is 5 minutes for a computer system analyst to submit by logging in and manually attesting that certain activities were performed in the form and manner specified by CMS with a set of authenticated credentials (84 FR 63140).

As shown in Table 89, we estimate an annual burden of 6,661 hours (79,927 responses × 5 minutes/60) and $615,838 (6,661 hr × $92.46/hr)).

TABLE 89: Estimated Burden for Improvement Activities Submission

	Burden Estimate
Total # of Respondents (Groups, Virtual Groups, and Individual Clinicians) to submit improvement activities data on behalf of clinicians during the 2019 MIPS performance period (a)	79,927
Total Annual Hours Per Respondent (b)	5 minutes
Total Annual Hours (c) = (a)*(b)	**6,661**
Labor rate for a computer systems analyst to submit improvement activities (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$615,838**

*Due to burden being estimated in fractions of hours, totals may reflect impact of rounding.

As shown in Table 90, using our unchanged currently approved per respondent burden estimate, the decrease of −23,886 in the number of respondents results in an adjustment of −1,990 hours (−23,886 responses × 5 minutes/60) at a cost of −$184,041 (−1,990 hr × $92.46/hr).

TABLE 90: Adjusted Burden for Improvement Activities Submission

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	8,651
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	6,661
Difference (c) = (b)-(a)	**-1,990**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$799,879
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$615,838
Difference (f) = (e)-(d)	**-$184,041**

j. ICRs Regarding the Nomination of Improvement Activities (§ 414.1360)

The requirements and burden associated with this rule's data submission will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53922), CY 2019 PFS final rule (83 FR 60017 through 60018), and the CY 2020 PFS final rule (84 FR 63141) for our previously finalized requirements and information collection burden for the nomination of improvement activities.

In the CY 2018 Quality Payment Program final rule, for the 2018 and future MIPS performance periods, stakeholders were provided an opportunity to propose new activities formally via the Annual Call for Activities nomination form that was posted on the CMS website (82 FR 53657). In section IV.A.3.c.(3)(b)(i)(B)(bb) of this rule, we are requiring nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible. Similar to the burden assumptions finalized in the CY 2020 PFS final rule for the nomination of quality measures, we believe this will require approximately 0.6 hours at $110.74/hr for a medical and health services manager and 0.4 hours at $212.78/hr for a physician to research existing measures and provide a rationale for the linkage (84 FR 63132). We previously estimated it would require 1.2 hours for a medical and health services manager or equivalent and 0.8 hours for a physician to nominate an improvement activity (84 FR 63141). Combined with our currently approved burden estimate, we now estimate 1.8 hours at $110.74/hr for a medical and health services manager or equivalent and 1.2 hours at $212.78/hr for a physician to nominate an improvement activity. This represents a change of +0.6 hours (1.8 hr—1.2 hr) for a medical and health services manager or equivalent and +0.4 hours (1.2 hr—0.8 hr) for a physician and an overall increase of 1 hour.

In section IV.A.3.c.(3)(b)(i)(A)(bb), we are making an exception to the established timeframe for nomination of improvement activities, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. Instead of only accepting nominations and modifications submitted February 1st through June 30th each year, we would accept nominations for the duration of the PHE as long as the improvement activity is still relevant. No other aspects of the Annual Call for Activities process would be affected (for example, criteria for nominating improvement activities, considerations for selection of improvement activities, or weighting policies would all still apply). While we expect additional nominations may be received as a result of this change, we do not have any data with which to estimate what the additional number may be. As a result, our burden estimate remains unchanged due to this provision. Additionally, in section IV.A.3.c.(3)(b)(ii)(B), beginning with the CY 2021 performance period and future years, we will consider agency-nominated improvement activities. Because these nominations would be submitted by federal agencies, the associated time is exempt from the PRA, and therefore, not included in our estimates. We also refer readers to

section VIII.H.15.e.(4)(c) where we discuss our impact analysis.

Due to the PHE for COVID–19, we continue to use our currently approved assumption that we will receive 31 nominations of new or modified activities which will be evaluated for the Improvement Activities Under Consideration (IAUC) list for possible inclusion in the CY 2022 Improvement Activities Inventory as we believe this estimate is more realistic than basing our estimate on the number of nominations received during the 2020 Annual Call for Activities.

As shown in Table 91, we estimate an annual information collection burden of 93 hours (31 nominations × 3 hr/nomination) at a cost of $14,095 (31 × [(1.8 hr × $110.74/hr) + (1.2 hr × $212.78/hr)]).

TABLE 91: Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
# of Nominations of New Improvement Activities (a)	31
# of Hours Per Medical and Health Services Manager to Identify and Nominate Activity (b)	1.8
# of Hours Per Physician to Identify Activity (c)	1.2
Annual Hours Per Respondent (d)= (b) + (c)	3.0
Total Annual Hours (e) = (a)*(d)	**93**
Cost to Identify and Submit Activity (@ medical and health services manager's labor rate of $110.74/hr) (f)	$199.33
Cost to Identify Improvement Activity (@ physician's labor rate of $212.78/hr) (g)	$255.34
Total Annual Cost Per Respondent (h)=(f)+(g)	$454.67
Total Annual Cost (i)=(a)*(h)	**$14,095**

As shown in Table 92, using our unchanged estimate of the number of activities nominated, the increase in the burden per nomination results in a change of 31 hours (31 nominations × 1 hr/nomination) at a cost of $4,698 (31 activities × [(0.6 hr × $110.74/hr) + (0.4 hr × $212.78/hr)]).

TABLE 92: Change in Estimated Burden for Nomination of Improvement Activities

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	62
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	93
Difference (c) = (b)-(a)	**+31**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$9,396
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$14,095
Difference (f) = (e)-(d)	**+$4,698**

k. Nomination of MVPs

The following reflects the burden associated with the first year of data collection associated with a new process available for all clinicians/third party intermediaries to nominate MVPs for inclusion in the Quality Payment Program. The requirements and burden associated with the Nomination of MVPs will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

Beginning with the 2022 performance period, we are requiring stakeholders to formally submit their MVP candidates utilizing a standardized template, which will be published in the QPP resource library for future implementation. Stakeholders should submit all information including a description of how their MVP abides by the MVP development criteria as described in section IV.A.3.a.(2)(a)(i) of this final rule, and provide rationales as to why specific measures and activities were chosen to construct the MVP. As MVP candidates are received, they will be reviewed, vetted, and evaluated by CMS and our contractors to determine if the MVP is feasible and ready for inclusion in the upcoming performance period. For the 2021 MIPS performance period, we assume 25 MVP nominations will be received and the estimated time required to submit all required information is 12 hours per nomination. We solicited comment on our estimate of the time required to nominate an MVP. We did not receive comments related to the estimate of time required to nominate an MVP.

Similar to the call for quality measures, nomination of Promoting Interoperability measures, and the nomination of improvement activities, we assume MVP nomination will be performed by both practice administration staff or their equivalents and clinicians. We estimate 7.2 hours at $110.74/hr for a medical and health services manager or equivalent and 4.8 hours at $212.78/hr for a physician to nominate an MVP. As shown in Table 93, we estimate an annual burden of 300 hours (25 nominations × 12 hr/nomination) at a cost of $45,467 (25 × [(7.2 hr × $110.74/hr) + (4.8 hr × $212.78/hr)]).

TABLE 93: Estimated Burden for Nomination of MVPs

	Burden Estimate
# of Nominations of New Improvement Activities (a)	25
# of Hours Per Medical and Health Services Manager (b)	7.2
# of Hours Per Physician (c)	4.8
Annual Hours Per Respondent (d)= (b) + (c)	12
Total Annual Hours (e) = (a)*(d)	**300**
Cost to Nominate an MVP (@ medical and health services manager's labor rate of $110.74/hr) (f)	$797.33
Cost to Nominate an MVP (@ physician's labor rate of $212.78/hr) (g)	$1,021.34
Total Annual Cost Per Respondent (h)=(f)+(g)	$1,818.67
Total Annual Cost (i)=(a)*(h)	**$45,467**

l. ICRs Regarding the Cost Performance Category (§ 414.1350)

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by CD or hardcopy. Moreover, the provisions of this final rule do not result in the need to add or revise or delete any claims data fields. Consequently, we are not setting out burden or making any changes under the 0938–1197 control number.

m. ICRs Regarding Partial QP Elections (§§ 414.1310(b) and 414.1430)

This rule did not propose any new or revised collection of information requirements related to the Partial QP Elections to participate in MIPS as a MIPS eligible clinician. However, we are adjusting our currently approved burden estimates based on updated projections for the 2021 MIPS performance period. The burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

As shown in Table 94, based on our predictive QP analysis for the 2021 QP performance period, which accounts for historical response rates in performance year 2019, we estimate that 100 APM Entities and 200 eligible clinicians (representing approximately 2,500 Partial QPs) will make the election to participate as a Partial QP in MIPS, a total of 300 elections which is a decrease of 1,722 from the 2,022 elections that are currently approved by OMB under the aforementioned control number. We continue to estimate it will take the APM Entity representative or eligible clinician 15 minutes (0.25 hr) to make this election. In aggregate, we estimate an annual burden of 75 hours (300 respondents × 0.25 hr/election) and $6,935 (75 hr × $92.46/hr).

TABLE 94: Estimated Burden for Partial QP Election

	Burden Estimate
# of respondents making Partial QP election (100 APM Entities, 200 eligible clinicians) (a)	300
Total Hours Per Respondent to Elect to Participate as Partial QP (b)	0.25
Total Annual Hours (c) = (a)*(b)	**75**
Labor rate for computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$6,935**

As shown in Table 95, using our unchanged currently approved per respondent burden estimate, the decrease in the number of Partial QP elections results in an adjustment of −430.5 hours (−1,722 elections × 0.25 hr) from our currently approved burden of 505.5 hours at a cost of −$39,804 (−430.5 hr × $92.46/hr) (84 FR 63142).

TABLE 95: Adjusted Burden for Partial QP Election

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	505.5
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	75
Difference (c) = (b)-(a)	**-430.5**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$46,739
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$6,935
Difference (f) = (e)-(d)	**-$39,804**

n. ICRs Regarding Other Payer Advanced APM Determinations: Payer-Initiated Process (§ 414.1445) and Eligible Clinician Initiated Process (§ 414.1445)

The following burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

(1) Payer Initiated Process (§ 414.1445)

This rule is not implementing any new or revised collection of information requirements related to the Payer-Initiated Process. However, we are adjusting our currently approved burden estimates based on updated projections for the 2021 MIPS performance period. As mentioned above, the adjusted burden will be submitted to OMB for approval.

As shown in Table 96, based on the actual number of requests received in the 2019 QP performance period, we estimate that in CY 2021 for the 2022 QP performance period 80 payer-initiated requests for Other Payer Advanced APM determinations will be submitted (10 Medicaid payers, 50 Medicare Advantage Organizations, and 20 remaining other payers), a decrease of 30 from the 110 total requests currently approved by OMB under the aforementioned control number. We continue to estimate it will take 10 hours for a computer system analyst per arrangement submission. We estimate an annual burden of 800 hours (80 submissions × 10 hr/submission) and $73,968 (800 hr × $92.46/hr).

TABLE 96: Estimated Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
# of other payer payment arrangements (10 Medicaid, 50 Medicare Advantage Organizations, 20 remaining other payers) (a)	80
Total Annual Hours Per other payer payment arrangement (b)	10
Total Annual Hours (c) = (a)*(b)	**800**
Labor rate for a computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (c)*(d)	**$73,968**

As shown in Table 97, using our unchanged currently approved per respondent burden estimate, the decrease in the number of payer-initiated requests from 110 to 80 results in an adjustment of −300 hours (−30 requests × 10 hr) from our currently approved burden of 1,100 hours at a cost of −$27,738 (−300 hr × $92.46/hr) (84 FR 63143).

TABLE 97: Adjusted Burden for Other Payer Advanced APM Identification Determinations: Payer-Initiated Process

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	1,100
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	800
Difference (c) = (b)-(a)	**-300**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$101,706
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$73,968
Difference (f) = (e)-(d)	**-$27,738**

(2) Eligible Clinician Initiated Process (§ 414.1445)

This rule is not implementing any new or revised collection of information requirements or burden related to the Eligible-Clinician Initiated Process. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the eligible clinician initiated process under that control number.

(3) Submission of Data for QP Determinations Under the All-Payer Combination Option (§ 414.1440)

This rule is not implementing any new or revised collection of information requirements related to the Submission of Data for QP Determinations under the All-Payer Combination Option. The requirements and burden are currently approved by OMB under control number 0938–1314 (CMS–10621). Consequently, we are not making any changes to the QP Determinations under the All-Payer Combination Option under that control number.

o. ICRs Regarding Voluntary Participants Election To Opt-Out of Performance Data Display on Physician Compare (§ 414.1395)

This rule is not implementing any new or revised collection of information requirements related to the election by voluntary participants to opt-out of public reporting on Physician Compare. However, we are adjusting our currently approved burden estimates based on data from the 2019 MIPS performance period. The burden will be submitted to OMB for approval under control number 0938–1314 (CMS–10621).

We refer readers to the CY 2018 Quality Payment Program final rule (82 FR 53924 through 53925), CY 2019 PFS final rule (83 FR 60022), and the CY 2020 PFS final rule (84 FR 63145 through 63146) for our previously finalized requirements and burden for voluntary participants to opt-out of public reporting on Physician Compare.

We estimate that 10 percent of the total clinicians and groups who will voluntarily participate in MIPS will also elect not to participate in public reporting. This results in a total of 3,486 (0.10 × 34,860 voluntary MIPS participants) clinicians and groups, a decrease of −6,556 from the currently approved estimate of 10,042 and a decrease of 6,418 from the estimate of 9,904 provided in the CY 2021 PFS proposed rule due to availability of updated data (85 FR 50367). Voluntary MIPS participants are clinicians that are not QPs and are expected to be excluded from MIPS after applying the eligibility requirements set out in the CY 2019 PFS final rule but have elected to submit data to MIPS. As discussed in the RIA section of the CY 2019 PFS final rule, we estimate that 33 percent of clinicians that exceed one (1) of the low-volume criteria, but not all three (3), will elect to opt-in to MIPS, become MIPS eligible, and no longer be considered a voluntary reporter (83 FR 60050).

Table 98 shows that for these voluntary participants, we continue to estimate it will take 0.25 hours for a computer system analyst to submit a request to opt-out. In aggregate, we estimate an annual burden of 871.5 hours (3,486 requests × 0.25 hr/request) and $80,579 (871.5 hr × $92.46/hr).

TABLE 98: Estimated Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
# of Voluntary Participants Opting Out of Physician Compare (a)	3,486
Total Annual Hours Per Opt-out Requester (b)	0.25
Total Annual Hours (c) = (a)*(b)	**871.5**
Labor rate for a computer systems analyst (d)	$92.46/hr
Total Annual Cost (e) = (a)*(d)	**$80,579**

As shown in Table 99, using our unchanged currently approved per respondent burden estimate, the decrease of −6,556 opt outs by voluntary participants results in an adjustment of −1,639 hours (−6,556 requests × 0.25 hr) at a cost of −$151,542 (−1,639 hr × $92.46/hr).

TABLE 99: Adjusted Burden for Voluntary Participants to Elect Opt Out of Performance Data Display on Physician Compare

	Burden Estimate
Total Annual Hours for Respondents in CY 2020 Final Rule (a)	2,510.5
Total Annual Hours for Respondents in CY 2021 Final Rule (b)	871.5
Difference (c) = (b)-(a)	**-1,639**
Total Annual Cost for Respondents in CY 2020 Final Rule (d)	$232,121
Total Annual Cost for Respondents in CY 2021 Final Rule (e)	$80,579
Difference (f) = (e)-(d)	**-$151,542**

p. Summary of Annual Quality Payment Program Burden Estimates

Table 100 summarizes this final rule's burden estimates for the Quality Payment Program for both the 2021 and 2022 performance periods. In the CY 2020 PFS final rule, the total estimated burden was 2,932,649 hours at a cost of $279,550,490 ($279,573,747—$23,257) (84 FR 63146). Accounting for updated wage rates and the subset of all Quality Payment Program ICRs discussed in this rule compared to the CY 2020 PFS final rule, the total estimated annual burden of continuing policies and information set forth in the CY 2020 PFS final rule into the 2021 and 2022 MIPS performance periods is 2,938,128 hours at a cost of $287,216,853; an increase of 5,479 hours and $7,666,363. To understand the burden implications of the policies in this rule, we provide an estimate of the total burden associated with continuing the policies and information collections set forth in the CY 2020 PFS final rule into the 2021 and 2022 MIPS performance periods. This burden estimate of 1,478,504 hours at a cost of $144,456,084 reflects the availability of more accurate data to account for all potential respondents and submissions across all the performance categories and more accurately reflect the exclusion of QPs from all MIPS performance categories, a difference of −1,459,624 hours and −$142,760,769. This burden estimate is lower than the burden approved for information collection related to the CY 2020 PFS final rule due to updated data and assumptions as well as the addition of the Open Authorization Credentialing and Token Request Process information collection, which is not a result of any new or revised policies in this rule or finalized in any previous final rule, but rather an operational improvement. The difference of −4,763 hours (1,459,624 hours −1,462,534 hours −1,854 hours) and −$421,117 ($142,760,769 −$143,134,204 −$47,681) between this estimate and the total burden shown in Table 103 is the reduction in burden associated with impacts of the policy to sunset the CMS Web Interface measures as a collection type/submission type; partially offset by an increase in burden due to a new information collection for nomination of MVPs, the policies to require QCDRs and qualified registries to conduct targeted audits as necessary, the policy to add a survey-based measure on telehealth that assesses patient-reported usage of telehealth services to the CAHPS for MIPS Survey, the policy to allow APM Entities to submit an extreme and uncontrollable circumstances exception application, and the policy to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible. We have included Table 100 to assist in understanding these differences. Note that the difference between the burden estimates for the 2021 and 2022 MIPS performance periods is entirely due to the finalized policy to sunset the CMS Web Interface measures as a collection type/submission type beginning in the 2022 MIPS performance period.

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TABLE 100: Summary of Changes in Burden from the CY 2020 PFS Final Rule

2021 MIPS Performance Period		
Burden Estimate Description	**Burden Hours**	**Burden Cost**
CY 2020 PFS Final Rule (a)	2,932,649	$279,550,490
CY 2021 PFS Final Rule w/ updated wage rates and ICRs (b)	2,938,128	$287,216,853
CY 2021 PFS Final Rule w/ updated data and assumptions (c)	1,478,509	$144,456,570
Change in burden due to updated data and assumptions (d) = (c) – (b)	**-1,459,619**	**-$142,760,284**
CY 2021 PFS Final Rule Total Burden (e)	1,479,672	$144,576,960
Total change in burden (f) = (e) – (b)	**-1,458,457**	**-$142,639,893**
Change in burden associated with policies (g) = (f) – (d)	**+1,163**	**+$120,391**
2022 MIPS Performance Period		
Burden Estimate Description	**Burden Hours**	**Burden Cost**
CY 2020 PFS Final Rule (h)	2,932,649	$279,550,490
CY 2021 PFS Final Rule w/ updated wage rates and ICRs (i)	2,938,128	$287,216,853
CY 2021 PFS Final Rule w/ updated data and assumptions (j)	1,478,504	$144,456,084
Change in burden due to updated data and assumptions (k) = (j) – (i)	**-1,459,624**	**-$142,760,769**
CY 2021 PFS Final Rule Total Burden (l)	1,473,741	$144,034,968
Total change in burden (as shown in Table 103) (m) = (l) – (i)	**-1,464,388**	**-$143,181,886**
Change in burden associated with policies (n) = (m) – (k)	**-4,763**	**-$421,117**

TABLE 101: Summary of Quality Payment Program Burden Estimates and Requirements

Requirement	Currently Approved Responses*	Finalized Responses	Change in Responses	Currently Approved Total Burden Hours*	Finalized Total Burden Hours	Change in Total Burden Hours
§ 414.1400 QCDR self-nomination (see section VII.B.5.c.(2))*	76	82	+6	608	826	+218
§ 414.1400 Registry self-nomination (see section VII.B.5.c.(3))*	153	193	+40	459	1,139	+680
Open Authorization Credentialing and Token Request Process (see section VII.B.5.d)	0	15	+15	0	15	+15
§§ 414.1325 and 414.1335 (Quality Performance Category) Medicare Part B Claims Collection Type (see section VII.B.5.e.(4))	94,846	29,273	-65,573	1,346,813	415,677	-931,137
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section VII.B.5.e.(5)): 2021 Performance Period	111,218	52,899	-58,319	1,010,193	480,482	-529,711
§§ 414.1325 and 414.1335 (Quality Performance Category) QCDR/ MIPS CQM Collection Type (see section VII.B.5.e.(5)): 2022 Performance Period	111,218	52,949	-58,269	1,010,193	480,890	-529,711
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section VII.B.5.e.(6)): 2021 Performance Period	43,333	50,409	+7,076	346,664	403,272	+56,608
§§ 414.1325 and 414.1335 (Quality Performance Category) eCQM Collection Type (see section VII.B.5.e.(6)): 2022 Performance Period	43,333	50,470	+7,137	346,664	403,800	+57,136
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section VII.B.5.e.(7)): 2021 Performance Period	104	111	+7	6,414	6,845	+431
§ 414.1325 and 414.1335 (Quality Performance Category) CMS Web Interface collection type (see section VII.B.5.e.(7)): 2022 Performance Period	104	0	-104	6,414	0	-6,414
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section VII.B.5.e.(9)): 2021 Performance Period	69	90	+21	17.25	22.5	+5.25
§§ 414.1325 and 414.1335 (Quality Performance Category) Registration and Enrollment for CMS Web Interface (see section VII.B.5.e.(9)): 2022 Performance Period	69	0	-69	17.25	0	-17.25
§ 414.1375 (Promoting Interoperability Performance Category) Reweighting Applications for Promoting Interoperability and Other Performance Categories (see section VII.B.5.g.(2))	30,620	52,099	+21,479	7,655	13,025	+5,370
§§ 414.1375 and 414.1380 (Promoting Interoperability Performance Category) Data Submission (see section VII.B.5.g.(3))	74,281	53,636	-20,645	198,083	143,029	-55,054
§ 414.1360 (Improvement Activities Performance Category) Data Submission (see section VII.B.5.i	103,813	79,927	-23,886	8,651	6,661	-1,990
§ 414.1360 (Improvement Activities Performance Category) Nomination of Improvement Activities (see section VII.B.5.j	31	31	0	62	93	+31
Nomination of MVPs (see section VII.B.5.k)	0	25	+25	0	300	+300
§ 414.1430 Partial Qualifying APM Participant (QP) Election (see section VII.B.5.m)	2,022	300	-1,722	505.5	75	-430.5
§ 414.1440 Other Payer Advanced APM Identification: Payer Initiated Process	110	80	-30	1,100	800	-300

Requirement	Currently Approved Responses*	Finalized Responses	Change in Responses	Currently Approved Total Burden Hours*	Finalized Total Burden Hours	Change in Total Burden Hours
(see section VII.B.5.n.(1)						
§ 414.1395 (Physician Compare) Opt Out for Voluntary Participants (see section VII.B.5.o	10,042	3,486	-6,556	2,510.5	871.5	-1,639
SUBTOTAL OMB 0938-1314 (CMS-10621): 2021 Performance Period	**470,718**	**322,656**	**-148,062**	**2,929,735**	**1,473,132**	**-1,456,603**
SUBTOTAL OMB 0938-1314 (CMS-10621): 2022 Performance Period	**470,718**	**322,566**	**-148,152**	**2,929,735**	**1,467,201**	**-1,462,534**
§§ 414.1325 and 414.1335 Beneficiary Responses to CAHPS for MIPS Survey (see section VII.B.5.e.(8))	39,039	29,952	-9,087	8,393	6,540	-1,854
SUBTOTAL OMB 0938-1222 (CMS-10450): 2021 and 2022 Performance Periods	**39,039**	**29,952**	**-9,087**	**8,393**	**6,540**	**-1,854**
TOTAL: 2021 Performance Period	**509,757**	**352,608**	**-157,149**	**2,938,128**	**1,479,672**	**-1,458,457**
TOTAL: 2022 Performance Period	**509,757**	**352,518**	**-157,239**	**2,938,128**	**1,473,741**	**-1,464,388**

*Total Responses is equal to the number of self-nomination applications plus the number of Corrective Action Plans submitted.

Table 102 provides the reasons for changes in the estimated burden for information collections in the Quality Payment Program segment of this final rule. We have divided the reasons for our change in burden into those related to new policies and those related to adjustments in burden from continued Quality Payment Program Year 4 policies that reflect updated data and revised methods.

TABLE 102: Reasons for Change in Burden Compared to the Currently Approved CY 2020 Information Collection Burden

Quality Payment Program Table	Changes in burden due to CY 2021 Final Rule policies	Adjustments in burden from continued CY 2020 Final Rule policies due to revised methods or updated data
Section VII.B.5.c.(2): QCDR Self-Nomination and other Requirements	Increase in burden due to policy requiring targeted audits, as necessary (+5 to +10 hours per audit).	Increase in number of respondents due to use of updated data from the 2020 MIPS performance period.
Section VII.B.5.c.(3): Qualified Registry Self-Nomination and other Requirements	Increase in number of responses (+10) and burden (+ 3 hrs per response) due to current policies not previously having a burden estimate as well as the provision to require additional information in Corrective Action Plans. Increase in burden due to policy requiring targeted audits, as necessary (+5 to +10 hours per audit).	Increase in number of respondents due to use of updated data from the 2020 MIPS performance period.
Section VII.B.5.d: Open Authorization Credentialing and Token Request Process	New information collection request.	Not applicable.
Section VII.B.5.e.(4): Quality Performance Category Medicare Part B Claims Collection Type	None.	Decrease in number of respondents due to use of updated data from the 2019 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VII.B.5.e.(5): Quality Performance Category QCDR/ MIPS CQM Collection Type	(2022 Performance Period) Increase in number of respondents (+7) due to the provision to sunset the CMS Web Interface measures as a collection type/submission type.	Decrease in number of respondents due to use of updated data from the 2019 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VII.B.5.e.(6): Quality Performance Category eCQM Collection Type	(2022 Performance Period) Increase in number of respondents due to the provision to sunset the CMS Web Interface measures as a collection type/submission type.	Increase in number of respondents due to use of updated data from the 2019 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VII.B.5.e.(7): Quality Performance Category CMS Web Interface Collection Type	(2022 Performance Period) Removal of information collection due to the provision to sunset the CMS Web Interface measures as a collection type/submission type.	(2021 Performance Period) Increase in number of respondents due to use of updated data from the 2019 MIPS performance period.
Section VII.B.5.e.(8): Beneficiary Responses to CAHPS for MIPS Survey	Increase in per response burden (+ 0.2 hrs) due to the provision to add a survey-based measure on telehealth.	Decrease in number of respondents due to updated data from 2019 MIPS performance period.
Section VII.B.5.e.(9): Registration for CMS Web Interface	(2022 Performance Period) Removal of information collection due to the provision to sunset the CMS Web Interface measures as a collection type/submission type.	(2021 Performance Period) Increase in number of respondents due to use of updated data from the 2020 MIPS performance period.
Section VII.B.5.g.(2): Reweighting Applications for Promoting Interoperability and Other Performance Categories	Increase in number of respondents due to the provision to allow APM Entities to submit an extreme and uncontrollable circumstances exception application.	Increase in number of applications submitted due to updated data from the 2019 MIPS performance period.

Quality Payment Program Table	Changes in burden due to CY 2021 Final Rule policies	Adjustments in burden from continued CY 2020 Final Rule policies due to revised methods or updated data
Section VII.B.5.g.(3): Promoting Interoperability Performance Category Data Submission	None.	Decrease in number of respondents due to use of updated data from the 2019 MIPS performance period and updated QP projections for the 2021 MIPS performance period.
Section VII.B.5.i: Improvement Activities Submission	None.	Decrease in number of respondents due to use of updated data from the 2019 MIPS performance period.
Section VII.B.5.j: Nomination of Improvement Activities	Increase in per response burden (+1 hour) due to the provision to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible.	None.
Section VII.B.5.k: Nomination of MVPs	New information collection request.	Not applicable.
Section VII.B.5.m: Partial QP Election	None	Decrease in number of respondents due to updated projections for the 2021 MIPS performance period.
Section VII.B.5.n.(1): Other Payer Advanced APM Identification: Other Payer Initiated Process	None.	Decrease in number of respondents due to updated projections for the 2021 MIPS performance period.
Section VII.B.5.o: Voluntary Participants to Elect to Opt Out of Performance Data Display on Physician Compare	None.	Decrease in the number of respondents due to use of updated data from the 2019 MIPS performance period.

C. Summary of Annual Burden Estimates for Requirements

TABLE 103: Annual Requirements and Burden

Regulation Section(s) Under Title 42 of the CFR	OMB Control Number	Respondents	Total Annual Responses	Burden per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§ 424.67 (Conditions for Payment, Form CMS-855A)	0938-0685	133	133	varies	532	varies	23,598
§ 424.67 (Conditions for Payment, Form CMS-855B)	0938-1377	23	23	varies	-89	varies	-4,091
§ 423.160(a) (Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA-PD Plan)	0938-TBD	148,750	560,430	5	743,750	36.62	27,236,125
§§ 414.1325 and 414.1335, 414.1360, 414.1375, 414.1380, 414.1395, 414.1400, 414.1430, and 414.1440 (Quality Payment Program)	0938-1314	123,619	-148,152	varies	1,462,534	varies	143,134,204
§§ 414.1325 and 414.1335 (Quality Payment Program)	0938-1222	29,952	-9,087	0.22	-1,854	25.72	-47,681
TOTAL		302,477	403,347	varies	2,204,873	varies	$170,342,155

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VIII. Regulatory Impact Analysis

A. Statement of Need

This final rule would make payment and policy changes under the Medicare PFS and implements required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Achieving a Better Life Experience Act (ABLE), the Protecting Access to Medicare Act of 2014 (PAMA), section 603 of the Bipartisan Budget Act of 2015, the Consolidated Appropriations Act of 2016, the Bipartisan Budget Act of 2018, and sections 2005, 6063, and 6111 of the SUPPORT for Patients and Communities Act of 2018. This final rule would also make changes to payment policy and other related policies for Medicare Part B.

This final rule is necessary to make policy changes under Medicare fee-for-service. Therefore, we included a detailed Regulatory Impact Analysis (RIA) to assess all costs and benefits of available regulatory alternatives and explained the selection of these regulatory approaches that we believe adhere to statutory requirements and, to the extent feasible, maximize net benefits.

B. Overall Impact

We examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). An RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We estimated, as discussed in this section, that the PFS provisions included in this final rule would redistribute more than $100 million in 1 year. Therefore, we estimate that this rulemaking is ''economically significant'' as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details, see the SBA's website at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and states are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers, and suppliers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this final rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. The PFS does not reimburse for services provided by rural hospitals; the PFS pays for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits on state, local, or tribal governments or on the private sector before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This final rule will impose no mandates on state, local, or tribal governments or on the private sector.

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

Executive Order 13771, entitled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017. This final rule is expected to be an E.O. 13771 regulatory action. We estimate the rule generates $1.23 million in annualized costs in 2016 dollars, discounted at 7 percent relative to year 2016 over a perpetual time horizon. Details on the estimated costs of this rule can be found in the preceding and subsequent analyses.

We prepared the following analysis, which together with the information provided in the rest of this preamble, meets all assessment requirements. The analysis explains the rationale for and purposes of this final rule; details the costs and benefits of the rule; analyzes alternatives; and presents the measures we would use to minimize the burden on small entities. As indicated elsewhere in this final rule, we discussed a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and implementing statutory provisions. We provide information for each of the policy changes in the relevant sections of this final rule. We are unaware of any relevant federal

rules that duplicate, overlap, or conflict with this final rule. The relevant sections of this final rule contain a description of significant alternatives if applicable.

C. Changes in Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compared payment rates for CY 2020 with payment rates for CY 2021 using CY 2019 Medicare utilization. The payment impacts in this final rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and would depend on the mix of services he or she furnishes. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Laboratory Fee Schedule (CLFS).

The PFS update adjustment factor for CY 2021, as required by section 1848(d)(19) of the Act, is 0.00 percent before applying other adjustments.

To calculate the CY 2021 PFS conversion factor (CF), we multiplied the product of the current year CF and the update adjustment factor by the budget neutrality adjustment described in the preceding paragraphs. We estimate the CY 2021 PFS CF to be 32.4085 which reflects the budget neutrality adjustment under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.00 percent update adjustment factor specified under section 1848(d)(19) of the Act. We estimate the CY 2021 anesthesia CF to be 20.0547 which reflects the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE 104: Calculation of the CY 2021 PFS Conversion Factor

CY 2020 Conversion Factor		36.0896
Statutory Update Factor	0.00 percent (1.0000)	
CY 2021 RVU Budget Neutrality Adjustment	-10.20 percent (0.8980)	
CY 2021 Conversion Factor		**32.4085**

TABLE 105: Calculation of the CY 2021 Anesthesia Conversion Factor

CY 2020 National Average Anesthesia Conversion Factor		22.2016
Statutory Update Factor	0.00 percent (1.0000)	
CY 2021 RVU Budget Neutrality Adjustment	-10.20 percent (0.8980)	
CY 2021 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.59 percent (1.0059)	
CY 2021 Conversion Factor		**20.0547**

Table 106 shows the payment impact on PFS services of the policies contained final rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 106 (CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 106.

- *Column A (Specialty):* Identifies the specialty for which data are shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2019 utilization and CY 2020 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2021 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2021 impact on total allowed charges of the changes in the PE RVUs.
- *Column E (Impact of MP RVU Changes):* This column shows the estimated CY 2021 impact on total allowed charges of the changes in the MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2021 combined impact on total allowed charges of all the changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

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TABLE 106: CY 2021 PFS Estimated Impact on Total Allowed Charges by Specialty

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
ALLERGY/IMMUNOLOGY	$247	5%	4%	0%	9%
ANESTHESIOLOGY	$2,020	-6%	-1%	0%	-8%
AUDIOLOGIST	$75	-4%	-2%	0%	-6%
CARDIAC SURGERY	$266	-5%	-2%	0%	-8%
CARDIOLOGY	$6,871	1%	0%	0%	1%
CHIROPRACTOR	$765	-7%	-3%	0%	-10%
CLINICAL PSYCHOLOGIST	$832	0%	0%	0%	0%
CLINICAL SOCIAL WORKER	$857	0%	1%	0%	1%
COLON AND RECTAL SURGERY	$168	-4%	-1%	0%	-5%
CRITICAL CARE	$378	-6%	-1%	0%	-7%
DERMATOLOGY	$3,767	-1%	0%	0%	-1%
DIAGNOSTIC TESTING FACILITY	$748	-1%	-2%	0%	-3%
EMERGENCY MEDICINE	$3,077	-5%	-1%	0%	-6%
ENDOCRINOLOGY	$508	10%	5%	1%	16%
FAMILY PRACTICE	$6,020	8%	4%	0%	13%
GASTROENTEROLOGY	$1,757	-3%	-1%	0%	-4%
GENERAL PRACTICE	$412	5%	2%	0%	7%
GENERAL SURGERY	$2,057	-4%	-2%	0%	-6%
GERIATRICS	$192	1%	1%	0%	3%
HAND SURGERY	$246	-2%	-1%	0%	-3%
HEMATOLOGY/ONCOLOGY	$1,707	8%	5%	1%	14%
INDEPENDENT LABORATORY	$645	-3%	-2%	0%	-5%
INFECTIOUS DISEASE	$656	-4%	-1%	0%	-4%
INTERNAL MEDICINE	$10,730	2%	1%	0%	4%
INTERVENTIONAL PAIN MGMT	$936	3%	3%	0%	7%
INTERVENTIONAL RADIOLOGY	$499	-3%	-5%	0%	-8%
MULTISPECIALTY CLINIC/OTHER PHYS	$153	-3%	-1%	0%	-3%
NEPHROLOGY	$2,225	4%	2%	0%	6%
NEUROLOGY	$1,522	3%	2%	0%	6%
NEUROSURGERY	$811	-4%	-2%	-1%	-6%
NUCLEAR MEDICINE	$56	-5%	-3%	0%	-8%
NURSE ANES / ANES ASST	$1,321	-9%	-1%	0%	-10%
NURSE PRACTITIONER	$5,100	5%	3%	0%	7%
OBSTETRICS/GYNECOLOGY	$636	4%	3%	0%	7%
OPHTHALMOLOGY	$5,343	-4%	-2%	0%	-6%
OPTOMETRY	$1,359	-2%	-2%	0%	-4%
ORAL/MAXILLOFACIAL SURGERY	$79	-2%	-2%	0%	-4%
ORTHOPEDIC SURGERY	$3,812	-3%	-1%	0%	-4%
OTHER	$48	-3%	-2%	0%	-5%
OTOLARNGOLOGY	$1,271	4%	3%	0%	7%
PATHOLOGY	$1,265	-5%	-4%	0%	-9%
PEDIATRICS	$67	4%	2%	0%	6%
PHYSICAL MEDICINE	$1,164	-3%	0%	0%	-3%
PHYSICAL/OCCUPATIONAL THERAPY	$4,973	-4%	-4%	0%	-9%
PHYSICIAN ASSISTANT	$2,901	5%	2%	0%	8%
PLASTIC SURGERY	$382	-4%	-3%	0%	-7%
PODIATRY	$2,133	-1%	0%	0%	-1%
PORTABLE X-RAY SUPPLIER	$95	-2%	-4%	0%	-6%
PSYCHIATRY	$1,112	4%	3%	0%	7%
PULMONARY DISEASE	$1,654	0%	0%	0%	1%
RADIATION ONCOLOGY AND RADIATION	$1,809	-3%	-3%	0%	-5%

(A) Specialty	(B) Allowed Charges (mil)	(C) Impact of Work RVU Changes	(D) Impact of PE RVU Changes	(E) Impact of MP RVU Changes	(F) Combined Impact
THERAPY CENTERS					
RADIOLOGY	$5,275	-6%	-4%	0%	-10%
RHEUMATOLOGY	$548	10%	5%	1%	15%
THORACIC SURGERY	$352	-5%	-2%	0%	-8%
UROLOGY	$1,810	4%	4%	0%	8%
VASCULAR SURGERY	$1,293	-2%	-4%	0%	-6%
TOTAL	**$97,008**	**0%**	**0%**	**0%**	**0%**

* Column F may not equal the sum of columns C, D, and E due to rounding.

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2. CY 2021 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The estimated impacts for some specialties, including endocrinology, rheumatology, family practice, and hematology/oncology reflect increases relative to other physician specialties. These increases can largely be attributed to previously finalized policies for increases in valuation for office/outpatient E/M visits which constitute nearly 20 percent of total spending under the PFS. These increases are also due to increases in value for particular services following the recommendations from the American Medical Association (AMA)'s Relative Value Scale Update Committee (RUC) and CMS review, increased payments as a result of finalized updates to supply and equipment pricing, and the continuing implementation of the adjustment to indirect PE allocation for some office-based services. For nephrologists, the increase in the valuations of the ESRD monthly capitation payments that have office/outpatient E/M visits explicitly included in their valuations result in estimated impacts of +6 percent. For clinical social workers and clinical psychologists, to the increase in the valuations for certain behavioral health services that are analogous to office/outpatient E/M visits result in estimated impacts of 0 to 1 percent.

The estimated impacts for several specialties, including radiology, nurse anesthetists, pathology, and cardiac surgery reflect decreases in payments relative to payment to other physician specialties which are largely the result of the redistributive effects of previously finalized changes to the office/outpatient E/M visits taking effect in 2021. These decreases are also due to the revaluation of individual procedures reviewed by the AMA's RUC and CMS, as well as decreased payments as a result of continuing implementation of the previously finalized updates to supply and equipment pricing. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased in over several years. For the physical/occupational therapy specialty, estimated impacts of -9 percent reflect increased valuations for therapy evaluation services that are analogous to office/outpatient E/M visits. However, therapy evaluation services do not account for a large portion of allowed charges for these specialties.

For emergency medicine practitioners, estimated impacts of -6 percent reflect a 2 percent gain as a result of increased valuations to emergency department visits using specialty society recommendations to maintain relativity with office/outpatient E/M visits. However, the magnitude of the office/outpatient E/M visit valuations are dampening the effect of increased valuations for the emergency department (ED) visits. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the CLFS. As a result, the estimated 5 percent decrease for CY 2021 is only applicable to approximately 17 percent of the Medicare payment to these entities.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table 106), including comments received in response to the rates. We remind stakeholders that although the estimated impacts are displayed at the specialty level, typically the changes are driven by the valuation of a relatively small number of new and/or potentially misvalued codes. The percentages in Table 106 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty, and compared to the same summed total from the previous calendar year. Therefore, they are averages, and may not necessarily be representative of what is happening to the particular services furnished by a single practitioner within any given specialty.

b. Impact

Column F of Table 106 displays the estimated CY 2021 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high volume procedures is available under ''downloads'' on the CY 2021 PFS final rule website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*. We selected these procedures for sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

We received public comments about the impacts of this provision. The following is a summary of the comments we received and our response.

Comment: In general, commenters from physician specialties who saw projected increases related to our previously finalized revaluation of the office/outpatient E/M code set, our implementation of HCPCS code G2211, and our revaluations of services analogous to office/outpatient E/Ms

were supportive, while those commenters from physician specialties who projected decreases objected. Many commenters expressed concern with the budget neutrality adjustments associated with implementing our previously finalized revaluation of the office/outpatient E/M codes, particularly for those specialties who do not bill for office/outpatient E/M visits.

Response: While we understand the concerns articulated by commenters, our approach to making the required budget neutrality adjustment to account for changes in expenditures resulting from changes to RVUs, including those for the office/outpatient E/M code set and other similar services, is consistent with the approach we have applied to achieve budget neutrality in the past in accordance with the requirements of the statute. The statutory waiver authorities available to the Secretary following a public health emergency declaration, which are largely established in section 1135 of the Act, do not include waiver authority that would allow for implementation of changes to the PFS outside of the budget neutrality requirements in statute. The changes we make to RVUs are directed at setting appropriate resource-based relative values in accordance with section 1848 of the Act, and any increases or decreases in estimated payments associated with our finalized policies are purely a result of our longstanding budget neutrality process.

Comment: Several commenters suggested that the Secretary use waiver authority in response to the PHE for COVID–19 to implement the revaluations to the office/outpatient E/M visits, analogous services, and HCPCS code G2211 without application of the budget neutrality adjustment. Several other commenters requested that CMS exempt specialties that do not predominantly bill for office/outpatient E/M services from the budget neutrality adjustment.

Response: While we understand the concerns articulated by the commenters, we reiterate that section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality. The Secretary's waiver authority pursuant to the public health emergency declaration for COVID–19 does not extend to authorize changes to the PFS outside of budget neutrality. Additionally, section 1848 of the Act does not grant the Secretary the authority to exempt categories of physicians or practitioners from the budget neutrality adjustments.

Comment: Some commenters requested that CMS provide additional analysis on the potential impact of our finalized policies on small businesses.

Response: We appreciate the interest from commenters and the request that we provide additional analysis on the potential impact of our finalized policies on small businesses. Our discussion of the potential impacts complies with RFA requirements regarding significant impact on a substantial number of small entities. Our longstanding policy for our impacts discussion is to provide analysis at the level of certain specialties, as identified in the specialty information captured in our Medicare provider enrollment files. We would note that the lack of granular, national and publicly available data that could be used to identify variability between localities, business types, and the specific mixture of Medicare/non-Medicare payment for a given business makes it difficult to project impacts on small businesses using our standard process.

D. Effect of Changes Related to Telehealth Services

As discussed in section II.F. of this final rule, we are adding nine new codes to the list of Medicare telehealth services list for CY 2021. These codes are:

- Group Psychotherapy (CPT 90853)
- Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99334–99335)
- Home Visits, Established Patient (CPT 99347–99348)
- Cognitive Assessment and Care Planning Services (CPT 99483)
- Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS G2211)
- Prolonged Services (HCPCS G2212)
- Psychological and Neuropsychological Testing (CPT 96121)

We are also adding the following services to the list of Medicare telehealth services provisionally on a category 3 basis:

- Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99336–99337)
- Home Visits, Established Patient (CPT 99349–99350)
- Emergency Department Visits, Levels 1–5 (CPT 99281–99285)
- Nursing facilities discharge day management (CPT 99315–99316)
- Psychological and Neuropsychological Testing (CPT 96130–96133; CPT 96136–96139)
- Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161–97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521–92524, 92507)
- Hospital discharge day management (CPT 99238–99239)
- Inpatient Neonatal and Pediatric Critical Care, Subsequent (CPT 99469, 99472, 99476)
- Continuing Neonatal Intensive Care Services (CPT 99478–99480)
- Critical Care Services (CPT 99291–99292)
- End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962)
- Subsequent Observation and Observation Discharge Day Management (CPT 99217; CPT 99224–99226)

Although we expect these changes to have the potential to increase access to care in rural areas, based on recent telehealth utilization of services already on the list, including services similar to the additions, we estimate there will only be a negligible impact on PFS expenditures from these additions. For example, services already on the list of permanent telehealth services are furnished via telehealth, on average, less than 0.1 percent of the time they are reported overall. The statutory payment requirements for Medicare telehealth services under section 1834(m) of the Act, such as the originating site requirements related to geographic location and site of service, limit increases in utilization outside of the PHE for the COVID–19 pandemic; however, we believe there is value in allowing physicians to furnish these additional services via telehealth, and for patients to receive broader access to this care through telehealth. Additionally, for services added to the Medicare telehealth list on a Category 3 basis, outside of the circumstances of the PHE for COVID–19, all of the statutory restrictions will also apply to these services. Even with the addition of the category 3 services for an additional year, we do not anticipate any significant increase in utilization after the PHE for COVID-ends. We note that due to flexibilities implemented during the PHE for the COVID–19 pandemic, particularly waivers of the statutory geographic and site-of-service restrictions, has led to increased utilization of telehealth services; [149]

[149] *https://aspe.hhs.gov/pdf-report/medicare-beneficiary-use-telehealth, https://aspe.hhs.gov/system/files/pdf/264071/Medicare-FFS-Spending-Utilization.pdf.*

however, we do not believe we have sufficient data to draw any further conclusions. CMS will need to conduct additional analyses once there are sufficient data such as a full year's worth of claims that will allow us to consider the effects of the PHE on utilization in the context of the annual/seasonal variations observed in the claims data that exist from one year to the next. Such analysis would inform CMS options for adopting any flexibilities on a permanent basis, as allowed by Medicare statute outside of the circumstances of the PHE. This information would also be taken into consideration for future ratesetting under the PFS.

E. Effect of Changes Related to Scopes of Practice

As discussed in section II.G. Scopes of Practice for PFS Services, of this final rule, we will allow certain NPPs to supervise diagnostic tests, which would authorize NPs, CNSs, PAs, CNMs, and CRNAs to provide the appropriate level of supervision assigned to diagnostic tests, to the extent authorized under State law and scope of practice. As for all services they furnish, in accordance with statute, the NP, CNS or PA necessarily would be working either under physician supervision or in collaboration with a physician. This flexibility may increase the capacity and availability of practitioners who can supervise diagnostic tests, which would alleviate some of the demand on physicians as the only source to perform this particular function.

We solicited comment on state scope of practice rules and they extent to which they specified supervision requirements for the supervision of diagnostic tests. Some commenters provided information on specific tests and thoughts on what practitioners could supervise such tests, these commenters provided information indicating that psychological and neuropsychological diagnostic tests are not within the scope of practice of the proposed NPPs, and require special training only available to psychologists and physicians. While this information provides some context to our policy discussion, overall, we have not located national detailed information indicating the degree to which NPP scope of practice includes supervision of auxiliary staff, especially for the subset of services that are diagnostic tests and note that here is a wide range of diagnostic tests, from a simple strep throat swab to more sophisticated and/or invasive tests such as X-rays and cardiology procedures. We would need to understand the scope of practice for many types of auxiliary staff (some of whom are not licensed) who could potentially provide these tests under the supervision of an NPP, including RNs, LPNs, medical assistants, radiologic technicians, and many others. However, as discussed earlier in this rule, our intent regarding this supervision flexibility is to allow NPPs with separate benefit categories under Medicare law to supervise the performance of diagnostic tests, regardless of the specific category of diagnostic tests, only to the extent their scope of practice and State laws authorize them to do so.

To the extent practice patterns change, there could be induced utilization that would increase costs, but this might be offset by reduced payment rates because direct payment to NPPs is at a lower rate than payment to physicians.

An alternative in the case of the provision concerning supervision of diagnostic tests was to maintain the status quo. That is, we noted that we could maintain the basic rule under § 410.32(b)(1) that allows only physicians as defined under Medicare law to supervise the performance of diagnostic tests. In that case, the pool of practitioners who could supervise diagnostic tests would remain at current levels and certain NPPs would be limited under Medicare from practicing to the full extent allowed by their state license and scope of practice.

We are finalizing the proposal to allow a physical therapist (PT) or occupational therapist (OT)—whether they are an enrolled private practice PT or OT or a therapist working for an institutional provider—who establishes a therapy maintenance program to assign the duties to a PTA or OTA, as clinically appropriate, to perform maintenance therapy services. We added this as a flexibility under the May 8th COVID–19 IFC for the duration of the PHE for COVID–19 based on respondents' feedback on scope of practice following the President's E.O. 13890. Our current requirements for maintenance therapy services restrict a PT's/OT's ability to delegate the performance of maintenance therapy services to PTAs and OTAs which is counter to the therapist's ability to use PTAs/OTAs in furnishing rehabilitative outpatient physical or occupational therapy services. In the CY 2021 PFS proposed rule (85 FR 50147), we proposed to allow PTs/OTs to oversee and delegate to a PTA or OTA the performance of physical and occupational therapy services in the same way, whether the therapy services are part of a plan of care geared toward rehabilitative or maintenance therapy. While therapy services furnished by PTs/OTs and their PTAs/OTAs are separately payable when they occur in different time slots (that is, if the PT/PTA or OT/OTA work together at the same time in furnishing a service to the patient, only one service is payable), we noted that we did not believe that there would be an increase in utilization since it is of no consequence whether the PTA/OTA is furnishing the service as rehabilitative or maintenance therapy. Additionally, we note that beginning January 1, 2022, payment for services furnished in whole or in part by a PTA/OTA (when the part by the PTA/OTA separate from the part of furnished by the PT/OT exceeds 10 percent of the service) will be paid at a lower rate (85 percent of the PFS fee schedule amount) which could offset any nominal increase in service volume. The alternative option—maintaining the status quo to require the PT/OT to personally furnish all maintenance therapy services, would not address the mandates established in E.O. 13890. Currently, in SNF and home health settings when payment for therapy is made under Part A, maintenance therapy can be furnished by a PT/OT or delegated to be performed by a PTA/OTA, and this provision would permit this to occur in all settings when therapy is paid under Part B.

F. Effect of Changes to Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088)

As discussed in section II.H. of this final rule, Valuation of Specific Codes, we are expanding the bundled payments described by HCPCS codes G2086, G2087, and G2088, finalized in the CY 2020 PFS final rule (84 FR 62673) to be inclusive of all SUDs. As noted in the CY 2020 PFS final rule (84 FR 62673), if a patient's treatment involves MAT, this bundled payment would not include payment for the medication itself. Billing and payment for medications under Medicare Part B or Part D would remain unchanged. We note that payment for the codes would be budget neutral under the PFS and therefore have no cost impact on PFS spending; however, this policy may have impacts on billing practices and services provided.

Currently, the codes most frequently used when billing for treatment of SUD include the E/M visit codes, psychotherapy codes, SBIRT codes, and potentially the Behavioral Health Integration codes. HCPCS codes G2086–G2088 offer a bundled payment that would allow a more streamlined

approach to billing in cases where all of the services described in the code descriptors are furnished. We note that these codes provide an option for billing, but are not required; therefore, in cases where only select services are being furnished, practitioners may continue to bill for the code that most accurately describes the service that was furnished, which could be, for example, an E/M visit code.

G. Effect of Modifications to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

Section 2005 of the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act established a new Medicare Part B benefit for OUD treatment services furnished by OTPs on or after January 1, 2020. As part of CY 2020 PFS rulemaking, we implemented coverage requirements, created new coding to describe bundled episodes of care for the treatment of OUD, and established payment methodologies to determine the payment amounts for the drug and non-drug components of an episode of care.

For CY 2021, we are creating two new add-on codes, one add-on code for nasal naloxone and another add-on code for injectable naloxone. Both add-on codes include a non-drug component for overdose education furnished in conjunction with naloxone. We are pricing nasal naloxone based upon the methodology set forth in section 1847A of the Act, except that the payment amount shall be ASP + 0. The price being finalized for the nasal naloxone add-on code is $92.13, which includes a payment of $2.53 for overdose education. We are contractor-pricing the injectable naloxone and will also include a payment of $2.53 for overdose education. We are limiting Medicare payment to OTPs for naloxone to one add-on code (HCPCS code G2215 or G2216) every 30 days, however, we will allow exceptions to this limit in the case where the beneficiary overdoses and uses the initial supply of naloxone dispensed by the OTP, to the extent that it is medically reasonable and necessary to furnish additional naloxone.

The estimated net Part B cost impact of the add-on codes for naloxone for CY 2021 is $0.5 million. The estimated net Part B 10-year impact is $5.6 million. This estimate is based on several assumptions. First, commenters noted that nasal naloxone is the most common formulation given to patients in an OTP and the price is being finalized is $92.13. This cost is to be updated to reflect changes in the average sales price (ASP); however, since future ASP updates are not available, the Medicare Economic Index (MEI) was used as a proxy. Based on partial 2020 utilization of the OTP benefit through September, roughly 20,000 beneficiaries received treatment at an OTP at some point during that time. We assumed that this would reach 25,000 by the end of 2020, and growth in future years would be consistent with projected growth in Part B fee-for-service enrollment. We assumed that beneficiaries who are provided naloxone would receive at least one supply of nasal naloxone as a standard part of the program because they are likely to be at risk for an overdose. A much smaller portion would receive a second supply, since it would only be provided if the first supply has been used. We assumed that approximately 1.1 doses would be provided per beneficiary. This figure is based on an August 2020 OIG report regarding opioid use under Medicare Part D, and it represents the average number of prescriptions per person receiving naloxone between 2016 and 2019 (see Exhibit B–2 on page 14).[150] We assumed that roughly 25 percent of beneficiaries receiving treatment OTPs would be provided with naloxone, because they may already have it from another source, and some OTPs may not have it available. The estimate also took into account that this benefit is not subject to beneficiary cost sharing. Additionally, any change to FFS benefits has an associated impact on payments to Medicare Advantage (MA) plans, so an adjustment was made to reflect this based on the projected distribution of spending in each year. Based on current projections, payments to MA plans represent roughly 46 percent of total Part B spending in 2022 this share and is expected to grow to almost 50 percent by 2030. This estimate also takes into account a premium offset which represents the impact on the Medicare program due to the change in the Part B premium as a result of the new add-on payment to OTPs for naloxone. In other words, since benefit spending is higher, the Part B premium will also be higher, which partially offsets the impact on benefit spending. The Part B FFS enrollment projections and MEI assumptions are based on the President's Fiscal Year 2021 Budget baseline that was released in February of 2020.

We believe that the benefits associated with establishing payment for naloxone and overdose education in the OTP setting justify the cost of the provision. As noted in section II.I. of this final rule, Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs), U.S. Surgeon General Jerome M. Adams, M.D., M.P.H. released a public health advisory stating that, ''Research shows that when naloxone and overdose education are available to community members, overdose deaths decrease in those communities. Therefore, increasing the availability and targeted distribution of naloxone is a critical component of our efforts to reduce opioid-related overdose deaths and, when combined with the availability of effective treatment, to ending the opioid epidemic.'' [151] We are adding naloxone and overdose education furnished in conjunction with naloxone to the definition of OUD treatment services in order to increase access to this important emergency treatment and to allow OTPs to be paid under Medicare for dispensing naloxone to Medicare beneficiaries who are receiving other OUD treatment services from the OTP. We believe allowing beneficiaries to access this important emergency treatment at the OTP may help decrease barriers to access because there are no copayments for services furnished by OTPs and beneficiaries will not need to visit a separate provider to access naloxone.

H. Other Provisions of the Regulation

1. Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions

In section III.A. of this final rule, we discuss statutory revisions to the data reporting period and phase-in of payment reductions. In accordance with section 105(a) of the FCAA and section 3718 of the CARES Act, we are making certain conforming changes to the data reporting and payment requirements in our regulations at part 414, subpart G. Specifically, for clinical diagnostic laboratory tests (CDLTs) that are not advanced diagnostic laboratory tests (ADLTs), we are revising § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017 and is required every 3 years beginning January 2022. This revision delays the next data reporting period under the CLFS by 2 years, that is, it will require the next data reporting during the period of January 1, 2022 through March 31, 2022. Subsequently, the next private payor

[150] *https://oig.hhs.gov/oei/reports/OEI-02-20-00320.pdf.*

[151] *https://www.hhs.gov/surgeongeneral/priorities/opioids-and-addiction/naloxone-advisory/index.html.*

rate-based CLFS update will be effective January 1, 2023 instead of January 1, 2021. In addition, we are making conforming changes to our requirements for the phase-in of payment reductions to reflect the CARES Act amendments. Specifically, we are revising § 414.507(d) to indicate that for CY 2021, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2020, and for CYs 2022 through 2024, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates, have changed since the first data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017 through March 31, 2017). In addition, as discussed in section III.A. of this final rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the conforming regulatory changes to the data reporting period would delay using updated private payor rate data and data reported by hospital outreach laboratories to set revised CLFS payment rates.

Due to the unforeseen changes in private payor rates, inclusion of hospital outreach laboratory data, and unpredictable nature of test volumes and their impact on calculating updated weighted medians private payor rates, we are uncertain as to whether the delay in data reporting would result in a measurable budgetary impact. In other words, in order to comprehend the impact of delayed reporting and subsequent implementation of updated CLFS rates, we would need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the delay in data reporting after collecting actual updated applicable information from applicable laboratories, including the collection of private payor rate data from applicable hospital outreach laboratories, and calculate the updated weighted medians of private payor rates.

With regard to the conforming changes to our requirements for the phase-in of payment reductions, we note that this revision shifts the 15 percent limitation on payment reductions from CYs 2021 through 2023, to CYs 2022 through 2024. Therefore, we believe this conforming regulatory amendment to the phase-in of payment reductions in § 414.507(d) is budget neutral for scoring purposes.

2. OTP Provider Enrollment Regulation Updates for Institutional Claim Submissions

We stated in section VII. of this final rule that:

- Section 424.67(b)(2) requires newly enrolling OTPs to pay an application fee at the time of enrollment under § 424.514.
- 300 currently enrolled OTPs would change their enrollment from a Form CMS–855B to a Form CMS–855A. We project that all such changes will occur in CY 2021.
- 10 OTPs that enroll using the Form CMS–855A would later change their enrollment to a Form CMS–855B. We project that these changes will occur in CY 2022 and CY 2023 (roughly 5 changes per year).

These 310 OTPs would be required to pay an application fee because said change to a Form CMS–855A or Form CMS–855B enrollment would constitute a new/initial enrollment.

The application fees for each of the past 3 calendar years (CY) were or are $569 (CY 2018), $586, (CY 2019), and $595 (CY 2020). Consistent with § 424.514, the differing fee amounts are predicated on changes/increases in the Consumer Price Index (CPI) for all urban consumers (all items; United State city average, CPI–U) for the 12-month period ending on June 30 of the previous year. As stated in a notice published in the November 23, 2020 **Federal Register** titled ''Medicare, Medicaid, and Children's Health Insurance Programs; Provider Enrollment Application Fee Amount for Calendar Year 2021'' (85 FR 74724), the fee amount for CY 2021 will be $599. This results in a total application fee cost for OTP changes to a Form CMS–855A enrollment of $179,700 ($599 × 300 OTPs).

Although we cannot predict changes to the CPI beyond CY 2021, the fee amounts between 2019 and 2021 increased by an average of $6 per year. We believe this is a reasonable barometer with which to estimate (strictly for projecting the total application fee costs for the 10 OTPs that we believe will switch to a Form CMS–855B enrollment) the fees for CY 2022 and CY 2023. Accordingly, we project a fee of $605 in CY 2022 and $611 in CY 2023. This results in a total application fee cost of $3,025 ($605 × 5 OTPs) in CY 2022 and $3,055 in CY 2023 ($611 × 5 OTPs). Over the next 3 years, therefore, the total application fee cost will be $185,780 ($179,700 + $3,025 + $3,055).

We received no comments on our application fee estimates.

3. Payment for Principal Care Management (PCM) Services in Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

After reviewing the PFS, FQHC, and RHC historical spending, including the first quarter of calendar year 2020 spending for the new principal care management codes under the PFS, we estimate the addition of these codes (G2064 and G2065) to G0511 would have a negligible impact on Medicare spending.

4. Changes to the Federally Qualified Health Center Prospective Payment System (FQHC PPS) for CY 2021: Rebasing and Revising of the FQHC Market Basket

The CY 2021 FQHC market basket and multi-factor productivity adjustment is 0.1 percentage point higher under the 2017-based FQHC market basket (1.7 percent) compared to under the 2013-based market basket (1.6 percent). Therefore, the economic impact of finalizing the FQHC market basket rebasing and revising for CY 2021 is approximately $1M and we consider this impact to be negligible. We determined this amount by applying a factor of 0.001 to the FQHC baseline, which was approximately $1,100 million in calendar year 2019. Over the next 10 years the rebasing methodology results in, at most, a difference of 0.1 percent compared to the prior methodology but it is not always higher. The difference in the payment updates is projected to be higher in the next 2 years but then lower or the same beyond that. Therefore, this initial negligible cost decreases over time and overall estimated spending will likely be unaffected.

5. Comprehensive Screenings for Seniors: Section 2002 of the Substance Use-Disorder Prevention That Promote Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)

We are implementing section 2002 of the Support Act by adding regulatory language to the existing Initial Preventive Physical Examination (IPPE) and Annual Wellness Visit (AWV) regulations to explicitly include elements regarding screening for potential substance use disorders and a review of current opioid prescriptions. We expect the new regulatory elements to add minimal burden since review of medical and social history, risk factor

identification, education, counseling, and referrals are already fundamental parts of the IPPE and AWV. Standard documentation in the medical record that these services were furnished would not change based on these new requirements. We note that in section VIII.C.2.a. of this RIA, we discuss the increase in payment for E/M visits in general. Accordingly, the increase in payment for E/M visits applies to the IPPE and AWV and the impact to 2021 expenditures is included in section VIII.C.2.a. of this RIA.

6. Medicaid Promoting Interoperability Program Requirements for Eligible Professionals (EPs)

In the Medicaid Promoting Interoperability Program, to keep electronic clinical quality measure (eCQM) specifications current and minimize complexity, we are aligning the eCQMs available for Medicaid EPs in 2021 with those available for MIPS eligible clinicians for the CY 2021 performance period. We anticipate that this alignment will reduce burden for Medicaid EPs by aligning the requirements for multiple reporting programs, and that the system changes required for EPs to implement this change will not be significant, as many EPs are expected to report eCQMs to meet the quality performance category of MIPS, and therefore, should be prepared to report on those eCQMs for 2021. Not implementing this alignment could lead to increased burden because EPs might have to report on different eCQMs for the Medicaid Promoting Interoperability Program, if they opt to report on newly added eCQMs for MIPS. We expect that this policy will have only a minimal impact on states, by requiring minor adjustments to state systems for 2021 to maintain current eCQM lists and specifications. Based on a sampling of funding requests, each state typically spends, on average, approximately $670,000 per year to operate its Medicaid Promoting Interoperability Program attestation system for EPs. Only a small fraction of those costs is typically attributable to updating eCQM specifications. We estimate that the costs for updating eCQM specifications under the policy will be approximately $100,000 per state. State expenditures to make any systems changes that will be required as a result of the provision will most likely be eligible for 90 percent federal financial participation.

For 2021, we are requiring that Medicaid EPs report on any six eCQMs that are relevant to the EP's scope of practice, including at least one outcome measure, or if no applicable outcome measure is available or relevant, at least one high priority measure, regardless of whether they report via attestation or electronically. This policy will generally align with the MIPS data submission requirement for eligible clinicians using the eCQM collection type for the quality performance category, which is established in § 414.1335(a)(1). If no outcome or high priority measure is relevant to a Medicaid EP's scope of practice, he or she could report on any six eCQMs that are relevant. This policy will be a continuation of our policy for 2020 and we believe it will not create new burden for EPs or states.

7. Medicare Shared Savings Program

a. Modifications to the Shared Savings Program Quality Reporting Requirements and Quality Performance Standard for Performance Year 2021 and Subsequent Performance Years

In section III.G.1.c. of this final rule, we are finalizing a modified version of our original proposal to allow for a gradual phase-in of the increase in the level of quality performance that would be required for all ACOs to meet the Shared Savings Program quality performance standard and the retention of the CMS Web Interface collection type for performance year 2021. The quality performance standard is the minimum performance level ACOs must achieve in order to share in any savings earned, avoid maximum losses under certain payment tracks, and avoid quality-related compliance actions.

Specifically, we are finalizing that an ACO would meet the quality performance standard if:

- For performance years 2021 and 2022, the ACO achieves a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores; and
- For performance year 2023 and subsequent performance years, the ACO achieves a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores.

We are also finalizing our proposal to exclude entities/providers eligible for facility-based scoring from the determination of the overall MIPS Quality performance category score because facility-based scoring is determined using the Hospital Value Based Purchasing (HVBP) Total Performance Score (TPS), which includes quality and cost. Please refer to section III.G.1.c. of this final rule for a detailed discussion of the policies used to inform the impacts for the change to the quality performance standard.

Our analysis of quality performance data reported by ACOs for performance years starting during 2019 indicates that the methodological changes in ACO quality scoring will reduce the mean ACO quality score relative to recent historical performance years where ACO quality performance scores have averaged 90 percent or more. Despite an expectation for a decreasing score for most ACOs and potentially a slight increase in the fraction of ACOs failing to achieve the minimum threshold for qualifying for potential shared savings, the provision is estimated to marginally increase overall shared savings payments to ACOs initially because ACOs that meet the quality performance standard will be eligible to share in savings at the maximum sharing rate, rather than subject to variable sharing rates based on their quality performance score. Our best estimate is that shared savings payments to ACOs will increase by $60 million for the 2021 performance year because of these changes, representing an increase in shared savings payments of only about 3 percent of projected total gross measured savings for ACOs earning shared savings for that year. The corresponding estimated increase in payments to ACOs would slightly decrease to $40 million in 2022 because, beginning that year, ACOs would no longer have the option of utilizing the Web Interface reporting option, which is projected to be favorable for most ACOs. Then for 2023 when the quality performance standard will increase to the 40th percentile across all MIPS Quality performance category scores, assuming the distribution of ACO quality performance scores remains static from the 2019 base data, we project roughly 1-in-5 ACOs could fall below the 40th percentile and therefore shared savings payments to ACOs would decrease by approximately $100 million for that performance year. In total, these estimates sum to roughly a budget neutral outcome across the 3-year performance years covering 2021–2023.

These estimates (and in particular the estimated $100 million reduction in shared savings payments in 2023) could differ if the universe of MIPS Quality performance category scores improves relative to ACOs' quality performance scores, or alternatively if ACOs, particularly ACOs at risk of failing, respond to the methodology change by boosting their performance, especially by 2023 when the quality performance standard is to be increased from the 30th to the 40th percentile. Taking into account such possibilities indicates the

combined 3-year impact of the changes to the quality performance standard could differ from the budget neutral projection by up to +/− $200 million. Recognizing the uncertainty regarding these estimates, we will continue to monitor emerging performance to determine the impact of a measured increase to the quality performance standard and may revisit the policy in a future rulemaking in order to promote an attainable standard and degree of improvement based on initial performance under the new methodology.

b. Modifications to the Shared Savings Program Beneficiary Assignment Methodology and Repayment Mechanism Requirements

We do not anticipate a material aggregate impact for the other changes we are finalizing related to the Shared Savings Program, specifically the changes related to repayment mechanism requirements (section III.G.3. of this final rule) and the assignment methodology (section III.G.2. of this final rule); however, the assignment methodology provisions may have differing effects on a subset of participating ACOs, for example by changing the competing ACO to which a beneficiary ultimately is assigned, for a small subset of beneficiaries.

c. Finalization of Shared Savings Program Policies Established in the May 8th COVID–19 IFC

As discussed in section III.G.5 of this final rule, in the May 8th COVID–19 IFC we modified Shared Savings Program policies including to forgo the 2021 application cycle and allow eligible ACOs to elect a 1-year extension of their agreement period; allow eligible ACOs to temporarily freeze their position along the BASIC track's glide path for PY 2021; and adjust certain program calculations to remove Parts A and B expenditures for episodes of care for treatment of COVID–19; and expand the definition of primary care services used in determining beneficiary assignment to include telehealth codes for virtual check-ins, e-visits, and telephonic communication. We also clarified the applicability of the program's extreme and uncontrollable circumstances policy to mitigate shared losses for the period of the PHE for COVID–19, beginning in January 2020 and for duration of the PHE for COVID–19. We are finalizing the Shared Savings Program's May 8th COVID–19 IFC provisions through this final rule with the following modifications. As discussed in section III.G.5.d. of this final rule, we are revising the regulation at § 425.611(b)(1)(ii) to align the timeframe for identifying discharges for acute care inpatient services for treatment of COVID–19 furnished by non-IPPS providers with the timeframe for the 20 percent adjustment to payments under the IPPS for individuals diagnosed with COVID–19 (which applies to discharges occurring during the PHE for COVID–19), for purposes of identifying episodes of care for treatment of COVID–19. As discussed in section III.G.5.e.(3) of this final rule, we are revising the regulation at § 425.400(c)(2) to specify that the additional primary care service codes will be used in conducting beneficiary assignment when the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the PHE for COVID–19 defined in § 400.200. We are also adding a new provision at § 425.400(c)(2)(ii) to specify that we will apply the additional primary care service codes, specified in § 425.400(c)(2)(i) (as renumbered), to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) of the PHE for COVID–19 as defined in § 400.200.

In total, the changes to the Shared Savings Program described in the May 8th COVID–19 IFC were estimated to reduce program spending by $1.43 billion over the 2020 to 2025 period (ranging from a reduction of $790 million to $2.12 billion), with most of the reduction ($1.11 billion) attributable to performance year 2020. We do not anticipate a material aggregate impact from the aforementioned revisions to § 425.611(b)(1)(ii), specified in section III.G.5.d. of this final rule, and § 425.400(c)(2), specified in section III.G.5.e.(3) of this final rule.

8. Modifications to Medicare Shared Savings Program Quality Reporting Requirements for Performance Year 2020 and Finalization of Shared Savings Program Policies Established in the March 31st COVID–19 IFC

As discussed in section III.I.1. of this final rule, we are finalizing our proposal to waive the CAHPS for ACOs reporting requirement for performance year 2020 and will assign automatic full credit to all ACOs for the CAHPS for ACOs survey measures. Based on recent ACO performance on the CAHPS measures, we estimate moving to a 100 percent score for the CAHPS measures will increase the final quality score for the group of all non-new ACOs by roughly 2 percentage points. This would translate to an estimated increase in total shared savings payments to ACOs of approximately $20 million.

As discussed in section III.I.3. of this final rule, in the March 31st COVID–19 IFC, we modified the extreme and uncontrollable circumstances policy to eliminate the restriction that the policy applies only if the quality reporting period is not extended. We are finalizing this change without modification in this final rule. The total impact of extending the extreme and uncontrollable circumstances policy despite the extension of the quality reporting period for 2019 is estimated to be $20 million with a range of uncertainty in such estimate spanning $15 million to $25 million.

9. Removal of Selected National Coverage Determinations

We proposed to remove nine older NCDs that no longer contain clinically pertinent and current information or that involve items or services that are used infrequently by beneficiaries. We are removing six of the nine proposed. Generally, proactively removing obsolete or unnecessary NCDs removes barriers to innovation and reduces burden for stakeholders and CMS. The NCDs fall into two impact categories. First, eliminating an NCD for items and services that were previously covered means that the item or service will no longer be automatically covered by Medicare. Instead, the coverage determinations for those items and services will be made by Medicare Administrative Contractors (MACs). Second, if the previous NCD barred coverage for an item or service under title XVIII, MACs would now be able to cover the item or service if the MAC determines that such action is appropriate under the statute. We believe that allowing local contractor flexibility in these cases better serves the needs of the Medicare program and its beneficiaries since we believe the future utilization for items and services within these policies will be limited, each affecting less than one percent of the Medicare FFS population.

For the three NCDs that are going from limited coverage to MAC discretion, claims data from 2019 show that less than one percent of the Medicare population are affected. Specifically, CMS provides limited coverage for specific conditions under NCD 20.5, Extracorporeal Immunoadsorption (ECI) using Protein A Columns, where CMS paid 1,918 Medicare FFS claims for 118 beneficiaries for a total expenditure of $3,757,178.36. Under NCD 100.9, Implantation of Gastroesophageal Reflux Device, CMS received no claims in

2019. CMS provides coverage for FDA approved labeled indications under NCD 110.19, Abarelix, and no claims were submitted in 2019 because the device is no longer marketed. If under MAC discretion, these items and services continue to be covered, we estimate there will be de minimis change to 2021 expenditures, compared to 2019. However, we note that MAC discretion may result in the MACs determining that in particular instances of these items and services, a noncoverage decision may be appropriate for the patient, which could result in a decrease in 2021 expenditures, compared to 2019. The three NCDs that we are not removing in this final rule, were also in this limited coverage category explained above. The current NCDs will continue to apply and we estimate there will be little significant difference in expenditures from 2019 to 2021. NCD 110.14, Apheresis (Therapeutic Pheresis), CMS paid 84,539 Medicare FFS claims for 10,641 beneficiaries for a total expenditure of $77,486,916.37. Under NCD 190.1, Histocompatability Testing, CMS paid 4,986 Medicare FFS claims for 2,525 beneficiaries for a total expenditure of $206,085.04. For NCD 190.3, Cytogenetic Studies, CMS paid 163,522 Medicare FFS claims for 145,212 beneficiaries for a total expenditure of $18,997,807.17.

For the three non-coverage NCDs we are removing, we would not expect to find historical claims data. We broadly noncover both Electrosleep Therapy (NCD 30.4) and Magnetic Resonance Imaging (NCD 220.2.1) for all indications. We noncover FDG PET (NCD 220.6.16) for three specific conditions. Because these NCDs provide for noncoverage, we do not have accurate claims data to estimate total impact. However, based on the diagnoses and services, we expect future claims to affect less than one percent of Medicare FFS beneficiaries. Furthermore, removing a national noncoverage NCD may reduce burden for stakeholders and CMS. It may also remove barriers to innovations and increase patient access to technologies that may now be beneficial for some uses.

10. Requirement for Electronic Prescribing for Controlled Substances for a Covered Part D Drug Under a Prescription Drug Plan or an MA–PD Plan

This provision does not have any cost to stakeholders other than what is reflected in the Collection of Information section of this final rule, including cost to Medicare. We expect this to be a one-time burden estimate of 994,500 hours (165,750 * 6 hr) at a cost of $36,418,590 (994,500 hr * 36.62) to prescribers.

We received public comments about the impacts of this policy. The following is a summary of the comments we received and our responses.

Comment: Several commenters noted the health care provider costs involved in implementing EPCS. One commenter recommended that CMS work with ONC to ensure that the cost of acquiring the electronic prescribing standard is part of the EHR certification criteria and to ensure that EHR developers cannot charge additional fees for building in this prescribing standard. Accordingly, the commenter requested that HHS take steps to minimize the cost of EPCS requirements to physician practices. Another commenter stated that their practice has delayed implementing EPCS due to the need to upgrade their EHR software, which has proven to be costly. The commenter stated that given the pandemic impact that amount is now unaffordable for their small primary care practice. Another commenter acknowledged that EPCS implementation costs can be high but that a prudent buyer of software support can find less expensive options.

Response: We share concerns about high health care provider costs associated with implementing EPCS, particularly during the PHE. An article in the Journal of the American Medical Association states that physicians in small private practices around the country have reported steep declines in revenues. Declining revenues have been so significant that some of practices have turned to GoFundMe.[152] However, neither ONC nor CMS have the authority to reduce EHR vendor charges for upgrades. We encourage those who provide software solutions to support EPCS make their products as accessible as possible and, as prescribers who do not implement the standard until 2022 will still be considered compliant, software providers will have more time to review their costs and for providers time to evaluate and chose among available options.

We have reflected these costs in our burden estimate in the Collection of Information section of this rule.

11. Medicare Part B Drug Payment for Drugs Approved Through the Pathway Established Under Section 505(b)(2) of the Food, Drug, and Cosmetic Act

As discussed in section III.L. of this final rule, we are not finalizing the section 505(b)(2) drug product proposals or the proposed corresponding regulation text changes for 2021. Thus, there are no impacts for CY 2021.

12. Updates to Certified Electronic Health Record Technology Due to the 21st Century Cures Act

In section III.M. of this final rule, we are updating the definitions of CEHRT for the Promoting Interoperability Programs and for the MIPS Promoting Interoperability performance category. We are finalizing that health care providers may use technology certified to either the existing or updated 2015 Edition certification criteria, with the extended compliance date of December 31, 2022, as described in timelines finalized in the 21st Century Cures Act final rule (85 FR 25670) and the ONC interim final rule (85 FR 70064). After that time, when ONC only allows certification under the 2015 Edition Cures Update, health care providers must use only technology certified to the 2015 Edition Cures Update. Additionally, in section III.M.3.b, we are also implementing flexibility such that participants in the Hospital IQR Program may use either the 2015 Edition certification criteria, or the 2015 Edition Cures update for CEHRT beginning in the CY 2020 reporting period/FY 2022 payment determination.

With the final policies, eligible hospitals and clinicians, and eligible clinicians will be required to update their EHR technology to meet the CEHRT definition under the 2015 Edition Cures Update. It is important to note that the regulatory impacts of the ONC 21st Century Cures Act final rule account for the quantified and unquantified costs and benefits to hospitals and clinicians associated with acquiring technology certified to the 2015 Edition Cures Update (85 FR 25905 through 25938). Specifically, ONC based their analysis regarding the number of hospitals, CAHs, and eligible clinicians that would be impacted by their regulatory action on the number of hospitals, CAHs, and eligible professionals that have historically participated in the CMS EHR Incentive Programs (now called the Promoting Interoperability Programs and the MIPS Promoting Interoperability performance category) (85 FR 25908). Because we expect that the eligibility criteria proposed under this rule will be a subset of those who participated in the EHR Incentive Programs (for example, the MIPS program has eligibility criteria for low-volume that the EHR Incentive program did not have), this regulatory impact analysis assumes that the cost to program participants to acquire the

[152] *https://jamanetwork.com/journals/jama/fullarticle/2767633.*

upgraded technology has been accounted for under the ONC 21st Century Cures Act final rule. However, we acknowledged ambiguity in attributing impacts from the ONC 21st Century Cures Act final rule and this policy and requested comment that would help with identification of effects that are dependent on these new regulatory provisions. (We further noted that if the ambiguity is ultimately resolved such that all the costs are attributed to the ONC 21st Century Cures Act final rule, leaving no costs associated with this final rule's certified EHR provisions, then these provisions would also yield no benefits.) We did not receive comments on the additional effects of these regulatory provisions and therefore finalize that there is not additional burden or benefit beyond what is captured in the ONC 21st Century Cures act final rule.

13. Proposal To Establish New Code Categories

In section III.N. of this final rule, we maintain the existing 4 Level II HCPCS codes (J0572 through and including J0575), to identify the current array of buprenorphine/naloxone products available on the U.S. market. The number of codes available for health care providers and coders to identify and report on claims remains constant, and therefore no additional burden is placed on coders or health care providers.

14. Medicare Diabetes Prevention Program Expanded Model Emergency Policy

a. Effects on Beneficiaries

In section III.O. of this final rule, we are finalizing certain Medicare Diabetes Prevention Program (MDPP) expanded model policies to allow CMS to remove the once per life time benefit for some MDPP beneficiaries, increase the number of virtual sessions, allow MDPP suppliers to start new cohorts, and allow certain MDPP suppliers to deliver time-limited virtual MDPP sessions in the event of extreme and uncontrollable circumstances that would adversely affect access to MDPP services. These changes would apply during the PHE for COVID–19 and any future 1135 waiver event, in the emergency area during the emergency period, as defined under section 1135(g) of the Act, when the Secretary has authorized waivers under section 1135 for such emergency area and period and CMS has determined that the 1135 waiver event may disrupt in-person MDPP services.

Throughout the rulemaking for the MDPP expanded model, we sought to ensure that the set of MDPP services would be delivered in-person, in a classroom-based setting, within an established interval timeline. At the time, the priority was placed on establishing a structured service that, when delivered within the confines of the rule, would create the least risk of fraud and abuse, increase the likelihood of success, and maintain the integrity of the data collected for evaluation purposes. However, circumstances such as the PHE for COVID–19 have led CMS to make changes to the MDPP expanded model, and to implement an Emergency Policy for MDPP that allows for temporary flexibilities and that prioritizes availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by section 1135 waiver events.

In the March 31st COVID–19 IFC, we sought to ensure that the set of MDPP services that had already started when the PHE for COVID–19 began could continue given the guidance from CDC that Medicare age beneficiaries stay home. The priority was to allow for temporary flexibilities that prioritize availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by the PHE for COVID–19. Given the extended duration of the PHE for COVID–19, we are finalizing the regulations in the March 31st COVID–19 IFC, amend the MDPP expanded model to revise certain MDPP policies during the PHE for COVID–19 and any future 1135 waiver event where such 1135 waiver event may cause a disruption to in-person MDPP services. These temporary flexibilities allow beneficiaries to either continue to have access to set of MDPP services through virtual sessions, pause in-person set of MDPP services and resume with the most recent attendance session of record, or restart MDPP from the beginning in accordance with the March 31st COVID–19 IFC (85 FR 19230). Under the current MDPP regulations, as implemented in the IFC, and for future section 1135 events, should MDPP suppliers deliver set of MDPP services virtually and beneficiaries opt to continue with the set of MDPP services virtually during the 1135 waiver event, those beneficiaries are not eligible to restart the set of MDPP services at a later date.

b. Effects on the Market

At this point, we cannot make clear estimates of the true costs of the MDPP Emergency Policy costs given the current Medicare enrollment. For an example, as part of the COVID–19 flexibilities, we are using authority under section 1135 of the Act to waive the supplier enrollment application fee for any applications submitted on or after March 1, 2020 in response to COVID–19. This, along with CDC's promotion of the temporary application fee waiver to its DPRP registered organizations, have led to an increase in MDPP supplier enrollment applications and approved suppliers. Currently, more than 266 organizations nationally are enrolled as MDPP suppliers, representing 966 locations across the US and its territories.

For the current PHE for COVID–19, we anticipated in the March 31st COVID–19 IFC that of the 1,818 beneficiaries identified through our monitoring data and the CDC's Diabetes Prevention Recognition Program (DPRP) data, 1,358 beneficiaries may be impacted by allowing both the once-per-lifetime benefit and the minimum weight loss requirement to be waived for those beneficiaries in the first 12 months of MDPP. Of those, we assumed that roughly half of the beneficiaries will want to restart their set of MDPP services after the PHE for COVID–19 ends, with a $279,748 cost impact of our waiving the once-per-lifetime benefit as part of the COVID–19 flexibilities, assuming that the estimated cost of year 1 of MDPP is $412.

For this MDPP Emergency Policy, we are updating our assumptions, based on subsequent data from the CDC regarding DPRP organizations' plans for managing their existing cohorts during the PHE for COVID–19, which include either continuing with their cohorts virtually, pausing set of MDPP services and restarting them virtually, or restarting at a later date after the emergency event ends. Based on these data, we assume that 20 percent of MDPP suppliers and 20 percent of beneficiaries will want to restart the set of MDPP services at the first core session after the emergency event ends, taking advantage of the once-per-lifetime requirement removal. We assume that future emergencies will be more geographic-specific, resulting from a natural disaster versus the national-level PHE for COVID–19. For future emergencies, we assume that 2,500 beneficiaries will be enrolled in MDPP in the impacted geographic region. We note that this number is currently an overestimate, and over time, it will likely be an underestimate. We also note that these assumptions are incorrect in cases where a geographic region suffers widespread damage, including to electrical and/or telecommunications systems. This assumption is based on number of suppliers who have reported to the CDC that they are pausing their services during the current PHE for COVID–19.

For the current 1135 event, we are assuming 20 percent of 2,500 beneficiaries will want to take advantage of the waiver in 2020. In this scenario, we assume there would be no virtual or physical access to set of MDPP services for some time, and the supplier will need to either pause or restart classes altogether until such infrastructure systems are back in place. We also assume that beneficiaries who opt to continue with the set of MDPP services virtually are within the first 12 months of the MDPP core service period, and will not be eligible to take advantage of the waived once-per-lifetime limit; and beneficiaries who are in year 2 of the set of MDPP services, as demonstrated by the effective date of the first core session, are not eligible to restart MDPP at the beginning. The cost per impacted geographic area of the removal of the once-per-lifetime limit is estimated to be $209,000. This assumes that MDPP suppliers are paid an estimated $418 due to beneficiaries reaching the following performance milestones: Beneficiary attended 9 sessions, and reached the 5 percent weight loss during interval 2 of the core maintenance session, and attended the required core maintenance sessions.

TABLE 107: Cost of MDPP Emergency Policy per Geographic Area Impacted by the Emergency

Recommended Waivers	Cost impact
Adjust the limit to the # Virtual sessions	$ 0
Remove the once per lifetime requirement	$ 209
Remove the MDPP services time periods and intervals	$ 0
Average Y1 MDPP Payments (Y1) with no action	$ 0
Total cost of MDPP Emergency Policy per PHE	$ 209

Units of Measurement in thousands

Assumptions: Estimated MDPP payments in Year 1: $418, assuming that beneficiaries attended 9 sessions, and reached the 5 percent weight loss during interval 2 of the core maintenance session. For future emergencies we assume that 2,500 beneficiaries in any geographic area will be impacted by a public health emergency, or 500 beneficiaries per geographic area.

15. Changes Due to Updates to the Quality Payment Program

In section IV.A. of this final rule, we included our finalized policies for the Quality Payment Program. In this section of the final rule, we present the overall and incremental impacts to the number of expected QPs and associated APM Incentive Payments. In MIPS, we estimate the total MIPS eligible population and the payment impacts by practice size for the 2021 MIPS performance period based on various finalized policies to modify the MIPS final score and the performance threshold discussed in section IV.A.3.e.(3) of this final rule and additional performance threshold finalized in the CY 2020 PFS final rule (84 FR 63040). For this RIA, we updated performance period and eligibility data to reflect information submitted in the 2019 MIPS performance period.

a. Estimated APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

From 2019 through 2024, through the Medicare Option, eligible clinicians receiving a sufficient portion of Medicare Part B payments for covered professional services or seeing a sufficient number of Medicare patients through Advanced APMs as required to become QPs, for the applicable performance period, will receive a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate payment amounts for Medicare covered professional services furnished during the calendar year immediately preceding the payment year. Beginning in payment year 2021, in addition to the Medicare Option, eligible clinicians may become QPs through the All-Payer Combination Option. The All-Payer Combination Option allows eligible clinicians to become QPs by meeting the QP payment amount or patient count threshold through a pair of calculations that assess a combination of both Medicare Part B covered professional services furnished through Advanced APMs and services furnished through Other Payer Advanced APMs.

The APM Incentive Payment is separate from and in addition to the payments for covered professional services furnished by an eligible clinician during that year. Eligible clinicians who become QPs for a year are not subject to MIPS reporting requirements and payment adjustments. Eligible clinicians who do not become QPs, but meet a lower threshold to become Partial QPs for the year, may elect to report to MIPS and, if they elect to report, would then be scored under MIPS and receive a MIPS payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment. For the 2021 QP Performance Period, as set forth in § 414.1430(a)(2), Partial QPs are eligible clinicians in Advanced APMs who have at least 50 percent, but less than 75 percent, of their payments for Part B covered professional services through an APM Entity, or furnish Part B covered professional services to at least 35 percent, but less than 50 percent, of their Medicare beneficiaries through an APM Entity. This MIPS payment adjustment may be positive, negative, or neutral. If an eligible clinician does not attain either QP or Partial QP status, and does not meet any another exemption category, the eligible clinician would be subject to MIPS, would report to MIPS, and would receive the corresponding MIPS payment adjustment.

Beginning in payment year 2026, the Conversion Factor (CF) used to calculate payment rates for services furnished by clinicians who achieve QP status for a year would be increased each year by 0.75 percent for the year, while the CF used to calculate payment rates for services furnished by clinicians who do not achieve QP status for the year would be increased by 0.25 percent. In addition, MIPS eligible clinicians would receive positive, neutral, or negative MIPS payment adjustments to payment for their Part B PFS services in a payment year based on performance during a prior performance period. Although the statute establishes overall payment rate and procedure parameters until 2026 and beyond, this impact

analysis covers only the fifth payment year (2023 payment year) of the Quality Payment Program.

Overall, we estimate that for the 2021 QP Performance Period between 196,000 and 252,000 eligible clinicians will become QPs, therefore be excluded from MIPS, and qualify for the lump sum APM incentive payment in Payment Year 2023 based on 5 percent of their Part B paid amounts for covered professional services in the preceding year. These paid amounts for QPs are estimated to be between approximately $14,000 million and $18,500 million in total for the 2021 performance year. The analysis for this final rule used the 2019 third snapshot participation file. We based APM Incentive Payment Amounts on paid amounts with service dates of January 1, through September 30, 2019. We multiplied the calculated amounts by 1.5 to approximate payment amounts for the full calendar year. We estimate that the total lump sum APM Incentive Payments will be approximately $700–900 million for the 2023 Quality Payment Program payment year.

In section IV.F.10.b. of this final rule, we projected the number of eligible clinicians that will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2021 QP Performance Period, as well as some Advanced APMs anticipated to be operational during the 2021 QP Performance Period. The projections also reflect an estimated number of eligible clinicians that would attain QP status through the All-Payer Combination Option. We note that the Next Generation ACO Model, previously scheduled to conclude December 2020, the Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), currently scheduled to conclude March 31, 2021, have been included in our analysis as we anticipate that these models will be Advanced APMs in 2021. The following APMs are expected to be Advanced APMs for the 2021 QP Performance Period:

- Bundled Payments for Care Improvement Advanced Model;
- Comprehensive Care for Joint Replacement Payment Model (CEHRT Track), if extended;
- Comprehensive Primary Care Plus (CPC+) Model;
- Direct Contracting Model;
- Kidney Care Choices Model;
- Maryland Total Cost of Care Model (Care Redesign Program; Maryland Primary Care Program);
- Medicare Shared Savings Program (Track 2, Track 3, Basic Track Level E, and the ENHANCED Track);
- Medicare ACO Track 1+ Model;
- Next Generation ACO Model, if extended;
- Oncology Care Model (Two-Sided Risk Arrangements);
- Primary Care First (PCF) Model; and
- Vermont All-Payer ACO Model (Vermont Medicare ACO Initiative).

We used the Participation Lists and Affiliated Practitioner Lists, as applicable, (*see* 81 FR 77444 through 77445 for information on the APM Participant Lists and QP determinations) for the Predictive QP determination file for 2019 to estimate the number of QPs, total Part B paid amounts for covered professional services, and the aggregate total of APM Incentive Payments for the 2021 QP Performance Period. We examined the extent to which Advanced APM participants would meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries furnished Part B covered professional services through the APM Entity.

b. Impact for the 2022 MIPS Payment Year

In section IV.A.3.d.(2)(a) of this final rule, we finalized the proposal to double the total points available for the complex patient bonus to up to 10 points. We expect this finalized policy to result in the median bonus to increase by 3 points, thus increasing MIPS final scores at the median by 3 points. We do not know the effects of the PHE for COVID–19 and its effect on MIPS performance in 2020, so we did not recreate the analysis and payment distributions with the updated bonus for the 2020 MIPS performance period. We expect the higher MIPS final scores would result in smaller payment adjustments for two reasons. First, we expect reductions to the budget neutral pool due to the higher scores. Second, for clinicians above the performance threshold or additional performance threshold, an increased score would mean more clinicians sharing the budget neutral pool and additional $500 million for exceptional performance and potentially lowering the scaling factor that is applied to the MIPS payment adjustment and additional payment adjustment.

c. Impact of the PHE for COVID–19 on CY 2019 QPP Performance Period Submissions Data

The PHE for COVID–19 overlapped with the CY 2019 submissions period and led us to trigger our automatic extreme and uncontrollable circumstances policy for the entire U.S. for the 2019 MIPS performance period. This policy means that clinicians who did not submit any information to MIPS or for certain performance categories could have the performance category scores reweighted (instead of receiving a performance category score of 0). We also published in the March 31st COVID–19 IFC in which we updated our application-based extreme and uncontrollable circumstances policy to provide more flexibility for clinicians impacted by the PHE for COVID–19. Specifically, we extended the application deadline from December 31, 2019 to April 30, 2020, and also modified the policy at § 414.1380(c)(2)(i)(A)(6) to create an exception for the 2019 performance period/2021 MIPS payment year only, such that if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the PHE for the COVID–19 pandemic, but also submits data for the quality, Promoting Interoperability, or improvement activities performance categories, the performance categories for which data are submitted would still be reweighted and the data submission would not effectively void the application for reweighting (85 FR 19278).

As a result of these policies, we needed to assess whether it would be appropriate to use CY 2019 QPP submissions data to assess CY 2021 MIPS performance and whether adjustments would need to be made to the data because clinicians did not submit information. To do so, we examined the distribution of final scores for clinicians who submitted data to MIPS for the CY 2019 performance period, irrespective if they applied for the application-based extreme and uncontrollable circumstances policy we established in the March 31st COVID–19 IFC, and compared the levels of non-engagement in MIPS to the CY 2018 performance period. When we considered whether we should remove clinicians who received reweighting due to our triggering of the automatic extreme and uncontrollable circumstances policy due to the PHE for COVID–19, we found excluding clinicians under this policy led to an increase in the number of clinicians not engaged with MIPS compared to the CY

2021 PFS proposed rule RIA, which uses CY 2018 MIPS submissions data. These clinicians who did not submit data for the CY 2019 submissions period did not have shared characteristics that would warrant adjustment for their missing data. Therefore, we selected to only exclude clinicians who qualified for automatic E&U prior to COVID–19 to be consistent with the RIA methodology in previous years. When we considered clinicians impacted by updates to the application-based COVID–19 extreme and uncontrollable circumstances policy as finalized (85 FR 19278) on the CY 2019 submissions data, we found that including clinicians affected by the application-based extreme and uncontrollable circumstances policy in our CY 2021 PFS final rule RIA model did not lead to a meaningful difference in the distribution scores compared to when we used CY 2018 Quality Payment Program submissions data. Given these findings, we decided to use the CY 2019 submissions data and continued to exclude clinicians who were affected by the automatic extreme and uncontrollable circumstances prior to the PHE for COVID–19 as finalized (82 FR 53895 through 53900).

To avoid overestimating the positive payment adjustments for the 2021 MIPS performance period due to the increased number of MIPS eligible clinicians who are not engaged, we adjusted the paid amount of non-engaged clinicians for the CY 2021 MIPS performance period to equal their proportion of paid amount prior to the PHE for COVID–19. We conducted a sensitivity analysis to examine the expected payment adjustment for the CY 2021 MIPS performance period in the absence of an adjustment to the paid amount. The results from this sensitivity analysis are presented in section VIII.H.15.e.(3) of this final rule.

d. Estimated Number of Clinicians Eligible for MIPS Eligibility for the 2023 MIPS Payment Year

(1) Methodology To Assess MIPS Eligibility

(a) Clinicians Included in the Model Prior To Applying the Low-Volume Threshold Exclusion

To estimate the number of MIPS eligible clinicians for the 2021 MIPS performance period in this final rule, our scoring model used a combination of the first determination period from the 2020 MIPS performance period (from October 1, 2018 to September 30, 2019) and data from the end of calendar year 2019 (from October 1, 2019 to December 31, 2019). The first determination period from the 2020 MIPS performance period eligibility file was selected as it was the most recent eligibility file available. We included 1.6 million clinicians (*see* Table 108) who had PFS claims from October 1, 2018 to December 31, 2019. As discussed in section VIII.H.15.c. of this final rule, we excluded from our analysis individual clinicians who were affected by the automatic extreme and uncontrollable circumstances policy finalized for the 2018 MIPS performance period/2020 MIPS payment year in the CY 2019 PFS final rule (83 FR 59876) prior to the PHE for COVID–19 as we are unable to predict how these clinicians would perform in a year where there was no extreme and uncontrollable event. We also excluded from our analysis submissions from clinicians that are CPC+ practitioners due to data limitations and an inability to model their behavior within the APM Performance Pathway. Finally, we did not exclude submitters with one or more categories identified as being suppressed as a result of bad data for the CY 2019 performance period because we did not receive the list of CY 2019 submissions considered as bad data in time for this final rule.

Clinicians are ineligible for MIPS (and are excluded from MIPS payment adjustment) if they are newly enrolled to Medicare; are QPs; are partial QPs who elect to not participate in MIPS; are not one of the clinician types included in the definition for MIPS eligible clinician; or do not exceed the low-volume threshold as an individual or as a group. Therefore, we excluded these clinicians when calculating the estimate of clinicians eligible for MIPS.

For the estimated MIPS eligible population for the 2023 MIPS payment year, we restricted our analysis to clinicians who are a physician (as defined in section 1861(r) of the Act), a physician assistant, nurse practitioner, and clinical nurse specialist (as such terms are defined in section 1861(aa)(5) of the Act); a certified registered nurse anesthetist (as defined in section 1861(bb)(2) of the Act); a physical therapist, occupational therapist, speech-language pathologist, audiologist, clinical psychologist, and registered dietitian or nutrition professional as finalized in the CY 2019 PFS final rule (83 FR 60076).

As noted previously, we excluded QPs from our scoring model since these clinicians are not MIPS eligible clinicians. To determine which clinicians in the initial population of 1.6 million should be excluded as QPs, we used Advanced APM payment and patient percentages from the APM Participant List for the first snapshot date for the 2020 QP performance period, supplemented by the most recent 2019 performance period APM participation data for those clinicians not on the 2020 first snapshot list. From this data, we calculated the QP determinations as described in the Qualifying APM Participant definition at § 414.1305 for the 2021 QP performance period. We assumed that all Partial QPs would elect to participate in MIPS and included them in our scoring model and eligibility counts. The projected number of QPs excluded from our model is 172,530. Due to data limitations, we could not identify specific clinicians who may become QPs in the 2021 Medicare QP Performance Period; hence, our model may underestimate or overestimate the fraction of clinicians and allowed charges for covered professional services that will remain subject to MIPS after the exclusions.

We also excluded newly enrolled Medicare clinicians from our model. To identify newly enrolled Medicare clinicians, we used the enrollment date from the 2019 Quality Payment Program performance period data.

(b) Assumptions Related To Applying the Low-Volume Threshold Exclusion

The low-volume threshold policy may be applied at the individual (that is, TIN/NPI) or group (that is, TIN) levels based on how data are submitted or at the APM Entity level if the clinician is part of an APM Entity in a MIPS APM (hereafter, a MIPS APM Entity) that elects to submit to MIPS. A clinician or group that exceeds at least one but not all three low-volume threshold criteria may become MIPS eligible by electing to opt-in and subsequently submitting data to MIPS, thereby getting measured on performance and receiving a MIPS payment adjustment. Our method of modeling opt-in participation is described later in this section.

Table 108 presents the estimated MIPS eligibility status and the associated PFS allowed charges of clinicians in the initial population of 1.6 million clinicians in the analysis of the 2021 MIPS performance period after using 2019 MIPS performance period data and applying the finalized policies for the 2021 MIPS performance period.

To apply the low-volume threshold, we need to understand whether clinicians participate as a group, virtual group, APM entity, or as individuals. For the purposes of this regulatory impact analysis, we made assumptions as to which clinicians would elect group reporting, virtual group or APM Entity reporting. One extreme and unlikely assumption is that no practices elect

group reporting, virtual group reporting, or participate in an APM Entity that elects MIPS reporting and the low-volume threshold is applied at the individual level. Although we believe a scenario in which clinicians would only participate as individuals is unlikely, this assumption is important because it quantifies the minimum number of MIPS eligible clinicians. For this final rule model, we estimate approximately 228,000 clinicians [153] would be MIPS eligible because they exceed the low volume threshold as individuals and are not otherwise excluded. In Table 108, we identify these clinicians as having ''required eligibility.''

For this RIA, we assume the following participation requirements for virtual groups and MIPS APM Entities that elect to participate in MIPS. We assume that TINs that registered as a virtual group for the CY 2019 MIPS performance period will continue to do so for the CY 2021 MIPS performance period. Due to data limitations and our inability to determine who would use the APM Performance Pathway versus the traditional MIPS submission mechanism for the 2021 MIPS performance period, our model assumes ACO APM Entities would elect to submit data to MIPS through the APM Performance Pathway and that participants in non-ACO APM Entities would participate in MIPS as an individual or group rather than as an APM Entity. We included those who are in MIPS APM ACOs in the 2019 performance period as well as the additional clinicians in the first snapshot date of the 2020 QP performance period.

Finally, we assume that groups that submitted to MIPS as a group will continue to do so for the CY 2021 MIPS performance period. Using CY 2019 MIPS performance period data, we can identify group reporting through the submission of improvement activities, Promoting Interoperability, or quality performance category data. Using these assumptions, we identified approximately 661,000 MIPS eligible clinicians who are eligible because they had the low-volume threshold applied to an identified group, APM entity, or virtual groups. In Table 108, we identify these clinicians who do not meet the low-volume threshold individually but are assumed to submit to MIPS as a group, virtual group or MIPS APM as having ''group eligibility.''

To model the opt-in policy finalized in the CY 2019 PFS final rule (83 FR 59735), we updated our methodology from the CY 2021 PFS proposed rule (85 FR 50384 through 50387) because actual opt-in participation data became available with the transition to the use of CY 2019 performance period data. We assumed clinicians who exceeded at least one but not all low-volume threshold criteria and who elected to opt-in to MIPS and submitted data for the CY 2019 MIPS performance period would also elect to opt-in to MIPS for the CY 2021 MIPS performance period.

These clinicians who met this opt-in participation assumption are identified in Table 108 as ''Opt-In eligibility''. In this final rule analysis, we estimate an additional 2,300 clinicians would be eligible through this ''opt-in'' policy for a total MIPS eligible clinician population of approximately 891,000. The leads to an associated $72 billion allowed PFS charges estimated to be included in the 2021 MIPS performance period.

[153] The count of 227,488 MIPS eligible clinicians for required eligibility includes those who participated in MIPS (200,373 MIPS eligible clinicians), as well as those who did not participate (27,115 MIPS eligible clinicians).

TABLE 108: Description of MIPS Eligibility Status for CY 2023 MIPS Payment Year Using the CY 2021 PFS Final Rule Assumptions**

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians*	CY 2021 PFS Final Rule estimates	
		Number of Clinicians	PFS allowed charges ($ in mil)*
Required eligibility (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Participate in MIPS	200,372	$48,461
	Do not participate in MIPS	27,115	$6,345
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria and submit as a group)	Submit data as a group	660,909	$17,061
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS and submit data)	Elect to opt-in and submit data	2,346	$51
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**890,742**	**$71,918**
Not MIPS Eligible			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Do not opt-in; or Do not submit as a group	381,771	$9,979
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	83,039	$460
Excluded for other reasons (Non-eligible clinician type, newly enrolled, QP)	Not applicable	269,905	$10,225
Total Number of Clinicians Not MIPS Eligible		734,715	$20,664
Total Number of Clinicians (MIPS and Not MIPS Eligible)		1,625,457	$92,582

* Estimated MIPS Eligible Clinician Population

** Table 108 does not include clinicians impacted by the automatic extreme and uncontrollable policy prior to PHE for COVID-19 (approximately 5,000 clinicians and $530 million in PFS allowed charges). It also does not include eligible clinicians in CPC+ APMs who otherwise would have been MIPS eligible.

*** Allowed charges estimated using 2018 and 2019 dollars. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

There are approximately 382,000 clinicians who are not MIPS eligible, but could be if their practice decides to participate or they elect to opt-in. We describe this group as ''Potentially MIPS eligible''. These clinicians would be included as MIPS eligible in the unlikely scenario in which all group practices elect to submit data as a group and all clinicians that could elect to opt-into MIPS do elect to opt-in. This assumption is important because it quantifies the maximum number of MIPS eligible clinicians. When this unlikely scenario is modeled, we estimate the MIPS eligible clinician population could be as high as 1.3 million clinicians.

Finally, there are some clinicians who would not be MIPS eligible either because they and their group are below

the low-volume threshold on all three criteria (approximately 83,000) or because they are excluded for other reasons (approximately 270,000).

Since eligibility among many clinicians is contingent on submission to MIPS as a group, virtual group, APM participation in a MIPS APM Entity that elects to report to MIPS, or election to opt-in, we will not know the number of MIPS eligible clinicians until the submission period for the 2021 MIPS performance period is closed. For this impact analysis, we used the estimated population of 890,742 MIPS eligible clinicians described above.

e. Estimated Impacts on Payments to MIPS Eligible Clinicians for the 2023 MIPS Payment Year

(1) Summary of Approach

In sections IV.A.3.c., IV.A.3.d. and IV.A.3.e. of this final rule, we present several provisions which impact the measures and activities that impact the performance category scores, final score calculation, and the MIPS payment adjustment. We discuss these changes in more detail in section VIII.H.15.e.(2) of this RIA as we describe our methodology to estimate MIPS payments for the 2023 MIPS payment year. We note that some of the MIPS policies in the CY 2020 PFS final rule were only defined for the 2020 MIPS performance period and 2022 MIPS payment year and did not continue to future years, such as the quality and cost performance category weights. Because we did not have category weights for the 2021 MIPS performance period, we could not calculate a final score for the 2021 MIPS performance period and 2023 MIPS payment year. Therefore, we could not create a baseline for the 2021 performance period that would allow us to fully distinguish between the impact of the previously finalized policies for the 2021 performance period and the finalized policies for the 2021 performance period. Our impact analysis looks at the total effect of the previously finalized and newly finalized MIPS policies on the MIPS final score and payment adjustment for the CY 2021 MIPS performance period/CY 2023 MIPS payment year.

The payment impact for a MIPS eligible clinician is based on the clinician's final score, which is a value determined by their performance (as an individual, group, virtual group, or APM Entity) in the four MIPS performance categories: Quality, cost, improvement activities, and Promoting Interoperability. As discussed in section VIII.H.15.e.(2) of this final rule, we generally used the most recently available data from the Quality Payment Program which is data submitted for the 2019 MIPS performance period.

The estimated payment impacts presented in this final rule reflect averages by practice size based on Medicare utilization. The payment impact for a MIPS eligible clinician could vary from the average and would depend on the combination of services that the MIPS eligible clinician furnishes. The average percentage change in total revenues that clinicians earn would be less than the impact displayed here because MIPS eligible clinicians generally furnish services to both Medicare and non-Medicare patients; this program does not impact payment from non-Medicare patients. In addition, MIPS eligible clinicians may receive Medicare revenues for services under other Medicare payment systems, such as the Medicare Federally Qualified Health Center Prospective Payment System, that would not be affected by MIPS payment adjustment factors.

(2) Methodology To Assess Impact

To estimate participation in MIPS for the CY 2021 Quality Payment Program for this final rule, we generally used 2019 MIPS performance period data. Our scoring model included the 890,742 estimated MIPS eligible clinicians as described in section VIII.H.15.b of this RIA.

To estimate the impact of MIPS policies on MIPS eligible clinicians, we generally used the 2019 MIPS performance period data, including data submitted for the quality, improvement activities, and Promoting Interoperability performance categories. We supplemented this information with CAHPS for MIPS and CAHPS for ACOs, the revised total per capita cost measure and Medicare Spending Per Beneficiary (MSPB) clinician measures that were finalized in the CY 2020 PFS final rule (84 FR 62969 through 62977), and other data sets.[154] We calculated a hypothetical final score for the 2021 MIPS performance period/2023 MIPS payment year for each MIPS eligible clinician using score estimates described in this section for quality, cost, Promoting Interoperability, and improvement activities performance categories.

[154] Data submitted to MIPS for the 2018 MIPS performance period data was used for the improvement score for the quality performance category. We also incorporated some additional data sources when available to represent more current data.

(a) Methodology To Estimate the Quality Performance Category Score

We estimated the quality performance category score using a similar methodology described in the CY 2020 PFS final rule (84 FR 63168 through 63169) with the following modifications that reflect the newly finalized policies for the 2021 MIPS performance period. As discussed in section IV.A.3.c.(1)(e)(i) of this final rule, we finalized as proposed to replace the All-Cause Readmission measure with the Hospital Wide Readmission measure and add the hip-knee complications measure for those for whom it is applicable. We used testing data for these new administrative claims measures.

As discussed in section IV.A.3.d.(1)(b) of this final rule, we are not finalizing our intent to use a performance period benchmark as opposed to a historical benchmark. Therefore, we used the 2019 MIPS performance period benchmarks because the performance data for this analysis came primarily from the 2019 MIPS performance period. The one exception where we used the 2019 MIPS performance period benchmarks was when we identified measures subject to the topped out scoring cap that was finalized (82 FR 53721 through 53727) using the 2020 MIPS performance period benchmark file. As discussed in section IV.A.3.c.(1) of this final rule, we applied the finalized quality performance category weight of 40 percent for the 2021 MIPS performance period.

Finally, we finalized the APM Performance Pathway policies as described in section IV.A.3.b. of this final rule. The APM Performance Pathway is available for APM entities and as discussed in section IV.A.3.(b).(3).(a) we are finalizing an alternate measure set consisting of the Web Interface measures for the CY 2021 performance period. For our RIA model, we assumed clinicians in APM Entities would continue to use the Web Interface collection type, if available, over the APM Performance Pathway. Due to data limitations, our analysis only applied Web Interface and the APM Performance Pathway scoring policies to ACO APM Entities. For ACOs, quality performance under the finalized APM Performance Pathway was modeled using Web Interface data for 2019 from the 2019 performance period submissions data. For the multiple chronic condition unplanned admissions measure under the APM Performance Pathway, the 2019 Shared Savings Program and the 2018 Next Generation ACO Model public use files

were used.[155] To estimate the Hospital Wide Readmission measure as finalized in section IV.A.3.c.(1)(e)(i), we aggregated the score for APM Entities. Data does not exist for APM performance pathway or MIPS quality measures for non-ACO APM Entities. Therefore, we assumed due to data limitations these non-ACO APM entities would not participate in the APP although they can participate in APP, either through the APP measures or Web Interface for the CY 2021 performance period. For the purposes of modeling, we assumed that their participating clinicians (or their groups) would participate in regular MIPS, and scored those clinicians using the available MIPS submissions of the clinician or its group. Therefore, because of data limitations our results may overestimate or underestimate the number of APM Entities that elect to participate in MIPS as an APM Entity and how they elect to participate.

(b) Methodology To Estimate the Cost Performance Category Score

In section IV.A.3.c.(2) of this final rule, we finalized as proposed a cost performance category weight of 20 percent for the 2021 MIPS performance period. We estimated the cost performance category score using the methodology described in the CY 2020 PFS final rule (84 FR 63169).

(c) Methodology To Estimate the Facility-Based Measurement Scoring

As finalized in the CY 2019 PFS final rule (83 FR 59856), we determine the eligible clinician's MIPS cost and quality performance category score in facility-based measurement based on Hospital VBP Program Total Performance Score for eligible clinicians or groups who meet the eligibility criteria, which we designed to identify those who primarily furnish services within a hospital. We estimated the facility-based score using the scoring policies finalized in the CY2018 Quality Payment Program final rule (82 FR 53763) and the methodology described in the CY 2020 PFS final rule (84 FR 63169).

(d) Methodology To Estimate the Promoting Interoperability Performance Category Score

In section IV.3.c.(4)(c)(ii)(B), we are finalizing as proposed to add the HIE bi-directional exchange measure for the 2021 performance period and subsequent years as an optional alternative to the two existing measures: The Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Incorporating Health Information measure. This provision provides clinicians the option of either reporting the new measure or the two existing measures. In section IV.3.c.(4)(c)(i) of this final rule, we finalized as proposed for the PDMP measure to remain optional and to double the bonus points from 5 to 10 points.

We used the CY 2019 MIPS Promoting Interoperability performance period data submissions data to estimate CY 2021 MIPS performance for the Promoting Interoperability performance category. Due to technical limitations, the data used do not capture the following policy changes between the CY 2019 and CY 2021 performance periods: (1) The doubling of the bonus points for clinicians who submitted the PDMP measure, (2) the removal of the Verify Opioid Treatment Agreement measure data, a measure that was finalized in the CY 2019 performance period (83 FR 59806) but removed in the CY 2020 performance period (84 FR 62994), and (3) the adoption of the finalized Health Information Exchange bi-directional exchange measure for the CY 2021 performance period. As a result, the estimated Promoting Interoperability performance category scores for the CY 2021 performance period may be a slight over- or under-estimate of performance in the Promoting Interoperability performance category.

(e) Methodology To Estimate the Improvement Activities Performance Category Score

We modeled the improvement activities performance category score based on CY 2019 MIPS performance period data and APM participation identified in section VIII.H.15.b of this final rule. We continued to apply the methodology described in the CY 2020 PFS final rule (84 FR 63170) to assign an improvement activities performance category score. For the APM participants identified in section IV.A.3.b.(2) of this final rule, as there was no APM performance pathway score in the previous final rule, we assigned an improvement activity performance category score of 100 percent.

(f) Methodology To Estimate the Complex Patient Bonus

In section IV.A.3.d.(2)(a) of this final rule, we finalized as proposed to continue the complex patient bonus for the 2021 MIPS performance period. Consistent with the policy to define complex patients as those with high medical risk or with dual eligibility, our scoring model used the complex patient bonus information calculated for the 2019 performance period data.

(g) Methodology To Estimate the Final Score

As discussed in sections IV.A.3.c.(1)(b), IV.A.3.c.(2)(a), and summarized in section IV.A.3.d.(2)(b) of this final rule, our model assigned a final score for each TIN/NPI by multiplying each performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points, and adding the complex patient bonus. After adding any applicable bonus for complex patients, we reset any final scores that exceeded 100 points equal to 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to section IV.A.3.d.(2)(b)(iii) of this final rule.

(h) Methodology To Estimate the MIPS Payment Adjustment

As described in section IV.A.3.e.(2) of this final rule, we applied the finalized hierarchy to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available.

We then calculated the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, minimum and maximum adjustment percentages and additional payment adjustment for exceptional performance (as finalized under § 414.1405), using the performance threshold of 60 points previously finalized in the CY 2020 PFS final rule (84 FR 63037) and the previously finalized additional performance threshold of 85 points (84 FR 63039 through 63040). In the alternatives considered discussed in section VIII.I.2. of this rule, we include the key statistics if the performance threshold was 50 as proposed in the CY 2021 PFS proposed rule (85 FR 50318). We used these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the paid amount for covered

[155] The public use files for the 2019 Medicare Shared Savings Program and 2018 Next Generation ACO Model can be accessed at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/program-data* and *https://innovation.cms.gov/innovation-models/next-generation-aco-model.*

professional services furnished by the MIPS eligible clinician. As discussed in section VIII.H.15.c. of this final rule, we adjusted the paid amount of non-engaged clinicians to equal their proportion of paid amount prior to the PHE for COVID–19.

(3) Impact of Payments by Practice Size

Using the assumptions provided above, our model estimates that $458 million would be redistributed through budget neutrality and that $500 million would be distributed to MIPS eligible clinicians that meet or exceed the additional performance threshold. The mean final score is 79.80 and the median is 85.27.

The model further estimates that the maximum positive payment adjustments are 5.3 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In the alternatives considered discussed in section VIII.I.2. of this rule, we include the details of the model in which the performance threshold was set to 50, which had been proposed in the 2021 PFS proposed rule. In this alternate model, $388 million would be redistributed through budget neutrality and the maximum positive payment adjustments would be 4.9 percent.

Table 109 shows the impact of the payment adjustments by practice size and based on whether clinicians are expected to submit data to MIPS. We estimate that a smaller proportion of clinicians in small practices (1–15 clinicians) who participate in MIPS will receive a positive or neutral payment adjustment compared to larger sized practices. Table 109 also shows that 93.0 percent of MIPS eligible clinicians that participate in MIPS are expected to receive positive or neutral payment adjustments. We want to highlight that we are using 2019 MIPS performance period submissions data to simulate a 2021 MIPS performance period final score, and it is likely that there will be changes that we cannot account for at this time, including services and payments disrupted by the PHE for COVID–19 or clinicians changing behavior because of the performance thresholds increased for the 2021 MIPS performance period to avoid a negative payment adjustment. In particular, we have not accounted for potential clinicians who might elect to apply for the extreme and uncontrollable circumstances policies for the CY 2021 performance period that we discuss in section IV.A.3.d.(2)(b)(iv)(B) of this final rule.

The combined impact of negative and positive adjustments and the additional positive adjustments for exceptional performance as a percent of paid amount among those that do not submit data to MIPS was not the maximum negative payment adjustment of 9 percent possible because some MIPS eligible clinicians that do not submit data to MIPS receive a non-zero score for the cost performance category, which utilizes administrative claims data and does not require separate data submission to MIPS. Among those who we estimate would not submit data to MIPS, 85 percent are in small practices (22,956 out of 27,115 clinicians who do not submit data). To address participation concerns, we have policies targeted towards small practices including technical assistance and special scoring policies to minimize burden and facilitate small practice participation in MIPS or APMs, which we describe in section H.15.e.(4)(b)(iv) of this final rule. We intend to continue working with stakeholders to improve engagement in MIPS among clinicians in small practices. It should also be noted that the estimated number of clinicians who do not submit data to MIPS may be an overestimate of non-engagement in MIPS for the CY 2021 MIPS performance period. This is because the PHE for COVID–19 may have resulted in fewer clinicians submitting data to MIPS or more clinicians may elect to apply for the extreme and uncontrollable circumstances policies due to the PHE for COVID–19 for 2021 MIPS performance period. Therefore, engagement levels in MIPS for the CY 2021 MIPS performance period may be differ from these reported estimates. We also note this participation data is generally based off participation for the 2019 performance period, which is associated with the 2021 MIPS payment year and had a performance threshold of 30 points, and that participation may change for the 2021 performance period when the performance threshold is 60 points.

TABLE 109: MIPS Estimated Payment Year 2023 Impact on Total Estimated Paid Amount by Participation Status and Practice Size*[a]

Practice Size*	Number of MIPS eligible clinicians	Percent MIPS Eligible Clinicians with Positive or Neutral Payment Adjustment	Percent MIPS Eligible Clinicians with a Positive Adjustment with Exceptional Payment Adjustment	Percent MIPS Eligible Clinicians with Negative Payment Adjustment	Combined Impact of Negative and Positive Adjustments and Exceptional Performance Payment as Percent of Paid Amount**
Among those submitting data* **					
1) 1-15	123,536	81.7%	46.9%	18.3%	1.0%
2) 16-24	40,688	87.5%	46.6%	12.5%	1.3%
3) 25-99	189,346	90.5%	50.6%	9.5%	1.5%
4) 100+	510,057	97.0%	55.6%	3.0%	1.7%
Overall	**863,627**	**93.0%**	**52.9%**	**7.0%**	**1.4%**
Among those not submitting data					
1) 1-15	22,956	0.0%	0.0%	100.0%	-8.6%
2) 16-24	1,225	0.0%	0.0%	100.0%	-8.7%
3) 25-99	2,212	0.0%	0.0%	100.0%	-8.7%
4) 100+	722	0.0%	0.0%	100.0%	-8.8%
Overall	**27,115**	**0.0%**	**0.0%**	**100.0%**	**-8.6%**

NOTE: Results of this model may change significantly if more clinicians apply for the application-based extreme and uncontrollable circumstances policy exception in CY 2021 because of the PHE for COVID-19.
*Practice size is the total number of TIN/NPIs in a TIN.
** 2019 data used to estimate 2021 performance period payment adjustments. Payments estimated using 2019 dollars trended to 2023. The percentage represents the total adjustments after taking all the positive adjustments and subtracting the negative adjustments for all MIPS eligible clinicians in the same respective practice size.
***Includes facility-based clinicians whose quality data is submitted through hospital programs.

As a sensitivity analysis of our COVID–19 adjustment on paid amount, we ran a model that did not adjust the paid amount of non-engaged clinicians to equal their proportion of paid amount prior to the PHE for COVID–19, our model estimates that $601 million would be redistributed through budget neutrality. The model further estimates that the maximum positive payment adjustments are 5.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance.

(4) Additional Impacts From Outside Payment Adjustments

(a) Burden Overall

In addition to the payment adjustments, we are finalizing several policies that have an impact on burden in the CY 2021 and CY 2022 MIPS performance periods. In section VII.B.5 of this final rule, we outline the costs of data collection that includes both policy updates and adjustments due to the use of updated data sources. For each finalized proposal included in this regulation which impacts our estimate of collection burden, the incremental burden for each is summarized in Table 110. We also provide additional burden discussions that we are not able to quantify.

TABLE 110: Incremental Burden from Associated Finalized Policies

Burden Description and associated finalized proposals	Burden Hours	Burden Dollars
Total burden associated with continuing the policies and ICRs set forth in the CY 2020 PFS final rule into the 2021 and 2022 MIPS performance periods (as discussed in section VII.B.5.p)	1,478,504	$ 144,456,084
Burden change due to finalized policy to sunset the CMS Web Interface measures as a collection type/submission type for CY 2022*	-5,926	-$ 541,507
Burden change due to finalized policy to require QCDRs and qualified registries to conduct targeted data audits, if necessary	730	$ 67,496
Burden change due to new ICR for Nomination of MVPs	300	$ 45,467
Burden change due to finalized policy to add a survey-based measure on telehealth to the CAHPS for MIPS Survey	100	$ 2,565
Burden change due to finalized policy to allow APM Entities to submit an extreme and uncontrollable circumstances exception application	1.75	$ 162
Burden change due to finalized policy to require nominated improvement activities to be linked to existing and related quality and cost measures, as applicable and feasible	31	$ 4,698
Total change in burden due to policy	**-4,763**	**-$ 421,117**
Total burden set forth in the CY 2021 PFS final rule	**1,473,741**	**$ 144,034,968**

* The total change in burden due to this policy includes a decrease in burden due to elimination of the "Quality Data Submission: CMS Web Interface collection type" ICR beginning with the 2022 MIPS performance period and "Group Registration for CMS Web Interface" ICR beginning with the 2022 MIPS performance period as well as an increase in burden for the "Quality Data Submission: MIPS CQM and QCDR collection type" and "Quality Data Submission: eCQM collection type" ICRs beginning with the 2022 MIPS performance period for respondents who previously submitted via the CMS Web Interface submitting data via an alternate collection type. See section VII.B.5. of this final rule.

(b) Additional Impacts to Clinicians

(i) Web Interface

As discussed in section IV.A.3.c.(1)(c) of this final rule, we are finalizing to sunset the CMS Web Interface measures as a collection type for groups and virtual groups with 25 or more eligible clinicians starting with the 2022 performance period. We recognize that the sunset of the CMS Web Interface for groups and virtual groups may be burdensome to current groups and virtual groups submitting quality data on CMS Web Interface measures. Such groups and virtual groups will need to select a different collection type/submission type and redesign their systems to be able to interact with the new collection type/submission type. Given that the Medicare Part B claims collection type is limited to small practices, the alternatives for these groups and virtual groups will be either the MIPS CQM, QCDR or eCQM collection types. Given the size of the affected groups and virtual groups, we believe the majority are likely to already be using a QCDR, qualified registry, or EHR as part of their practice workflow. Of the 3,613 TINs comprised of 25 or more clinicians who submitted MIPS data via a collection type other than the CMS Web Interface, 57 percent reported via the MIPS CQM and QCDR collection type and 43 percent reported via the eCQM collection type. For groups converting from Web Interface, there will be some non-recurring costs associated with modifying clinical and MIPS data reporting workflows to utilize an alternate collection type. For any remaining groups and virtual groups there will also be registry fees paid to a QCDR or qualified registry or the financial expense of purchasing/licensing and deploying an EHR system. Because we are unable to assess either the existing workflows of each individual group and virtual group or the decisions each group and virtual group will make in response to this finalized proposal, we cannot quantify the resulting economic impact. While there may be an initial increase in burden for current groups and virtual groups utilizing the CMS Web Interface measures having to transition to the utilization of a different collection type/submission type, we recognize that we will also be reducing reporting requirements. Groups and virtual groups will no longer have to completely report on all pre-determined CMS Web Interface measures and will be able to select their own measures (at least 6) to report.

Groups and virtual groups account for less than 20 percent of organizations utilizing the CMS Web Interface measures while ACOs participating in the Medicare Shared Savings Program and Next Generation ACO Model account for more than 80 percent. With an 80 percent reduction and a continued decrease interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures, it is not fiscally viable, feasible, or sustainable for MIPS to continue to make available the CMS Web Interface measures as a collection type/submission type. There would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface. In assessing the utilization of the CMS Web Interface by groups and virtual groups, there has been a substantial decrease in participation each year since the inception of MIPS in the 2017 performance period. From 2017 to 2019, the number of groups eligible to report quality measures via the CMS Web Interface (groups registered to utilize the

CMS Web Interface) decreased by approximately 45 percent. Similarly, the number of groups utilizing the CMS Web Interface as a collection type decreased by approximately 40 percent from 2017 to 2019. In our cost analysis, operating and maintaining the CMS Web Interface for significantly smaller number of groups and virtual groups would not be cost-effective. To operate and maintain the CMS Web Interface measures solely for groups and virtual groups, there would be an increase in cost and needed resources under MIPS associated with the items such as the establishment and maintenance of CMS Web Interface benchmarks, assignment and sampling, technical support, and education and outreach; thus, there would be proportionally higher costs associated with the operationalization and maintenance of the CMS Web Interface with a significantly smaller number of groups and virtual groups utilizing the CMS Web Interface measures as a collection type/submission type.

(ii) Administrative Claims Measure

As discussed in section IV.A.3.c.(1)(d), we are finalizing as proposed to add two new administrative claims measures beginning in the 2021 MIPS performance period and for future performance periods. We acknowledge there are administrative burdens and related financial costs associated with each administrative claims measure that clinicians, groups, and organizations may choose to monitor. However, because these costs can vary significantly due to organizational size, number of administrative claims measures being reported, volume of clinicians reporting each measure, and the specific methods employed to improve performance, we are unable to provide an estimate of the financial impact each clinician, group, or organization may experience. In summary, we are acknowledging that while there is no data submission requirements per § 414.1325(a)(2)(i) for administrative claim measures, there may be associated costs for clinicians and group practices to monitor new administrative claim measures; however, we are unable to quantify that impact.

(iii) Modifications to the Improvement Activities Inventory

As discussed in section IV.A.3.c.(3)(b)(iii) of this final rule, we are finalizing the removal of one obsolete improvement activity, modification of two existing improvement activities, and adoption of the COVID–19 improvement activity added via IFC. We refer readers to Appendix 2 of this final rule for further details. We do not believe these finalized changes to the inventory will impact time or financial burden on stakeholders because MIPS eligible clinicians are still required to submit the same number of activities and the per response time for each activity is uniform. We do not expect these finalized changes to the inventory to affect our currently approved information collection burden estimates in terms of neither the number of estimated respondents nor the burden per response. We anticipate that the vast majority of clinicians performing improvement activities, to comply with existing MIPS policies, will continue to perform the same activities under the policies established in this final rule because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified per rulemaking (82 FR 54175). Most of the improvement activities in the Inventory remain unchanged for the 2020 MIPS performance period.

(c) Stakeholders Nominating Improvement Activities

In section IV.A.3.c.(3)(b)(i)(A)(bb) of this final rule, we are finalizing as proposed to make an exception to the established timeframe for nomination of improvement activities, such that during a PHE, stakeholders can nominate improvement activities outside of the established Annual Call for Activities timeframe. While we expect additional nominations may be received as a result of this exception, we do not have any data with which to estimate what the additional number may be but we assume the additional costs associated with nominating new improvement activities are unchanged. Additionally, in section IV.A.3.c.(3)(b)(ii)(B) of this rule, we are finalizing as proposed beginning with the CY 2021 performance period and future years to consider agency-nominated improvement activities. We are unable to estimate the number of improvement activity nominations we will receive, but similar to the per respondent estimate we have provided in section VII.B.5.j. of this final rule, we assume it will require 3 hours at $55.75/hr for a GS–13 Step 5 to nominate an improvement activity for a total cost of $167.25 (3 hrs × $55.75/hr) per activity.

(iv) Impact on Small Practices

As described in section VIII.H.15.e.(3) of this final rule RIA, we found 85 percent of clinicians who did not submit data to MIPS were in small practices. However, the estimated number of MIPS eligible clinicians who do not submit data and receive a negative payment adjustment, including those in small practices, may be smaller in the CY 2021 performance period due to the PHE for COVID–19. For example, clinicians in small practices may avoid a negative payment adjustment due to non-engagement if they apply for the application-based extreme and uncontrollable circumstances policy exception for the CY 2021 performance period. Furthermore, CMS is committed to identifying flexibilities and options to help clinicians in small practices participate meaningfully and successfully in MIPS. Specifically, CMS excludes individual MIPS eligible clinicians or groups with less than or equal to $90,000 in allowed charges for covered professional services under the Medicare PFS, fewer than or equal to 200 Medicare Part B patients who are furnished covered professional services under the Medicare PFS, or fewer than or equal to 200 covered professional services under the Medicare PFS. We continue to give solo practitioners and practices with 10 or fewer clinicians the choice to form a virtual group to participate with other practices. For the quality performance category, we continue to: (1) Allow clinicians in small practices to continue submitting quality data for covered professional services at both the individual and group level through the Medicare Part B claims submission type; (2) award small practices 3 points for quality measures that don't meet data completeness requirements; and (3) award 6 bonus points to small practices, as long as one measure is submitted. For the Promoting Interoperability performance category, we continue to allow clinicians to apply to have this category reweighted to zero (if not qualified for automatic reweighting) for: (1) Small practices; (2) clinicians with insufficient internet connectivity; (3) clinicians with extreme and uncontrollable circumstances; (4) lack of control over availability of certified EHR technology (CEHRT); and (5) use of decertified EHR technology. For the improvement activities performance category, small practices and those in rural locations and in health professional shortage areas (or HPSAs) have reduced reporting requirements. For small practices or those located in a rural or HPSAs: (1) Medium-weighted activities are worth 20 points of the total category score; and (2) High-weighted activities are worth 40 points of the total category score. Finally, in terms of technical assistance, we launched the Small, Underserved,

and Rural Support initiative to provide free, customized technical assistance to clinicians in small practices. This 5-year program was funded by the Medicare Access and CHIP Reauthorization Act (MACRA). The Quality Payment Program technical assistance initiative in 2017 was part of our comprehensive education and outreach effort to help clinicians successfully participate in the Quality Payment Program. Our technical assistance achieved notable success during the first 2 years of the program, including receiving customer satisfaction ratings of 99.8 percent in 2017 and 98.7 percent in 2018. We also recognize that our technical assistance initiative led to a 95 percent participate rate in 2017.

(d) Impact on Third Party Intermediaries

In section IV.A.3.g. of this rule, we finalized as proposed multiple changes to the third party intermediary regulations at § 414.1400. Specifically, we are: (1) Amending current requirements for approval of third party intermediaries to take into account past performance and provision of inaccurate information regarding MIPS program requirements to eligible clinicians; (2) requiring attendance by all third party intermediaries for training and support sessions; (3) requiring that QCDRs and qualified registries must conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits; (4) incrementally increasing requirements for QCDR measure testing and clarify what is meant by full testing; and (5) requiring third party intermediaries to submit a CAP to address identified deficiencies and data issues as well as actions to prevent recurrence.

With regard to the amendments to current requirements for approval of third party intermediaries, we do not anticipate this to require any additional effort for affected entities as the revision is to allow CMS to utilize already available information to make approval decisions.

The finalized requirement for attendance at training and support sessions and the associated burdens on third parties closely aligns to expectations previously established in the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77374) and (81 FR 77384 through 77386). With regard to survey vendors, we previously finalized the CMS-approved survey vendor approval criteria in § 414.1400(e) as discussed in the CY 2018 PFS final rule (83 FR 59907 through 59908). Among the approval criteria, § 414.1400(e)(3) established the requirement that the entity has successfully completed, and has required its subcontractors to successfully complete, vendor training(s) administered by CMS or its contractors. Therefore, we assume no additional impact for survey vendors as a result of this finalized proposal. We do not have data on the number of health IT vendors that missed training and support sessions, but the most recent data cites 684 health IT developers through program year 2016 of the Medicare EHR Incentive Program.[156] In CY 2019, 16 total training and support sessions were missed by 14 QCDRs and 33 total sessions were missed by 27 qualified registries. Based on historical frequency and duration, we expect future training and support sessions to continue occurring monthly for approximately 2 hours each. For QCDRs and qualified registries, we estimate an impact of 98 hours [(16 sessions by QCDRs + 33 sessions by qualified registries) × 2 hours]. We lack insight into the exact occupation of session attendees, but for estimating purposes we assume a Physician labor rate of $212.78/hr and estimate a total burden of $20,852 ($212.78/hr × 98 hours).

We do not anticipate a significant impact to QCDRs and qualified registries resulting from the finalized proposal to require QCDRs and qualified registries to conduct an annual data validation audit and if one or more deficiencies or data errors are identified also conduct targeted audits. First, we are not revising our burden estimates because the finalized data validation requirements are similar to existing expectations which we have already accounted for the associated burden as stated in the CY 2017 Quality Payment Program final rule (81 FR 77383 through 77384) and the CY 2019 PFS final rule (83 FR 59998 through 59999). Second, we believe that the finalized requirements for conduct of the data validation audits are aligned with methods and procedures which stakeholders currently utilize.

With regard to the proposal to require QCDRs and qualified registries to conduct targeted audits if one or more data errors are identified during data validation audits, we sought comment on the expected frequency of targeted audits and the anticipated scope of effort. We did not receive comments related to the expected frequency of targeted audits and the anticipated scope of the effort. However, we are including burden estimates associated with this finalized requirement in section VII.B.5.c.(2) and (3) of the Collection of Information for this rule. Due to the unknown scope of patient records that may need to be audited, we estimate a range of effort to complete a targeted data audit from a minimum of 5 hours to a maximum of 10 hours at a cost ranging from $462.30 ($92.46/hr × 5 hrs) to $924.60 ($92.46/hr × 10 hrs) per targeted audit. In the 2019 MIPS performance period, 37 of the 84 qualified registries (44%) and 23 of the 77 QCDRs (30%) that submitted 2019 MIPS quality data were required to complete a targeted audit. Based on the results of the 2020 self-nomination period, 58 QCDRs and 127 qualified registries have been approved for the 2021 MIPS performance period; assuming the same percentages, we estimate a total of 73 QCDRs and qualified registries (58 × 30% + 127 × 44%) will be required to complete targeted audits. Per these assumptions, we estimate the total impact associated with completing targeted audits will range from 365 hours (73 audits × 5 hrs/audit) at a cost of $33,748 (73 audits × $462.30/audit) to 730 hours (73 audits × 10 hrs/audit) at a cost of $67,496 (73 audits × $924.60/audit).

Because the finalized proposal to incrementally increase requirements for QCDR measure testing is not changing the requirements for fully testing measures, but is instead implementing an incremental approach to achieve previously finalized requirements, we do not anticipate any additional impact as a result of the finalized policy.

As discussed in section VII.B.5.c.(3) of this rule, we estimate the total burden impact associated with the provision to require CAPs to be 30 hours (10 respondents × 3 hr/respondent) at a cost of $2,774 for all respondents (10 respondents × $277.38/respondent).

f. Assumptions & Limitations

We note several limitations to our estimates of clinicians' MIPS eligibility and participation, negative MIPS payment adjustments, and positive payment adjustments for the 2023 MIPS payment year. Due to the PHE for COVID–19, we are aware that there may be changes in health care delivery and billing patterns that will impact results for the 2023 MIPS payment year that we were not able to model with our historic data sources. The scoring model results presented in this final rule assume that CY 2019 Quality Payment Program data submissions and performance are representative of CY 2021 Quality Payment Program data submissions and performance. The estimated performance for CY 2021 MIPS

[156] *https://dashboard.healthit.gov/quickstats/pages/FIG-Vendors-of-EHRs-to-Participating-Professionals.php.*

performance period using CY 2019 Quality Payment Program data may be underestimated because the performance threshold to avoid a negative payment adjustment for the 2019 MIPS performance period/2021 MIPS payment year was significantly lower (30 out of 100 points) than the performance threshold for the 2021 MIPS performance period/2023 MIPS payment year (60 out of 100). We anticipate clinicians may submit more performance categories to meet the higher performance threshold to avoid a negative payment adjustment. Finally, with the PHE for COVID–19 continuing in the 2021 MIPS performance period, we are uncertain of how many clinicians will apply for extreme and uncontrollable circumstances policy and not be required to submit data to MIPS.

In our MIPS eligible clinician assumptions, we assumed that clinicians who elected to opt-in in the CY 2019 Quality Payment Program and submitted data would continue to elect to opt-in in the CY 2020 performance period. It is difficult to predict whether clinicians will elect to opt-in to participate in MIPS with the finalized policies.

There are additional limitations to our estimates: (1) To the extent that there are year-to-year changes in the data submission, volume and mix of services provided by MIPS eligible clinicians, the actual impact on total Medicare revenues will be different from those shown in Table 109; and (2) our cost data does not overlap with CY 2019 so we may not be capturing performance for all clinicians. Due to the limitations described, there is considerable uncertainty around our estimates that is difficult to quantify.

I. Alternatives Considered

This final rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our policies and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this final rule, we presented the estimated impact on total allowed charges by specialty.

1. Alternatives Considered for the MDPP Expanded Model Emergency Policy

For the MDPP Expanded Model Emergency Policy, no alternatives were considered. If we do not take action it will have an extremely negative impact to MDPP supplier and beneficiaries; which would threaten the success of the entire expanded model; as beneficiaries would become ineligible and not be able to finish the program, MDPP suppliers would not be paid for services rendered, and no new cohorts of set of MDPP services could be started, effectively ending the expanded model test.

2. Alternatives Considered for the Quality Payment Program

For purposes of the payment impact on the Quality Payment Program, we view the performance threshold as a critical factor affecting the distribution of payment adjustments. We ran a separate model with a performance threshold of 50 which was previously proposed in the CY 2021 PFS proposed rule (85 FR 50318) as an alternative to the finalized performance threshold of 60. The model with a performance threshold of 50 has the same mean and median final score as our model of finalized policies since the performance threshold does not change the final score. We estimate that $388 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 4.9 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 4.5 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

In addition, we view the cost performance category weight as a critical factor affecting final scores. We ran two separate models with cost performance category weights of 15 and 30, with corresponding quality performance category weights of 45 and 30, respectively (as an alternative to the finalized cost performance category weight of 20 and quality performance category weight of 40) to estimate the impact of keeping the weights consistent with the CY 2020 PFS final rule and a more aggressive increase in the cost performance category weight. The model with a cost performance category weight of 15 has a mean score of 80.21 and a median score of 86.07. The model with a cost performance category weight of 30 has a mean score of 78.38 and a median score 83.18. We refer readers to section IV.A.3.c.(2)(a) for additional discussion on the selection of the cost performance category weight.

Finally, we report the findings if Web Interface were removed as a collection type in the CY 2021 performance period. The model with the removal of Web Interface as a collection type has a final score mean of 78.36 and median of 83.05. We estimate that $459 million would be redistributed through budget neutrality. There would be a maximum payment adjustment of 6.6 percent after considering the MIPS payment adjustment and the additional MIPS payment adjustment for exceptional performance. In addition, 7.2 percent of MIPS eligible clinicians would receive a negative payment adjustment among those that submit data.

3. Alternatives Considered for Changes Related to Scopes of Practice

With regard to the proposal concerning supervision of diagnostic tests by certain NPPs, an alternative would be to maintain the status quo. That is, we could maintain the basic rule under § 410.32(b)(1) that allows only physicians as defined under Medicare law to supervise the performance of diagnostic tests. In that case, the pool of practitioners who could supervise diagnostic tests would remain at current levels and certain NPPs would be limited under Medicare from practicing to the full extent allowed by their state license and scope of practice. However, this alternative would fail to address the mandates established in E.O. 13890.

With regard to the provision to allow a PTA/OTA to furnish maintenance therapy services, an alternative would be maintaining the status quo to require the PT/OT to personally furnish all maintenance therapy services. However, this alternative would not address the mandates established in E.O. 13890. It would also be inconsistent with our policy in SNF and home health settings when payment for therapy is made under Part A, maintenance therapy can be furnished by a PT/OT or delegated to be performed by a PTA/OTA.

4. Alternatives Considered for Refinements to Values for Certain Services To Reflect Revisions to Payment for Office/Outpatient Evaluation and Management (E/M) Visits and Promote Payment Stability During the PHE for COVID–19

As we noted in section II.F. of this final rule, we sought comment on how we might refine the utilization assumptions for HCPCS add on code G2211. In the proposed rule, we assumed that HCPCS add-on code G2211 would be reported with all office/outpatient visits for the specialties listed in the following public use file at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2020-PFS-FR-EM-Add-on-Code.zip.*

As we discussed in section II.F. of this final rule, we considered alternative assumptions regarding utilization for HCPCS add-on code G2211. Several commenters suggested that CMS reduce its utilization assumptions to between 10 percent and 25 percent of reported office/outpatient E/M visits and could range as high as 25 percent of reported office/outpatient E/M visits. These commenters cited that it would take time for medical societies to educate their members about appropriate use, ongoing implementation of the office/outpatient E/M visit codes, electronic health records integration, and the persistence of the COVID–19 pandemic in many parts of the country. Thus, one alternative was to assume that HCPCS add-on code G2211 would be reported for 25 percent of office/outpatient E/M visits listed in the public use file. As we noted in section II.F. of this final rule, while we generally agree with commenters that practitioners will not report HCPCS add-on code G2211 with every visit, we disagree that it will be as low as 25 percent of all reported visits.

We also considered an alternative where these specialties would report HCPCS add-on code G2211 with their office/outpatient E/M visits 90 percent of the time. As we noted in section II.F. of this final rule, because we are not implementing any additional policies that restrict the billing of this code, we are assuming that utilization will be 90 percent of office/outpatient E/M visits for these specialties.

J. Impact on Beneficiaries

We do not believe these provisions will have a negative impact on beneficiaries given overall PFS budget neutrality.

1. Medicare Diabetes Prevention Program Expanded Model Emergency Policy

This change would have a positive impact on affected MDPP beneficiaries, as it would allow them to maintain eligibility for the program, and request virtual sessions if needed for successful completion of attendance and weight loss milestones. It would also allow them to start set of MDPP services virtually, allowing remote digital technology to capture body weight measurement or self-reported weight measurements from a participant's personal home digital scale. Finally, if continuing with set of MDPP services is not an option for beneficiaries during the PHE for COVID–19, the Emergency Policy allows beneficiaries to restart their set of MDPP services, maximizing beneficiary options and access to MDPP both during the PHE for COVID–19 and after it ends.

2. Quality Payment Program

There are several changes in this rule that would have an effect on beneficiaries. In general, we believe that many of these changes, including those intended to improve accuracy in payment through regular updates to the inputs used to calculate payments under the PFS, would have a positive impact and improve the quality and value of care provided to Medicare beneficiaries. For example, several of the new measures include patient-reported outcomes, which may be used to help patients make more informed decisions about treatment options. Patient-reported outcome measures provide information on a patient's health status from the patient's point of view and may also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which may not otherwise be available through routine clinical data collection. Patient-reported outcomes are factors frequently of interest to patients when making decisions about treatment.

K. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assumed that the total number of unique commenters on this year's proposed rule will be the number of reviewers of this rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the rule. For these reasons we thought that the number of commenters would be a fair estimate of the number of reviewers of this rule. We welcomed any comments on the approach in estimating the number of entities which will review this rule.

We also recognized that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We sought comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this rule. For each facility that reviews the rule, the estimated cost is $885.92 (8.0 hours × $110.74). Therefore, we estimated that the total cost of reviewing this regulation is $35,637,904 ($885.92 × 40,227 reviewers on this year's proposed rule).

L. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Tables 111 and 112 (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2020 to CY 2021 based on the FY 2021 President's Budget baseline.

TABLE 111: Accounting Statement: Classification of Estimated Expenditures

CATEGORY	TRANSFERS
CY 2021 Annualized Monetized Transfers	Estimated increase in expenditures of $0.0 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 112: Accounting Statement: Classification of Estimated Costs, Transfer, and Savings

CATEGORY	TRANSFER
CY 2021 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.0 billion
From Whom to Whom?	Beneficiaries to Federal Government.

M. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides an RIA. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 423

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

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

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

PART 400—INTRODUCTION; DEFINITIONS

■ 1. The authority citation for part 400 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 44 U.S.C. Chapter 35.

■ 2. Section 400.200 is amended by revising the definition of ''Public Health Emergency'' to read as follows:

§ 400.200 General definitions.

* * * * *

Public Health Emergency (PHE) means the Public Health Emergency determined to exist nationwide as of January 27, 2020, by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID–19, including any subsequent renewals.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 3. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 4. Section 410.15 is amended in paragraph (a)—

■ a. By adding a definition for ''A review of any current opioid prescriptions'' in alphabetical order;

■ b. In the definition of ''First annual wellness visit providing personalized prevention plan services'' by revising paragraph (xi) and adding paragraphs (xii) and (xiii);

■ c. In the definition of ''Subsequent annual wellness visit providing personalized prevention plan services'' by revising paragraph (ix) and adding paragraphs (x) and (xi).

The additions and revisions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

* * * * *

First annual wellness visit providing personalized prevention plan services * * *

(xi) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(xii) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xiii) Any other element determined appropriate through the national coverage determination process.

* * * * *

Subsequent annual wellness visit providing personalized prevention plan services * * *

(ix) Furnishing of a review of any current opioid prescriptions as that term is defined in this section.

(x) Screening for potential substance use disorders including a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(xi) Any other element determined appropriate through the national coverage determination process.

* * * * *

■ 5. Section 410.16 is amended in paragraph (a)—

■ a. By adding the definition for ''A review of any current opioid prescriptions'' in alphabetical order;

■ b. In the definition of ''Initial preventive physical examination'' by revising paragraphs (6) and (7) and adding paragraphs (8) and (9).

The additions and revisions read as follows:

§ 410.16 Initial preventive physical examination: Conditions for and limitations on coverage.

(a) * * *

A review of any current opioid prescriptions means, with respect to the individual determined to have a current prescription for opioids, all of the following:

(i) A review of the potential risk factors to the individual for opioid use disorder;

(ii) An evaluation of the individual's severity of pain and current treatment plan;

(iii) The provision of information on non-opioid treatment options; and

(iv) A referral to a specialist, as appropriate.

* * * * *

Initial preventive physical examination * * *

(6) A review of any current opioid prescriptions as defined in this section.

(7) Screening for potential substance use disorders to include a review of the individual's potential risk factors for substance use disorder and referral for treatment as appropriate.

(8) Education, counseling, and referral, as deemed appropriate by the physician or qualified nonphysician practitioner, based on the results of the review and evaluation services described in this section.

(9) Education, counseling, and referral, including a brief written plan such as a checklist provided to the individual for obtaining an electrocardiogram, as appropriate, and the appropriate screening and other preventive services that are covered as separate Medicare Part B benefits as described in sections 1861(s)(10), (jj), (nn), (oo), (pp), (qq)(1), (rr), (uu), (vv), (xx)(1), (yy), (bbb), and (ddd) of the Act.

* * * * *

■ 6. Section 410.32 is amended by—

■ a. Revising paragraphs (b)(1) and (b)(2)(iii)(B);

■ b. Adding paragraph (b)(2)(ix); and

■ c. Revising paragraph (b)(3)(ii).

The revisions and addition read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(1) *Basic rule.* Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act or, to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) * * *

(iii) * * *

(B) Furnished under the general supervision of a physician or clinical psychologist; or under the general supervision of a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist or certified nurse-midwife, to the extent they are authorized to perform the tests under their scope of practice and applicable State laws.

* * * * *

(ix) Diagnostic tests performed by a physician assistant authorized to perform the tests under their scope of practice and applicable State laws.

(3) * * *

(ii) *Direct supervision* in the office setting means the physician (or other supervising practitioner) must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician (or other supervising practitioner) must be present in the room when the procedure is performed. Until the later of the end of the calendar year in which the PHE as defined in § 400.200 of this chapter ends or, December 31, 2021, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

* * * * *

■ 7. Section 410.67 is amended—

■ a. In paragraph (b), by revising paragraph (7) and adding paragraph (8) in the definition of ''Opioid use disorder treatment service'';

■ b. By revising paragraph (d)(2)(i)(A); and

■ c. By adding paragraph (d)(4)(i)(E).

The additions and revision read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

Opioid use disorder treatment service * * *

(7) Periodic assessment services required under § 8.12(f)(4) of this title, that are furnished during a face-to-face encounter, including services furnished via two-way interactive audio-video communication technology, as clinically appropriate, and in compliance with all applicable requirements. During the Public Health Emergency, as defined in § 400.200 of this chapter, in cases where a beneficiary does not have access to two-way audio-video communications technology, periodic assessments can be furnished using audio-only telephone calls if all other applicable requirements are met.

(8) Opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug, and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication.

* * * * *

(d) * * *

(2) * * *

(i) * * *

(A) *Implantable and injectable medications.* For implantable and injectable medications, the payment is determined using the methodology set forth in section 1847A of the Act, except that the payment amount must be 100 percent of the ASP, if ASP is used; and the payment must be 100 percent of the wholesale acquisition cost (WAC), if WAC is used.

* * * * *

(4) * * *

(i) * * *

(E) Take-home supply of opioid antagonist medications that are approved by the Food and Drug Administration under section 505 of the Federal, Food, Drug and Cosmetic Act for the emergency treatment of known or suspected opioid overdose and overdose education furnished in conjunction with opioid antagonist medication, an adjustment will be made when these medications are dispensed. This adjustment will be limited to once every 30 days, except when a further take home supply of these medications is medically reasonable and necessary. The opioid treatment program must document in the medical record the reason(s) for the exception. The amount of the drug component of the

adjustment will be determined using the methodology in paragraph (d)(2)(i) of this section. The amount of the non-drug component of the adjustment will be determined based on the CY 2020 Medicare payment rate for CPT code 96161.

* * * * *

■ 8. Section 410.78 is amended by revising paragraph (a)(3) and (f) to read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

* * * * *

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph (f), changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. During the Public Health Emergency, as defined in § 400.200 of this chapter, we will use a subregulatory process to modify the services included on the Medicare telehealth list during the Public Health Emergency, taking into consideration infection control, patient safety, and other public health concerns resulting from the emergency. CMS maintains the list of services that are Medicare telehealth services under this section, including the current HCPCS codes that describe the services on the CMS website.

■ 9. Section 410.79 is amended by revising paragraphs (c)(3)(i) and (ii) and (e) to read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(c) * * *

(3) * * *

(i) Except as set forth in paragraph (c)(3)(ii) of this section—

(A) The MDPP services period ends upon completion of the core services period described in paragraph (c)(2)(i) of this section, unless the MDPP beneficiary qualifies for the first ongoing maintenance session interval, in accordance with paragraph (c)(1)(ii) of this section.

(B) If the MDPP beneficiary qualifies for the first ongoing maintenance session interval as described in paragraph (c)(1)(ii) of this section, the MDPP services period ends upon completion of that maintenance session interval, unless the MDPP beneficiary qualifies for a subsequent ongoing maintenance session interval, in accordance with paragraph (c)(1)(iii) of this section, in which case the MDPP service period ends upon completion of the last ongoing maintenance session interval for which the beneficiary qualified.

(ii) In the case of an applicable 1135 waiver event as defined in paragraph (e) of this section, the MDPP services period may be suspended and resumed or restarted in accordance with paragraph (e) of this section.

* * * * *

(e) *MDPP expanded model emergency policy.* (1) Notwithstanding paragraphs (a) through (d) of this section, the policies described in this paragraph (e) apply during the Public Health Emergency (PHE) as defined in § 400.200 of this chapter and during any future 1135 waiver event that CMS determines may disrupts in-person MDPP services (an ''applicable 1135 waiver event''). For purposes of this paragraph (e), ''1135 waiver event'' means an emergency period and emergency area, as such terms are defined in section 1135(g) of the Act, for which the Secretary has authorized one or more waivers under section 1135 of the Act.

(2)(i) CMS determines that an 1135 waiver event may disrupt in-person MDPP services if MDPP suppliers would likely be unable to conduct classes in-person, or MDPP beneficiaries would likely be unable to attend in-person classes, for reasons related to health, safety, or site availability or suitability. Health and safety reasons may include, but are not limited to, the avoidance of transmission of contagious diseases, compliance with laws and regulations during an 1135 waiver event, or the physical safety of MDPP beneficiaries and MDPP coaches, as defined in § 424.205(a) of this chapter, during an 1135 waiver event.

(ii) If CMS determines that an 1135 waiver event may disrupt in-person MDPP services, CMS will communicate such determination for purposes of the policies described in this paragraph (e), to all affected MDPP suppliers.

(3) The following changes apply under this paragraph (e), when CMS has determined that an 1135 waiver event may disrupt in-person MDPP services:

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A) and (c)(1)(iii)(A) of this section do not apply.

(ii) MDPP suppliers may start new cohorts during the PHE as defined in § 400.200 of this chapter or an applicable 1135 waiver event only if a baseline weight measurement can be obtained as described in paragraph (e)(3)(iii) of this section.

(iii) MDPP suppliers can obtain weight measurements for MDPP beneficiaries for the baseline weight and any weight loss based performance achievement goals in the following manner:

(A) In-person, when the weight measurement can be obtained safely and in compliance with all applicable laws and regulations;

(B) Via digital technology, such as scales that transmit weights securely via wireless or cellular transmission; or

(C) Self-reported weight measurements from the at-home digital scale of the MDPP beneficiary. Self-reported weights must be obtained during live, synchronous online video technology, such as video chatting or video conferencing, wherein the MDPP coach observes the beneficiary weighing themselves and views the weight indicated on the at-home digital scale, a date-stamped photo or video recording of the beneficiary's weight with the beneficiary visible on the scale, or a recording of the beneficiary's weight, with the beneficiary visible on the scale, submitted by the MDPP beneficiary to the MDPP supplier. The photo or video must clearly document the weight of the MDPP beneficiary as it appears on his/her digital scale on the date associated with the billable MDPP session.

(iv) The virtual session limits described in paragraphs (d)(2) and (d)(3)(i) and (ii) of this section do not apply, and MDPP suppliers may provide all MDPP sessions virtually during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event. If the beneficiary began the MDPP services period virtually, or changed from in-person to virtual services during the PHE as defined in § 400.200 of this chapter or applicable 1135 waiver event, he/she may continue to receive the MDPP set of services virtually even after the PHE or 1135 waiver event has concluded, until the end of the beneficiary's MDPP services period, so long as the provision of virtual services complies with all of the following requirements:

(A) The curriculum furnished during the virtual session addresses the same CDC-approved DPP curriculum topic as the regularly scheduled session.

(B) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session on the same day as a regularly scheduled session.

(C) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session per week.

(D) Virtual sessions are furnished in a manner consistent with the DPRP standards for virtual sessions.

(E) The MDPP supplier offers virtual sessions only upon an individual MDPP beneficiary's request or agreement to receive services virtually.

(F) The MDPP supplier offers to an MDPP beneficiary:

(*1*) No more than 16 virtual sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(*2*) No more than 6 virtual sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period; and

(*3*) No more than 12 virtual sessions offered monthly during the ongoing maintenance session intervals, months 13 through 24.

(v) MDPP suppliers may suspend the in-person delivery of the set of MDPP services, when necessary due to the applicable 1135 waiver event, and subsequently resume in-person services either upon the end date of the 1135 waiver event emergency period or an effective date specified by CMS. Upon resumption of the set of MDPP services on an in-person basis, the following paragraphs apply:

(A) Beneficiaries who were receiving MDPP services as of March 31, 2020 whose in-person sessions are suspended due to the PHE as defined in § 400.200 of this chapter may elect to restart the set of MDPP services at the beginning or resume with the most recent attendance session of record.

(B) Beneficiaries who begin the set of MDPP services on or after January 1, 2021 who are in the first 12 months of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may elect to restart the set of MDPP services at the beginning or may resume with the most recent attendance session of record.

(C) Beneficiaries who began the set of MDPP services on or after January 1, 2021 who are in the second year of the set of MDPP services as of the start of an applicable 1135 waiver event, whose in-person sessions are suspended due to the applicable 1135 waiver event, and who elect not to continue with MDPP services virtually, may restart the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event or may resume with the most recent attendance session of record.

(D) Beneficiaries whose in-person sessions are suspended due to the applicable 1135 waiver event who elect to continue with MDPP services virtually, as described in paragraph (e)(2)(i) of this section, are not eligible to restart the set of MDPP services at a later date, but may elect to suspend the virtual set of MDPP services and resume the set of in-person MDPP services with the most recent attendance session of record.

(E) Beneficiaries may make an election as described in paragraph (e)(3)(v)(A), (B), (C), or (D) of this section, as applicable, only one time per applicable1135 waiver event.

(F) Beneficiary eligibility, as described in paragraph (c)(1)(i) of this section, will not be impacted by any changes to the beneficiary's body mass index (BMI) or reduction in hemoglobin A1c, fasting plasma glucose, or 2-hour plasma glucose test values achieved during the set of MDPP services or any intervening time in which a beneficiary has suspended the set of MDPP services. MDPP suppliers will utilize the following weight measurements as the baseline weight for purposes of determining all weight-loss achievements:

(*1*) For an MDPP beneficiary who began receiving the set of MDPP services before March 31, 2020, has suspended services during an applicable 1135 waiver event, and then elects to restart the set of MDPP services at the first core session, the MDPP supplier must record a new baseline weight on the date of first core session that restarts the set of MDPP services.

(*2*) For an MDPP beneficiary who began receiving the set of MDPP services on or after January 1, 2021, has suspended services during an applicable 1135 waiver event, and then resumes the set of MDPP services either at the most recent attendance session of record or restarts the ongoing maintenance session interval in which they were participating at the start of the applicable 1135 waiver event, the MDPP supplier must use the baseline weight recorded at the beneficiary's first core session.

(vi) The minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in paragraphs (c)(1)(ii)(B) and (c)(1)(iii)(B) of this section are waived only for MDPP beneficiaries who were receiving the MDPP set of services prior to January 1, 2021.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 10. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 11. Section 414.502 is amended by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period, except that for the data reporting period of January 1, 2022 through March 31, 2022, the data collection period is January 1, 2019 through June 30, 2019.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period, except that for the data collection period of January 1, 2019 through June 30, 2019, the data reporting period is January 1, 2022 through March 31, 2022.

* * * * *

■ 12. Section 414.504 is amended by revising paragraph (a)(1) to read as follows:

§ 414.504 Data reporting requirements.

(a) * * *

(1) For CDLTs that are not ADLTs, initially January 1, 2017 and every 3 years beginning January 1, 2022.

* * * * *

■ 13. Section 414.507 is amended by revising paragraphs (d) introductory text and (d)(4) and adding paragraph (d)(7) to read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2024, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(4) 2021—0.0 percent of the payment rate established in 2020.

* * * * *

(7) 2024—15 percent of the payment rate established in 2023.

* * * * *

■ 14. Section 414.1305 is amended—
■ a. By revising the definition of ''Attestation'';
■ b. In the definition of ''Certified Electronic Health Record Technology (CEHRT)'' by revising paragraphs (1)(ii)(D) and (2)(ii) introductory text;
■ c. By revising the definition of ''Collection type'';
■ d. By removing the definition of ''Full TIN APM'';
■ e. By revising the definitions of ''Low-volume threshold'', ''Meaningful EHR user for MIPS'', and ''MIPS APM'';
■ f. By adding definition for ''Physician Compare'' in alphabetical order; and
■ g. By revising the definitions of ''Primary care services'', ''Submission type'', and ''Submitter type''.

The revisions and addition read as follows:

§ 414.1305 Definitions.

* * * * *

Attestation means a secure mechanism, specified by CMS, with respect to a particular performance period, whereby a MIPS eligible clinician or group may submit the required data for the Promoting Interoperability or the improvement activities performance categories of MIPS in a manner specified by CMS.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * * *

(1) * * *

(ii) * * *

(D) The certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category, including the applicable measure calculation certification criterion at 45 CFR 170.314(g)(1) or (2) or 45 CFR 170.315(g)(1) or (2) for all certification criteria that support an objective with a percentage-based measure.

* * * * *

(2) * * *

(ii) Necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category including the following:

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS Clinical Quality Measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; for the 2019 through 2023 MIPS payment years, CMS Web Interface measures; the CAHPS for MIPS survey; and administrative claims measures.

* * * * *

Low-volume threshold means:

(1) For the 2019 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has Medicare Part B allowed charges less than or equal to $30,000 or provides care for 100 or fewer Medicare Part B-enrolled individuals.

(2) For the 2020 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the low-volume threshold determination period described in paragraph (4) of this definition, has allowed charges for covered professional services less than or equal to $90,000 or furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals.

(3) For the 2021 and 2022 MIPS payment years, the low-volume threshold that applies to an individual eligible clinician, group, or APM Entity group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

(4) For the 2019 and 2020 MIPS payment years, the low-volume threshold determination period is a 24-month assessment period consisting of:

(i) An initial 12-month segment that spans from the last 4 months of the calendar year 2 years prior to the performance period through the first 8 months of the calendar year preceding to the performance period; and

(ii) A second 12-month segment that spans from the last 4 months of the calendar year 1 year prior to the performance period through the first 8 months of the calendar year performance period. An individual eligible clinician, group, or APM Entity group that is identified as not exceeding the low-volume threshold during the initial 12-month segment will continue to be excluded under § 414.1310(b)(1)(iii) for the applicable year regardless of the results of the second 12-month segment analysis. For the 2019 MIPS payment year, each segment of the low-volume threshold determination period includes a 60-day claims run out. For the 2020 MIPS payment year, each segment of the low-volume threshold determination period includes a 30-day claims run out.

(5) Beginning with the 2023 MIPS payment year, the low-volume threshold that applies to an individual eligible clinician, or group that, during the MIPS determination period, has allowed charges for covered professional services less than or equal to $90,000, furnishes covered professional services to 200 or fewer Medicare Part B-enrolled individuals, or furnishes 200 or fewer covered professional services to Medicare Part B-enrolled individuals.

Meaningful EHR user for MIPS means a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, and reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, supports information exchange and the prevention of health information blocking, and engages in activities related to supporting providers with the performance of CEHRT.

* * * * *

MIPS APM means:

(1) For the 2019 through 2022 MIPS payment years, an APM that meets the criteria specified under § 414.1370(b).

(2) Beginning with the 2023 MIPS payment year, an APM that meets the criteria as set forth in § 414.1367(b).

* * * * *

Physician Compare means the Physician Compare internet website of the Centers for Medicare & Medicaid Services (or a successor website).

Primary care services for purposes of CMS Web Interface and CAHPS for MIPS survey beneficiary assignment means the set of services identified by the following:

(1) CPT codes:

(i) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient); 99304 through 99318 (codes for professional services furnished in a nursing facility, excluding professional services furnished in a SNF for claims identified by place of service (POS) modifier 31); 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit); 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by POS modifier 12); 99487, 99489, and 99490 (codes for chronic care management); and 99495 and 99496 (codes for transitional care management services); and

(ii) Beginning with the 2023 MIPS payment year, 99421, 99422, and 99423 (codes for online digital evaluation and management services (e-visit)); 99441,

99442, and 99443 (codes for telephone evaluation and management services); and 96160 and 96161 (codes for administration of health risk assessment).

(2) HCPCS codes:

(i) G0402 (code for the Welcome to Medicare visit); and G0438 and G0439 (codes for the annual wellness visits); and

(ii) Beginning with the 2023 MIPS payment year, G2010 (code for remote evaluation of patient video/images); and G2012 (code for virtual check-in).

* * * * *

Submission type means the mechanism by which the submitter type submits data to CMS, including, but not limited to:

(1) Direct;

(2) Log in and upload;

(3) Log in and attest;

(4) Medicare Part B claims; and

(5) For the 2019 through 2023 MIPS payment years, the CMS Web Interface.

Submitter type means the MIPS eligible clinician, group, Virtual Group, APM Entity, or third party intermediary acting on behalf of a MIPS eligible clinician, group, Virtual Group, or APM Entity, as applicable, that submits data on measures and activities under MIPS.

* * * * *

■ 15. Section 414.1310 is amended by revising paragraphs (b)(1)(iii) and (e)(1) to read as follows:

§ 414.1310 Applicability.

* * * * *

(b) * * *

(1) * * *

(iii) Does not exceed the low volume threshold.

(A) Beginning with the 2021 MIPS payment year, if an individual eligible clinician or group exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the individual eligible clinician or group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such solo practitioners and groups that elect to participate in MIPS as a virtual group (except for APM Entity groups in MIPS APMs), the virtual group election under § 414.1315 constitutes an election under this paragraph (b)(1)(iii)(A) and results in the solo practitioners and groups being treated as MIPS eligible clinicians for the applicable MIPS payment year.

(B) For the 2021 and 2022 MIPS payment years, if an APM Entity group in a MIPS APM exceeds at least one, but not all, of the low-volume threshold criteria and elects to participate in MIPS as a MIPS eligible clinician, the APM Entity group is treated as a MIPS eligible clinician for the applicable MIPS payment year. For such APM Entity groups in MIPS APMs, only the APM Entity group election can result in the APM Entity group being treated as MIPS eligible clinicians for the applicable MIPS payment year.

* * * * *

(e) * * *

(1) Except as provided under §§ 414.1317(b) and 414.1370(f)(2), each MIPS eligible clinician in the group will receive a MIPS payment adjustment factor (or additional MIPS payment adjustment factor) based on the group's combined performance assessment.

* * * * *

■ 16. Section 414.1317 is added to read as follows:

§ 414.1317 APM Entity groups.

(a) *APM entity group determination.* The APM Entity group will be determined according to the requirements set forth in § 414.1425(b)(1).

(1) In addition to the dates set forth in § 414.1425(b)(1), for purposes of MIPS, the APM Entity group includes an eligible clinician who is on a Participation List on December 31 of the MIPS performance period.

(2) For purposes of MIPS scoring, the APM Entity group will be comprised only of those eligible clinicians within the APM Entity group who are determined to be MIPS eligible at the individual or group level.

(3) For purposes of calculating the APM Entity group score, MIPS scores submitted by virtual groups will not be included.

(b) *APM Entity group scoring.* The MIPS final score calculated for the APM Entity is applied to each MIPS eligible clinician in the APM Entity group. The MIPS payment adjustment is applied at the TIN/NPI level for each of the MIPS eligible clinicians in the APM Entity group.

(1) *Determination of performance category score for each MIPS eligible clinician in an APM Entity.* For APM Entities, where a performance category is not reported by the APM Entity, CMS uses one score for each MIPS eligible clinician in an APM Entity group to derive a single average APM Entity score for the performance category. The applicable score for each MIPS eligible clinician is the higher of either:

(i) A group score based on the measure data for the performance category reported by a TIN for the MIPS eligible clinician according to MIPS submission and reporting requirements for groups.

(ii) An individual score based on the measure data for the performance category reported by the MIPS eligible clinician according to MIPS submission and reporting requirements for individuals.

(iii) In the event that a MIPS eligible clinician in an APM Entity receives an exception from the reporting requirements, such eligible clinician will be assigned a null score when CMS calculates the APM Entity's performance category score.

(2) *Cost scoring for APM Entity groups.* The cost performance category weight is zero percent for APM Entities in MIPS APMs.

(3) *Improvement scoring for APM Entity groups.* For an APM Entity for which CMS calculated a total performance category score for one or more participants in the APM Entity for the preceding MIPS performance period, CMS calculates an improvement score for each performance category for which a previous year's total performance category score is available as specified in § 414.1380(b).

(4) *Extreme and uncontrollable circumstances.* Beginning with the 2022 MIPS payment year, an APM Entity may submit to CMS an application described at § 414.1380(c)(2)(i)(A)(*6*) and (c)(2)(i)(C)(2) requesting reweighting of all four MIPS performance categories and for all MIPS eligible clinicians in the APM Entity group, based on extreme and uncontrollable circumstances.

(i) An APM Entity must demonstrate in its application to CMS that greater than 75 percent of its participant MIPS eligible clinicians would be eligible for reweighting the Promoting Interoperability performance category for the applicable performance period.

(ii) If CMS approves the request for reweighting based on an APM Entity's application, and if MIPS data are submitted for the APM Entity for the applicable performance period, all four of the MIPS performance categories will be reweighted for the APM Entity group notwithstanding the data submission.

■ 17. Section 414.1320 is amended by revising paragraphs (d) introductory text and (d)(1) and adding paragraph (g) to read as follows:

§ 414.1320 MIPS performance period.

* * * * *

(d) Beginning with the 2023 MIPS payment year, the performance period for:

(1) The quality and cost performance categories is the full calendar year (January 1 through December 31) that occurs 2 years prior to the applicable MIPS payment year, except as otherwise specified for administrative claims-

based measures in the MIPS final list of quality measures described in § 414.1330(a)(1).

* * * * *

(g) For purposes of the 2024 MIPS payment year and each subsequent MIPS payment year, the performance period for:

(1) The Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year.

(2) [Reserved]

■ 18. Section 414.1325 is amended by revising paragraph (c)(1) to read as follows:

§ 414.1325 Data submission requirements.

* * * * *

(c) * * *

(1) For the quality performance category, the direct; login and upload; Medicare Part B claims (beginning with the 2021 MIPS payment year, for small practices only); and for the 2019 through 2023 MIPS payment years, CMS Web Interface (for groups consisting of 25 or more eligible clinicians or a third party intermediary submitting on behalf of a group) submission types.

* * * * *

■ 19. Section 414.1330 is amended by adding paragraphs (b)(4) and (5) to read as follows:

§ 414.1330 Quality performance category.

* * * * *

(b) * * *

(4) 40 percent of a MIPS eligible clinician's final score for the MIPS payment year 2023.

(5) 30 percent of a MIPS eligible clinician's final score for the MIPS payment year 2024 and future years.

■ 20. Section 414.1350 is amended by adding paragraphs (d)(4) and (5) to read as follows:

§ 414.1350 Cost performance category.

* * * * *

(d) * * *

(4) 20 percent of the MIPS final score for MIPS payment year 2023.

(5) 30 percent of the MIPS final score for MIPS payment year 2024 and each subsequent MIPS payment year.

■ 21. Section 414.1367 is added to read as follows:

§ 414.1367 APM performance pathway.

(a) *General.* Beginning with the 2023 MIPS payment year, the APM Performance Pathway is a MIPS scoring methodology available to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM.

(b) *Criteria for MIPS APMs.* MIPS APMs are those in which:

(1) APM Entities participate in the APM under an agreement with CMS or through a law or regulation; and

(2) The APM bases payment on quality measures and cost/utilization.

(c) *MIPS performance category scoring in the APM Performance Pathway*—(1) *Quality.* Except as provided in paragraphs (c)(1)(i) and (ii) of this section, the quality performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(1) based on the APM Performance Pathway quality measure set established by CMS through rulemaking for a MIPS payment year.

(i) Each submitted measure that does not have a benchmark or meet the case minimum requirement is excluded from the MIPS eligible clinician, group, or APM Entity group's total measure achievement points and total available measure achievement points.

(ii) Any measure that is identified as topped out is not subject to the scoring cap described at § 414.1380(b)(1)(iv).

(2) *Cost.* The cost performance category weight is zero percent for MIPS eligible clinicians who are scored through the APM Performance Pathway.

(3) *Improvement activities.* The improvement activities performance category score is calculated for a MIPS eligible clinician, group, or APM Entity group in accordance with § 414.1380(b)(3) based on the activities required by the MIPS APM that are included in the MIPS final inventory of improvement activities described in § 414.1355(a) (excluding any such activities that the MIPS eligible clinician, group, or APM Entity group does not perform). MIPS eligible clinicians, groups, or APM Entities may report additional improvement activities in accordance with § 414.1360.

(4) *Promoting interoperability.* The promoting interoperability performance category will be scored for the MIPS eligible clinician, group, or APM Entity as described in § 414.1375.

(d) *APM Performance Pathway performance category weights*—(1) *Performance category weights.* Subject to paragraph (d)(2) of this section, the performance category weights used to calculate the final score for a MIPS eligible clinician, group, or APM Entity reporting through the APM performance Pathway are:

(i) Quality: 50 percent.

(ii) Cost: 0 percent.

(iii) Improvement Activities: 20 percent.

(iv) Promoting Interoperability: 30 percent.

(2) *Reweighting MIPS performance categories.* If CMS determines, in accordance with § 414.1380(c)(2), that a different scoring weight should be assigned to the quality or promoting interoperability performance category, CMS will redistribute the performance category weights as follows:

(i) If CMS reweights the quality performance category to 0 percent: Promoting Interoperability performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(ii) If CMS reweights the Promoting Interoperability performance category to 0 percent: Quality performance category is reweighted to 75 percent, and Improvement Activities performance category is reweighted to 25 percent.

(e) *Final score.* The final score is calculated for a MIPS eligible clinician, group, or APM Entity in accordance with § 414.1380(c).

■ 22. Section 414.1370 is amended by revising paragraph (a) to read as follows:

§ 414.1370 APM scoring standard under MIPS.

(a) *General.* For the 2019 through 2022 MIPS payment years, the APM scoring standard is the MIPS scoring methodology applicable for MIPS eligible clinicians identified on the Participation List for the performance period of an APM Entity participating in a MIPS APM.

* * * * *

■ 23. Section 414.1380 is amended—

■ a. By revising paragraph (b)(1)(i) introductory text;

■ b. In paragraph (b)(1)(i)(A)(*1*) by removing ''for the 2019 through 2022 MIPS payment years'' and adding in its place ''for the 2019 through 2023 MIPS payment years'';

■ c. By revising paragraphs (b)(1)(iii);

■ d. In paragraph (b)(1)(v)(A)(*1*)(*ii*) by removing ''For the 2019 through 2022 MIPS payment years'' and adding in its place ''For the 2019 through 2023 MIPS payments years'';

■ e. In paragraph (b)(1)(v)(B)(*1*)(*i*) by removing ''For the 2019 through 2022 MIPS payment years'' and adding in its place ''For the 2019 through 2023 MIPS payment years'';

■ f. In paragraph (b)(1)(vi)(C)(*4*) by removing ''For the 2020 through 2022 MIPS payment years'' and adding in its place ''For the 2020 through 2023 MIPS payment years'';

■ g. By revising paragraph (b)(1)(vii)(A);

■ h. By removing paragraph (b)(1)(viii);
■ i. By revising paragraphs (c)(2)(i)(A)(*4*) and (*5*);
■ j. By adding paragraphs (c)(2)(ii)(E) and (F);
■ k. By revising paragraph (c)(3) introductory text and (c)(3)(iii); and
■ l. By adding paragraph (c)(3)(iv).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(i) *Measure achievement points.* For the 2019 through 2023 MIPS payment years, MIPS eligible clinicians receive between 3 and 10 measure achievement points (including partial points) for each measure required under § 414.1335 on which data is submitted in accordance with § 414.1325 that has a benchmark at paragraph (b)(1)(ii) of this section, meets the case minimum requirement at paragraph (b)(1)(iii) of this section, and meets the data completeness requirement at § 414.1340 and for each administrative claims-based measure that has a benchmark at paragraph (b)(1)(ii) of this section and meets the case minimum requirement at paragraph (b)(1)(iii) of this section. The number of measure achievement points received for each such measure is determined based on the applicable benchmark decile category and the percentile distribution. MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 on which no data is submitted in accordance with § 414.1325. MIPS eligible clinicians that submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the required measures with the greatest number of measure achievement points. Beginning with the 2021 MIPS payment year, MIPS eligible clinicians that submit data in accordance with § 414.1325 on a single measure via multiple collection types are scored only on the data submission with the greatest number of measure achievement points.

* * * * *

(iii) *Minimum case requirements.* Except as otherwise specified for administrative claims-based measures in the MIPS final list of quality measures described in § 414.1330(a)(1), the minimum case requirement is 20 cases.

* * * * *

(vii) * * *

(A) For each measure that is submitted, if applicable, and impacted by significant changes, performance is based on data for 9 consecutive months of the applicable CY performance period. If such data are not available or may result in patient harm or misleading results, the measure is excluded from a MIPS eligible clinician's total measure achievement points and total available measure achievement points. For purposes of this paragraph (b)(1)(vii)(A), ''significant changes'' means changes to a measure that are outside the control of the clinician and its agents and that CMS determines may result in patient harm or misleading results. Significant changes include, but are not limited to, changes to codes (such as ICD–10, CPT, or HCPCS codes), clinical guidelines, or measure specifications. CMS will publish on the CMS website a list of all measures scored under this paragraph (b)(1)(vii)(A) as soon as technically feasible, but by no later than the beginning of the data submission period at § 414.1325(e)(1).

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(*4*) For the Promoting Interoperability performance category for the 2021, 2022 and 2023 MIPS payment years, the MIPS eligible clinician is a physical therapist, occupational therapist, clinical psychologist, qualified audiologist, qualified speech-language pathologist, or a registered dietitian or nutrition professional. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

(*5*) For the Promoting Interoperability performance category for the 2019, 2020, 2021, 2022, and 2023 MIPS payment years, the MIPS eligible clinician is a nurse practitioner, physician assistant, clinical nurse specialist, or certified registered nurse anesthetist. In the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(ii) * * *

(E) For the 2023 MIPS payment year:

TABLE 6 TO PARAGRAPH (c)(2)(ii)(E)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	40	20	15	25
No Cost	55	0	15	30
No Promoting Interoperability	65	20	15	0
No Quality	0	20	15	65
No Improvement Activities	55	20	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	80	20	0	0
No Quality and no Improvement Activities	0	20	0	80

(F) For the 2024 MIPS payment year:

TABLE 7 TO PARAGRAPH (c)(2)(ii)(F)

Reweighting scenario	Quality (%)	Cost (%)	Improvement activities (%)	Promoting Interoperability (%)
No Reweighting Needed:				
Scores for all four performance categories	30	30	15	25
No Cost	55	0	15	30
No Promoting Interoperability	55	30	15	0
No Quality	0	30	15	55
No Improvement Activities	45	30	0	25
No Cost and no Promoting Interoperability	85	0	15	0
No Cost and no Quality	0	0	15	85
No Cost and no Improvement Activities	70	0	0	30
No Promoting Interoperability and no Quality	0	50	50	0
No Promoting Interoperability and no Improvement Activities	70	30	0	0
No Quality and no Improvement Activities	0	30	0	70

* * * * *

(3) *Complex patient bonus.* For the 2020, 2021, 2022, and 2023 MIPS payment years, provided that a MIPS eligible clinician, group, virtual group or APM entity submits data for at least one MIPS performance category for the applicable performance period for the MIPS payment year, a complex patient bonus will be added to the final score for the MIPS payment year, as follows:

* * * * *

(iii) The complex patient bonus cannot exceed 5.0 except as provided in paragraph (c)(3)(iv) of this section.

(iv) For the 2022 MIPS payment year, the complex patient bonus is calculated pursuant to paragraphs (c)(3)(i) and (ii) of this section, and the resulting numerical value is then multiplied by 2.0. The complex patient bonus cannot exceed 10.0.

* * * * *

■ 24. Section 414.1400 is amended—

■ a. By revising paragraphs (a)(2)(i) and (ii) and (a)(4);

■ b. By revising paragraph (b) heading and paragraph (b)(2) introductory text;

■ c. By adding paragraphs (b)(2)(iv) and (v);

■ d. By adding paragraphs (b)(3)(v)(C)(*1*) and (*2*);

■ e. By revising paragraphs (b)(3)(v)(E) and (b)(3)(vi);

■ f. By removing paragraphs (b)(3)(vii)(H) and (L);

■ g. By redesignating paragraphs (b)(3)(vii)(I), (J), (K), (M), and (N) as paragraphs (b)(3)(vii)(H), (I), (J), (K), and (L), respectively;

■ h. By revising paragraph (c) heading;

■ i. By adding paragraphs (c)(2)(iii) and (iv); and

■ j. By revising paragraph (f)(1)(i).

The additions and revisions read as follows:

§ 414.1400 Third party intermediaries.

(a) * * *

(2) * * *

(i) Except as provided under paragraph (a)(2)(ii) of this section, QCDRs, qualified registries, and Health IT vendors must be able to submit data for all of the following MIPS performance categories:

(A) Quality, except:

(*1*) The CAHPS for MIPS survey; and

(*2*) For qualified registries and Health IT vendors, QCDR measures;

(B) Improvement activities; and

(C) Promoting Interoperability, if the eligible clinician, group, or virtual group is using CEHRT; however, a third party intermediary may be excepted from this requirement if its MIPS eligible clinicians, groups or virtual groups fall under the reweighting policies at § 414.1380(c)(2)(i)(A)(*4*) or (*5*) or (c)(2)(i)(C)(*1*) through (*7*) or (c)(2)(i)(C)(*9*).

(ii) Health IT vendors that do not support MIPS Value Pathways must be able to submit data for at least one of the MIPS performance categories described in paragraphs (a)(2)(i)(A) through (C) of this section.

* * * * *

(4) Third party intermediary approval criteria—

(i) To be approved as a third party intermediary, an entity must agree to meet the applicable requirements of this section, including, but not limited to, the following:

(A) A third party intermediary's principle place of business and retention of any data must be based in the U.S.

(B) If the data is derived from CEHRT, a QCDR, qualified registry, or health IT vendor must be able to indicate its data source.

(C) All data must be submitted in the form and manner specified by CMS.

(D) If the clinician chooses to opt-in in accordance with § 414.1310, the third party intermediary must be able to transmit that decision to CMS.

(E) The third party intermediary must provide services throughout the entire performance period and applicable data submission period.

(F) Prior to discontinuing services to any MIPS eligible clinician, group, or virtual group during a performance period, the third party intermediary must support the transition of such MIPS eligible clinician, group, or virtual group to an alternate third party intermediary, submitter type, or, for any measure on which data has been collected, collection type according to a CMS approved a transition plan.

(ii) The determination of whether to approve an entity as a third party intermediary for a MIPS payment year may take into account:

(A) Whether the entity failed to comply with the requirements of this section for any prior MIPS payment year for which it was approved as third party intermediary; and

(B) Whether the entity provided inaccurate information regarding the requirements of this subpart to any eligible clinician.

(iii) Beginning with the 2023 MIPS payment year, third party intermediaries must attend and complete training and support sessions in the form and manner, and at the times, specified by CMS.

* * * * *

(b) *QCDRs.* * * *

(2) *QCDR conditions for approval.* In addition to the other requirements in this section, the criteria for an entity to be approved as a QCDR include the following:

* * * * *

(iv) Beginning with the 2023 payment year, the QCDR must conduct annual data validation audits in accordance with this paragraph (b)(2)(iv).

(A) The QCDR must conduct data validation for the payment year prior to submitting any data for that payment

year to CMS for purposes of the MIPS program.

(B) The QCDR must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The QCDR must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants.

(D) The QCDR must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The QCDR shall conduct each data validation audit using a sampling methodology that meets the following requirements:

(*1*) Uses a sample size of at least 3 percent of the TIN/NPIs for which the QCDR will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the QCDR must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the QCDR may use a sample size of 50 TIN/NPIs.

(*2*) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each QCDR data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only the MIPS quality measures and QCDR measures, as applicable, that are relevant to the performance period will be used for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the QCDR must report the results of each data validation audit, including the overall data deficiencies or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or error, and, how and when each deficiency or data error type was corrected.

(v) Beginning with the 2023 MIPS payment year, the QCDR must conduct targeted audits in accordance with this this paragraph (b)(2)(v).

(A) If a data validation audit under paragraph (b)(2)(iv) of this section identifies one or more deficiency or data error, the QCDR must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The QCDR must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The QCDR must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraph (b)(2)(iv)(E) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the QCDR must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, and how and when each deficiency or data error type was corrected.

(3) * * *

(v) * * *

(C) * * *

(*1*) To be approved for the 2024 MIPS payment year, a QCDR measure must be face valid. To be approved for the 2025 MIPS payment year and future years, a QCDR measure must be face valid for the initial MIPS payment year for which it is approved and fully tested for any subsequent MIPS payment year for which it is approved.

(*2*) To be included in an MIPS Value Pathway for the 2024 MIPS payment year and future years, a QCDR measure must be fully tested.

* * * * *

(E) Beginning with the 2022 MIPS payment year, CMS may provisionally approve the individual QCDR measures for 1 year with the condition that QCDRs address certain areas of duplication with other approved QCDR measures or MIPS quality measures in order to be considered for the program in subsequent years. If such areas of duplication are not addressed, CMS may reject the duplicative QCDR measure.

(vi) Beginning with the 2023 MIPS payment year, QCDR measures may be approved for 2 years, at CMS discretion by attaining approval status by meeting QCDR measure considerations and requirements. Upon annual review, CMS may revoke a QCDR measure's second year approval, if the QCDR measure is found to be: Topped out; duplicative of a more robust measure; reflects an outdated clinical guideline; or if the QCDR self-nominating the QCDR measure is no longer in good standing.

* * * * *

(c) *Qualified registries.* * * *

(2) * * *

(iii) Beginning with the 2023 payment year, the qualified registry must conduct annual data validation audits in accordance with this paragraph (c)(2)(iii).

(A) The qualified registry must conduct their data validation audits prior to submitting any data to CMS for purposes of the MIPS program.

(B) The qualified registry must conduct data validation on data for each performance category for which it will submit data, including if applicable the Quality, Improvement Activities, and Promoting Interoperability performance categories.

(C) The qualified registry must conduct data validation on data for each submitter type for which it will submit data, including if applicable MIPS eligible clinicians, groups, virtual groups, voluntary participants, and opt-in participants.

(D) The qualified registry must use clinical documentation (provided by the clinicians they are submitting data for) to validate that the action or outcome measured actually occurred or was performed.

(E) The qualified registry shall conduct each data validation audit using a sampling methodology that meets the following:

(*1*) Uses a sample size of at least 3 percent of the TIN/NPIs for which the qualified registry will submit data to CMS, except that if a 3 percent sample size would result in fewer than 10 TIN/NPIs, the qualified registry must use a sample size of at least 10 TIN/NPIs, and if a 3 percent sample size would result in more than 50 TIN/NPIs, the qualified registry may use a sample size of 50 TIN/NPIs.

(*2*) Uses a sample that includes at least 25 percent of the patients of each TIN/NPI in the sample, except that the sample for each TIN/NPI must include a minimum of 5 patients and does not need to include more than 50 patients.

(F) Each qualified registry data validation audit must include the following:

(*1*) Verification of the eligibility status of each eligible clinician, group, virtual group, opt-in participant, and voluntary participant.

(*2*) Verification of the accuracy of TINs and NPIs.

(*3*) Calculation of reporting and performance rates.

(*4*) Verification that only MIPS quality measures and qualified registry measures that are relevant to the performance period will be utilized for MIPS submission.

(G) In a form and manner and by a deadline specified by CMS, the qualified registry must report data validation results, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by any deficiency or data error, how and when each deficiency or data error type was corrected.

(iv) Beginning with the 2023 MIPS payment year, the qualified registry must conduct targeted audits in accordance with this paragraph (c)(2)(iv).

(A) If a data validation audit under paragraph (c)(2)(iii) of this section identifies one or more deficiency or data error, the qualified registry must conduct a targeted audit into the impact and root cause of each such deficiency or data error for that MIPS payment year.

(B) The qualified registry must conduct any required targeted audits for the MIPS payment year and correct any deficiencies or data errors identified through such audit prior to the submission of data for that MIPS payment year.

(C) The qualified registry must conduct the targeted audit using the sampling methodology that meets the requirements described in paragraphs (c)(2)(iii)(E)(*1*) and (*2*) of this section. The sample for the targeted audit must not include data from the sample used for the data validation audit in which the deficiency or data error was identified.

(D) In a form and manner and by a deadline specified by CMS, the qualified registry must report the results of each targeted audit, including the overall deficiency or data error rate, the types of deficiencies or data errors discovered, the percentage of clinicians impacted by each deficiency or data error, how and when each deficiency or data error type was corrected.

* * * * *

(f) * * *

(1) * * *

(i) Require the third party intermediary to submit a corrective action plan (CAP) by a date specified by CMS. The CAP must address the following issues, unless different or additional information is specified by CMS:

(A) The issues that contributed to the non-compliance.

(B) The impact to individual clinicians, groups, or virtual groups, regardless of whether they are participating in the program because they are MIPS eligible, voluntary participating, or opting in to participating in the MIPS program.

(C) The corrective actions to be implemented by the third party intermediary to ensure that the non-compliance has been resolved and will not recur in the future.

(D) The detailed timeline for achieving compliance with the applicable requirements.

* * * * *

■ 25. Section 414.1435 is amended by revising paragraph (c)(1) to read as follows:

§ 414.1435 Qualifying APM participant determination: Medicare option.

* * * * *

(c) * * *

(1) Attributed beneficiaries are determined from each Advanced APM Entity's attributed beneficiary lists generated by each Advanced APM's specific attribution methodology except as set forth in this paragraph (c)(1).

(i) Beneficiaries who have been prospectively attributed to an APM Entity for a QP Performance Period will be excluded from the attribution-eligible beneficiary count for any other APM Entity that is participating in an APM where that beneficiary would be ineligible to be added to the APM Entity's attributed beneficiary list.

(ii) [Reserved]

* * * * *

■ 26. Section 414.1450 is amended by revising paragraphs (b)(1) and (c) to read as follows:

§ 414.1450 APM incentive payment.

* * * * *

(b) * * *

(1) The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment.

* * * * *

(c) *APM Incentive Payment recipient.* CMS will pay the APM Incentive Payment amount for a payment year to a solvent TIN or TINs associated with the QP identified at a specific step in the following hierarchy. If no TIN or TINs with which the QP has an association can be identified at a step, CMS will move to the next and successive steps listed in paragraphs (c)(1) through (8) of this section until CMS identifies a TIN or TINs with which the QP is associated, and to which CMS will make the APM Incentive Payment.

(1) Any TIN associated with the QP that, during the QP Performance Period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(2) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity through which the eligible clinician achieved QP status;

(3) Any TIN associated with the QP that, during the APM Incentive Payment base period, is associated with an APM Entity participating in an Advanced APM through which the eligible clinician had achieved QP status;

(4) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated in an APM Entity in an Advanced APM;

(5) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in any track of the APM through which the eligible clinician achieved QP status;

(6) Any TIN associated with the QP that, during the APM Incentive Payment base period, participated with an APM Entity in an APM other than an Advanced APM;

(7) Any TIN associated with the QP that submitted a claim for covered professional services furnished by the QP during the APM Incentive Payment base period, even if such TIN has no relationship to any APM Entity or APM; then

(8) If we have not identified any TIN associated with the QP to which we can make the APM Incentive Payment, we will attempt to contact the QP via a public notice to request their Medicare payment information. The QPs identified in the public notice, or any other eligible clinicians who believe that they are entitled to an APM Incentive Payment must then notify CMS of their claim as directed in the public notice by November 1 of the payment year, or 60 days after CMS announces that initial payments for the year have been made, whichever is later. After that time, any claims by a QP to an APM Incentive Payment will be forfeited for such payment year.

* * * * *

■ 27. Section 414.1455 is revised to read as follows:

§ 414.1455 Limitation on review.

(a) There is no right to administrative or judicial review under sections 1869, 1878, or otherwise, of the Act of the following:

(1) The determination that an eligible clinician is a QP or Partial QP under § 414.1425.

(2) The determination of the amount of the APM Incentive Payment under § 414.1450, including any estimation as part of such determination.

(b)(1) An eligible clinician or APM Entity may request targeted review of a QP or Partial QP determination only if they believe in good faith that, due to a CMS clerical error, an eligible clinician was omitted from a Participation List.

(2) If CMS determines that there was such a clerical error, if the QP determination for the eligible clinician would have been made at the APM Entity level under § 414.1425(b)(1), CMS will assign to the eligible clinician the most favorable QP status that was determined at the APM Entity level on any snapshot dates for the relevant QP Performance Period on which the eligible clinician participated in the APM Entity.

(3) The process for targeted review is as follows:

(i) An eligible clinician or APM Entity may submit a request for targeted review.

(ii) All requests for targeted review must be submitted during the targeted review request submission period, which is a 60-day period that begins with the publication of MIPS performance feedback as described at § 414.1385(a)(2). The targeted review request submission period may be extended as specified by CMS.

(iii) All requests for targeted review must be submitted in accordance with the form and manner specified by CMS.

(iv) A request for targeted review may be denied if the request is duplicative of another request for a targeted review; the request is not submitted during the targeted review request submission period; or the request is outside the scope of targeted review specified in this section. If the targeted review request is denied, CMS will make no changes to the QP status of the eligible clinician for whom targeted review was requested.

(v) CMS will respond to each timely submitted request for targeted review.

(vi) A request for targeted review may include additional information in support of the request at the time it is submitted. CMS may also request additional information from the requestor. If CMS requests additional information relating to the eligible clinician or the APM Entity group that is the subject of a request for targeted review, responsive information must be provided and received by CMS within 30 days of the request. If CMS does not receive a timely response to a request for additional information, CMS may make a final decision on the targeted review request based on the information available.

(vii) If targeted review requests reveal a pattern of CMS error with impacts that extend beyond the scope of eligible clinicians or APM Entities that submitted such targeted review requests, CMS may adjust the QP status of other affected eligible clinicians as provided in paragraph (b)(2) of this section.

(viii) Decisions on a targeted review request are final, and not subject to any further administrative or judicial review in accordance with paragraph (a) of this section.

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 28. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 29. Section 415.172 is amended by revising paragraph (a) introductory text, (a)(2), and (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought. In residency training sites that are located outside a metropolitan statistical area, physician fee schedule payment may also be made if a teaching physician is present during the key portion of the service, including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought. For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, if a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made if a teaching physician is present during the key portion of the service including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought.

* * * * *

(2) In the case of evaluation and management services, except as otherwise provided in this paragraph (a)(2), the teaching physician must be present in person during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(i) In residency training sites that are located outside of a metropolitan statistical area, the teaching physician may be present through audio/video real-time communications technology during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(ii) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the teaching physician may be present through audio/video real-time communications technology during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(b) *Documentation.* Except as otherwise provided in this paragraph (b), except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), §§ 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document that the teaching physician was present at the time the service (including a Medicare telehealth service) is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

(1) In residency training sites that are located outside of a metropolitan statistical area only, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and

certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document whether the teaching physician was physically present or present through audio/video real-time communications technology at the time the service (including a Medicare telehealth service) is furnished. The medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through audio/video real-time communications technology. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

(2) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document whether the teaching physician was physically present or present through audio/video real-time communications technology at the time the service (including a Medicare telehealth service) is furnished. The medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through audio/video real-time communications technology. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

* * * * *

■ 30. Section 415.174 is amended by revising paragraph (c) and adding paragraph (d) to read as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

* * * * *

(c) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the requirements in paragraph (a)(3) of this section for a teaching physician to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met through audio/video real-time communications technology.

(d) In residency training sites that are located outside of a metropolitan statistical area only, the requirements in paragraph (a)(3) of this section for a teaching physician to direct the care and then to review the services furnished by each resident during or immediately after each visit may be met through audio/video real-time communications technology.

■ 31. Section 415.180 is revised to read as follows:

§ 415.180 Teaching setting requirements for the interpretation of diagnostic radiology and other diagnostic tests.

(a) *General rule.* Physician fee schedule payment is made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed or reviewed by a physician other than a resident.

(1) In residency training sites that are located outside of a metropolitan statistical area only, physician fee schedule payment may also be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the interpretation of review of the diagnostic radiology test.

(2) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, physician fee schedule payment may also be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the interpretation or review of the diagnostic radiology or diagnostic test.

(b) [Reserved]

■ 32. Section 415.184 is revised to read as follows:

§ 415.184 Psychiatric services.

(a) Physician fee schedule payment is made for psychiatric services furnished under an approved GME program if the requirements of §§ 415.170 and 415.172 are met, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

(b) In residency training sites that are located outside of a metropolitan statistical area, the requirement for the presence of the teaching physician during the service in which a resident is involved may be met through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the service.

(c) For all teaching settings during the Public Health Emergency, as defined in § 400.200 of this chapter, for the COVID–19 pandemic, the requirement for the presence of the teaching physician during the service in which a resident is involved may also be met through audio/video real-time communications technology. The medical records must document the extent of the teaching physician's participation in the service.

■ 33. Section 415.208 is amended by revising paragraph (b) heading and paragraph (b)(2) introductory text to read as follows:

§ 415.208 Services of moonlighting residents.

* * * * *

(b) *Services in teaching hospitals.*

* * *

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if criteria in paragraphs (b)(2)(i) through (iii) of this section are met. The services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if criteria in paragraphs (b)(2)(i) through (iii) of this section are met. The medical record must include documentation to demonstrate in each case that these criteria are satisfied.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

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

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

■ 35. Section 423.160 is amended by adding paragraph (a)(5) to read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(5) On January 1, 2021, prescribers must, except in circumstances in which the Secretary waives the requirement, conduct all prescribing for all Schedule II, III, IV, and V controlled substances electronically using the applicable standards in paragraph (b) of this section. Compliance actions against those not in compliance with this requirement will commence January 1, 2022.

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 36. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 37. Section 424.67 is amended by—

■ a. Revising paragraphs (b)(1) introductory text, (b)(1)(ii), (b)(2) and (3), and (b)(5) introductory text;

■ b. Redesignating paragraphs (c) through (f) as paragraphs (d) through (g), respectively;

■ c. Adding new paragraph (c); and

■ d. Revising newly redesignated paragraph (e)(2)(i).

The revisions and additions read as follows:

§ 424.67 Enrollment requirements for opioid treatment programs (OTP).

* * * * *

(b) * * *

(1) Fully complete and submit, as applicable, the Form CMS–855A or Form CMS–855B application (or their successor applications) and any applicable supplement or attachment thereto to its applicable Medicare contractor. This includes, but is not limited to, the following:

* * * * *

(ii) Certifying via the Form CMS–855A or Form CMS–855B (as applicable) and/or the applicable supplement or attachment thereto that the OTP meets and will continue to meet the specific requirements and standards for enrollment described in paragraphs (b) and (e) of this section.

(2) Comply with the application fee requirements in § 424.514. (This includes OTPs enrolling under the circumstances described in paragraph (c)(2) of this section.)

(3)(i) Except as stated in paragraph (b)(3)(ii) of this section, successfully complete the assigned categorical risk level screening required under, as applicable, § 424.518(b) and (c).

(ii) For currently enrolled OTPs that are changing their OTP enrollment from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, successfully complete the limited level of categorical screening under § 424.518(a) if the OTP has already completed, as applicable, the moderate or high level of categorical screening under § 424.518(b) or (c), respectively.

* * * * *

(5) Report on the Form CMS–855A or Form CMS–855B (as applicable) and/or any applicable supplement all OTP staff who meet the definition of ''managing employee'' in § 424.502. Such individuals include, but are not limited to, the following:

* * * * *

(c) *Clarification of required enrollment forms.* (1) An OTP may only be enrolled as an OTP via the Form CMS–855A or Form CMS–855B but not both.

(2) If a currently enrolled OTP is changing its OTP enrollment from a Form CMS–855B enrollment to a Form CMS–855A enrollment, or vice versa, the effective date of billing that was established for the OTP's prior enrollment under §§ 424.520(d) and 424.521(a) is applied to the OTP's new enrollment.

* * * * *

(e) * * *

(2) * * *

(i) The provider does not have a current, valid certification by SAMHSA as required under paragraph (b)(4)(i) of this section or fails to meet any other applicable requirement or standard in this section, including, but not limited to, the OTP standards in paragraphs (b)(6) and (e)(1) of this section.

* * * * *

■ 38. Section 424.518 is amended by redesignating paragraphs (a)(1)(xii) through (xvii) as paragraphs (a)(1)(xiii) through (xviii) and adding a new paragraph (a)(1)(xii) to read as follows:

§ 424.518 Screening levels for Medicare providers and suppliers.

* * * * *

(a) * * *

(1) * * *

(xii) Opioid treatment programs (if § 424.67(b)(3)(ii) applies).

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 39. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 40. Section 425.100 is amended by revising paragraph (b) to read as follows:

§ 425.100 General.

* * * * *

(b) An ACO is eligible to receive payments for shared savings under subpart G of this part if all of the following conditions are met:

(1) The ACO meets or exceeds the applicable minimum savings rate established under § 425.604, § 425.605, § 425.606, § 425.609, or § 425.610.

(2) The ACO meets the minimum quality performance standards established under § 425.500 (for performance years or a performance period beginning on or before January 1, 2020), or under the quality performance standard established under § 425.512 (for performance years beginning on or after January 1, 2021).

(3) The ACO otherwise maintains its eligibility to participate in the Shared Savings Program under this part.

* * * * *

§ 425.112 [Amended]

■ 41. Section 425.112 is amended in paragraph (b)(2)(i) by removing the reference ''§ 425.500'' and adding in its place the references ''§ 425.500 or § 425.510, as applicable''.

§ 425.200 [Amended]

■ 42. Section 425.200 is amended in paragraph (d) by removing the reference ''§ 425.500(c)'' and adding in its place the references ''§ 425.500(c) or § 425.510, as applicable''.

■ 43. Section 425.204 is amended by—

■ a. Revising paragraphs (f)(3)(i) through (iv);

■ b. Adding paragraph (f)(3)(v); and

■ c. Revising paragraphs (f)(4)(iv), (f)(5), and (f)(6)(ii) introductory text.

The revisions and addition read as follows:

§ 425.204 Content of the application.

* * * * *

(f) * * *

(3) * * *

(i) An ACO participating in Track 2 must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(ii) An ACO entering an agreement period in Levels C, D, or E of the BASIC track or the ENHANCED track must demonstrate the adequacy of its repayment mechanism prior to the start of its agreement period, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iii) An ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the

adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to, a two-sided model, Level C, Level D, or Level E of the BASIC track, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iv) An ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the ACO, provided that the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section, and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(v) As part of its application, a re-entering ACO must submit documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the re-entering ACO, provided that the ACO is the same legal entity as an ACO that previously participated in the program, and the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(4) * * *

(iv)(A) In the case of an ACO that has submitted a request to enter a new participation agreement for an agreement period starting on or after January 1, 2022 and is a renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program: If the ACO wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to at least the amount calculated by CMS in accordance with paragraph (f)(4)(ii) of this section.

(B) Under the following circumstances, an ACO that renewed its participation agreement for an agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism.

(*1*) The ACO elected to continue to use its existing repayment mechanism for the agreement period beginning on July 1, 2019, or January 1, 2020, and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated at the time of renewal application according to paragraph (f)(4)(ii) of this section.

(*2*) The repayment mechanism amount for performance year 2021, as recalculated pursuant to paragraph (f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(*3*) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(iv)(B). The ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of this paragraph (f).

(5) After the repayment mechanism has been used to repay any portion of shared losses owed to CMS, the ACO must replenish the amount of funds available through the repayment mechanism within 90 days. The resulting amount available through the repayment mechanism must be at least the amount specified by CMS in accordance with paragraph (f)(4) of this section.

(6) * * *

(ii) For a renewing ACO, or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program, that wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the existing repayment mechanism must be amended to meet one of the following criteria.

* * * * *

■ 44. Section 425.224 is amended by revising paragraph (b)(1)(ii)(A) to read as follows:

§ 425.224 Application procedures for renewing ACOs and re-entering ACOs.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(A) Whether the ACO demonstrated a pattern of failure to meet the quality performance standards or met any of the criteria for termination under § 425.316(c)(1)(ii) or (c)(2)(ii).

* * * * *

§ 425.302 [Amended]

■ 45. Section 425.302 is amended in paragraph (a)(1) by removing the reference ''§ 425.500'' and adding in its place the references ''§ 425.500 or § 425.510, as applicable''.

■ 46. Section 425.316 is amended by revising paragraph (c) to read as follows:

§ 425.316 Monitoring of ACOs.

* * * * *

(c) *Monitoring ACO compliance with quality performance standards.* To identify ACOs that are not meeting the quality performance standards, CMS will review an ACO's submission of quality measurement data under § 425.500 or § 425.512. CMS may request additional documentation from an ACO, ACO participants, or ACO providers/suppliers, as appropriate. If an ACO does not meet quality performance standards or fails to report on one or more quality measures, CMS will take the following actions:

(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* (i) The ACO may be given a warning for the first time it fails to meet the minimum attainment level on at least 70 percent of the measures, as determined under § 425.502, in one or more domains and may be subject to a CAP. CMS may forgo the issuance of the warning letter depending on the nature and severity of the noncompliance and instead subject the ACO to actions set forth at § 425.216 or immediately terminate the ACO's participation agreement under § 425.218.

(ii) The ACO's compliance with the quality performance standards will be re-evaluated the following year. If the ACO continues to fail to meet the quality performance standard in the following year, the agreement will be terminated.

(iii) An ACO will not qualify to share in savings in any year it fails to report accurately, completely, and timely on the quality performance measures.

(2) *For performance years beginning on or after January 1, 2021.* (i) If the ACO fails to meet the quality performance standard, CMS may take one or more of the actions prior to termination specified in § 425.216. Depending on the nature and severity of the noncompliance, CMS may forgo pre-termination actions and may

immediately terminate the ACO's participation agreement under § 425.218.

(ii) CMS will terminate an ACO's participation agreement under any of the following circumstances:

(A) The ACO fails to meet the quality performance standard for 2 consecutive performance years within an agreement period.

(B) The ACO fails to meet the quality performance standard for any 3 performance years within an agreement period, regardless of whether the years are in consecutive order.

(C) A renewing ACO or re-entering ACO fails to meet the quality performance standard for the last performance year of the ACO's previous agreement period and this occurrence was either the second consecutive performance year of failed quality performance or the third nonconsecutive performance year of failed quality performance during the previous agreement period.

(D) A renewing ACO or re-entering ACO fails to meet the quality performance standard for 2 consecutive performance years across 2 agreement periods, specifically the last performance year of the ACO's previous agreement period and the first performance year of the ACO's new agreement period.

* * * * *

■ 47. Section 425.400 is amended by—
■ a. Revising paragraph (c)(1)(iv) introductory text;
■ b. Adding paragraph (c)(1)(v); and
■ c. Revising paragraph (c)(2).

The revisions and addition read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(iv) For performance years (or a performance period) during 2019, and performance year 2020 as follows:

* * * * *

(v) For the performance year starting on January 1, 2021, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*3*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a SNF).

(*4*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*5*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home for claims identified by place of service modifier 12).

(*6*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(v)).

(*7*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*8*) 99439 (code for non-complex chronic care management).

(*9*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*10*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*11*) 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*12*) 99495 and 99496 (codes for transitional care management services).

(*13*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0402 (code for the Welcome to Medicare visit).

(*2*) G0438 and G0439 (codes for the annual wellness visits).

(*3*) G0442 (code for alcohol misuse screening service).

(*4*) G0443 (code for alcohol misuse counseling service).

(*5*) G0444 (code for annual depression screening service).

(*6*) G0463 (code for services furnished in ETA hospitals).

(*7*) G0506 (code for chronic care management).

(*8*) G2010 (code for the remote evaluation of patient video/images).

(*9*) G2012 (code for virtual check-in).

(*10*) G2058 (code for non-complex chronic care management).

(*11*) G2064 and G2065 (codes for principal care management services).

(*12*) G2214 (code for psychiatric collaborative care model).

(2)(i) When the assignment window (as defined in § 425.20) for a benchmark or performance year includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter, in determining beneficiary assignment, we use the primary care service codes identified in paragraph (c)(1) of this section, and additional primary care service codes as follows:

(A) CPT codes:

(*1*) 99421, 99422, and 99423 (codes for online digital evaluation and management services).

(*2*) 99441, 99442, and 99443 (codes for telephone evaluation and management services).

(B) HCPCS codes:

(*1*) G2010 (code for the remote evaluation of patient video/images).

(*2*) G2012 (code for virtual check-in).

(ii) The additional primary care service codes specified in paragraph (c)(2)(i) of this section are applicable to all months of the assignment window (as defined in § 425.20), when the assignment window includes any month(s) during the COVID–19 Public Health Emergency defined in § 400.200 of this chapter.

■ 48. Section 425.500 is amended by revising the section heading and paragraph (d) to read as follows:

§ 425.500 Measures to assess the quality of care furnished by an ACO for performance years (or a performance period) beginning on or before January 1, 2020.

* * * * *

(d) *Patient experience of care survey.* (1) For performance years (or a performance period) beginning in 2014 through 2019, ACOs must select a CMS-certified vendor to administer the survey and report the results accordingly.

(2) For performance year 2020, CMS waives the CAHPS for ACOs reporting requirement and will assign all ACOs automatic credit for the CAHPS for ACOs survey measures.

* * * * *

■ 49. Section 425.502 is amended by revising the section heading to read as follows:

§ 425.502 Calculating the ACO quality performance score for performance years (or a performance period) beginning on or before January 1, 2020.

* * * * *

■ 50. Section 425.508 is amended by revising the paragraph (a) heading and adding paragraph (b) to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

(a) *For performance years (or a performance period) beginning in 2017–2020.* * * *

(b) *For performance years beginning on or after January 1, 2021.* ACOs must submit the quality data via the Alternative Payment Model Performance Pathway (APP) established under § 414.1367 of this chapter, to satisfactorily report on behalf of the

eligible clinicians who bill under the TIN of an ACO participant for purposes of the MIPS Quality performance category of the Quality Payment Program.

■ 51. Section 425.510 is added to subpart F to read as follows:

§ 425.510 Application of the Alternative Payment Model Performance Pathway (APP) to Shared Savings Program ACOs for performance years beginning on or after January 1, 2021.

(a) *General.* (1) CMS establishes quality performance measures to assess the quality of care furnished by the ACO. If the ACO demonstrates to CMS that it has satisfied the quality performance requirements in this subpart, and the ACO meets all other applicable requirements, the ACO is eligible to receive shared savings.

(2) CMS seeks to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.

(b) *Quality reporting.* ACOs must report quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS.

(c) *Audit and validation of data.* CMS retains the right to audit and validate quality data reported by an ACO under paragraph (b) of this section according to § 414.1390 of this chapter.

■ 52. Section 425.512 is added to subpart F to read as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) *Establishing a quality performance standard*—(1) *Overall standard.* The quality performance standard is the overall standard the ACO must meet in order to be eligible to receive shared savings for a performance year. An ACO will not qualify to share in savings in any year it fails to meet the quality performance standard.

(2) *For performance year 2022 and subsequent performance years.* For the first performance year of an ACO's first agreement period under the Shared Savings Program, if the ACO meets the data completeness requirement at § 414.1340 of this chapter and case minimum requirement at § 414.1380 of this chapter on the three measures it is actively required to report and fields a CAHPS for MIPS survey via the APP, the ACO will meet the quality performance standard.

(3) *For performance years 2021 and 2022*—(i) *Designation of quality performance standard.* For all ACOs, except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 30th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) *For performance year 2021.* If an ACO does not report any of the ten CMS Web Interface measures or any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO will not meet the quality performance standard.

(iii) *For performance year 2022.* If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO will not meet the quality performance standard.

(4) *For performance years 2023 and subsequent performance years.* (i) For all ACOs, except as specified in paragraph (a)(2) of this section, CMS designates the quality performance standard as the ACO reporting quality data via the APP established under § 414.1367 of this chapter, according to the method of submission established by CMS and achieving a quality performance score that is equivalent to or higher than the 40th percentile across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

(ii) If an ACO does not report any of the three measures it is actively required to report and does not field a CAHPS for MIPS survey via the APP, the ACO will not meet the quality performance standard.

(b) *Extreme and uncontrollable circumstances.* For performance year 2021 and subsequent performance years, including the applicable quality data reporting period for the performance year, CMS uses an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances instead of the methodology specified in paragraph (a) of this section as follows:

(1) CMS determines the ACO was affected by an extreme and uncontrollable circumstance based on either of the following:

(i) Twenty percent or more of the ACO's assigned beneficiaries reside in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance.

(A) Assignment is determined under subpart E of this part.

(B) In making this determination, CMS uses the quarter four list of assigned beneficiaries.

(ii) The ACO's legal entity is located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance. An ACO's legal entity location is based on the address on file for the ACO in CMS' ACO application and management system.

(2) If CMS determines the ACO meets the requirements of paragraph (b)(1) of this section, CMS calculates the ACO's quality score as follows:

(i) For performance years 2021 and 2022, the ACO's minimum quality performance score is set to the equivalent of the 30th percentile MIPS Quality performance category score for the relevant performance year as determined under paragraph (a)(3) of this section.

(ii) For performance year 2023 and subsequent performance years, the ACO's minimum quality performance score is set to the equivalent of the 40th percentile MIPS Quality performance category score for the relevant performance year as determined under paragraph (a)(4) of this section.

(3) If the ACO reports quality data via the APP and meets data completeness and case minimum requirements:

(i) For performance years 2021 and 2022, CMS will use the higher of the ACO's quality performance score or the equivalent of the 30th percentile MIPS Quality performance category score for the relevant performance year.

(ii) For performance year 2023 and subsequent performance years, CMS will use the higher of the ACO's quality performance score or the equivalent of the 40th percentile MIPS Quality performance category score for the relevant performance year.

(4) CMS applies determinations made under the Quality Payment Program with respect to—

(i) Whether an extreme and uncontrollable circumstance has occurred; and

(ii) The affected areas.

(5) CMS has sole discretion to determine the time period during which an extreme and uncontrollable circumstance occurred, the percentage of the ACO's assigned beneficiaries residing in the affected areas, and the location of the ACO legal entity.

■ 53. Section 425.600 is amended by revising paragraph (f)(4)(i) to read as follows:

§ 425.600 Selection of risk model.

* * * * *

(f) * * *

(4) * * *

(i) The quality performance standard as described in § 425.502(a) or § 425.512(a), as applicable.

* * * * *

■ 54. Section 425.601 is amended by revising paragraphs (a)(9) and (f)(5)(iv) to read as follows:

§ 425.601 Establishing, adjusting, and updating the benchmark for agreement periods beginning on July 1, 2019, and in subsequent years.

(a) * * *

(9) For the second and each subsequent performance year during the term of the agreement period, the ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), for a change to the ACO's beneficiary assignment methodology selection under § 425.226(a)(1), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures of beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under paragraph (a)(8) of this section, according to the ACO's assigned beneficiaries for BY3.

* * * * *

(f) * * *

(5) * * *

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in paragraph (a)(9) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (f)(1) and (2) of this section used in calculating the adjustment under either paragraph (a)(8) or (e) of this section.

* * * * *

■ 55. Section 425.602 is amended by revising paragraph (a)(8) to read as follows:

§ 425.602 Establishing, adjusting, and updating the benchmark for an ACO's first agreement period beginning on or before January 1, 2018.

(a) * * *

(8) The ACO's benchmark is adjusted for the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b) and for a change to the beneficiary assignment methodology specified in subpart E of this part, as applicable, to take into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

* * * * *

■ 56. Section 425.603 is amended by revising paragraphs (c)(8) and (c)(9)(ii)(B)(*4*)(*iv*) to read as follows:

§ 425.603 Resetting, adjusting, and updating the benchmark for a subsequent agreement period beginning on or before January 1, 2019.

* * * * *

(c) * * *

(8) The ACO's benchmark is adjusted for the following, as applicable: For the addition and removal of ACO participants or ACO providers/suppliers in accordance with § 425.118(b), and for a change to the beneficiary assignment methodology specified in subpart E of this part. To adjust the benchmark, CMS does the following:

(i) Takes into account the expenditures for beneficiaries who would have been assigned to the ACO in any of the 3 most recent years prior to the start of the agreement period.

(ii) Redetermines the regional adjustment amount under paragraph (c)(9) of this section, according to the ACO's assigned beneficiaries for BY3.

(9) * * *

(ii) * * *

(B) * * *

(*4*) * * *

(*iv*) If CMS adjusts the ACO's benchmark, as specified in paragraph (c)(8) of this section, CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage used in calculating the adjustment in paragraphs (c)(9)(ii)(B)(*1*) and (*2*) of this section.

* * * * *

■ 57. Section 425.604 is amended by revising paragraphs (c) and (d) to read as follows:

§ 425.604 Calculation of savings under the one-sided model.

* * * * *

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* In order to qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For the performance year beginning on January 1, 2021.* To qualify for shared savings, an ACO must meet or exceed its minimum savings rate determined under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the one-sided model will receive a shared savings payment of up to 50 percent of all savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) *For the performance year beginning on January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under Track 1 will receive a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

■ 58. Section 425.605 is amended by revising paragraphs (c), (d)(1)(i)(A), (d)(1)(ii)(A), (d)(1)(iii)(A), (d)(1)(iv)(A), and (d)(1)(v)(A) to read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

* * * * *

(c) *Qualification for shared savings payment*—(1) *For performance years beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For performance years beginning on or after January 1, 2021.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) * * *

(1) * * *

(i) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or*

before January 1, 2020. An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level A, receives a shared savings payment of 40 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(i)(B) of this section).

* * * * *

(ii) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of up to 40 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level B, receives a shared savings payment of 40 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(ii)(B) of this section).

* * * * *

(iii) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level C, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iii)(B) of this section).

* * * * *

(iv) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level D, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(iv)(B) of this section).

* * * * *

(v) * * *

(A) *Final sharing rate*—(*1*) *For performance years beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of up to 50 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

(*2*) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment of 50 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section).

* * * * *

■ 59. Section 425.606 is amended by revising paragraphs (c), (d), and (f) to read as follows:

§ 425.606 Calculation of shared savings and losses under Track 2.

* * * * *

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For the performance year beginning on January 1, 2021.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under Track 2 will receive a shared savings payment of up to 60 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) *For the performance year beginning on January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under Track 2 will receive a shared savings payment of 60 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

(f) *Shared loss rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in paragraph (d)(1) of this section (that is, 1 minus the final shared savings rate determined under paragraph (d)(1) of this section). The shared loss rate—

(i) May not exceed 60 percent; and

(ii) May not be less than 40 percent.

(2) *For the performance year beginning on January 1, 2021.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

(A) Calculate the quotient of the MIPS Quality performance category points

earned divided by the total MIPS Quality performance category points available.

(B) Calculate the product of the quotient determined in paragraph (f)(2)(i)(A) of this section and 60 percent.

(C) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(2)(i)(B) of this section. The shared loss rate—

(*1*) May not exceed 60 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet the quality performance standard established in § 425.512, the shared loss rate is 60 percent.

* * * * *

■ 60. Section 425.610 is amended by revising paragraphs (c), (d), and (f) to read as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

* * * * *

(c) *Qualification for shared savings payment*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the minimum quality performance standards established under § 425.502, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(2) *For performance years beginning on or after January 1, 2021.* To qualify for shared savings, an ACO must meet the minimum savings rate requirement established under paragraph (b) of this section, meet the quality performance standard established under § 425.512, and otherwise maintain its eligibility to participate in the Shared Savings Program under this part.

(d) *Final sharing rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment of up to 75 percent of all the savings under the updated benchmark, as determined on the basis of its quality performance under § 425.502 (up to the performance payment limit described in paragraph (e)(2) of this section).

(2) *For performance years beginning on or after January 1, 2021.* An ACO that meets all the requirements for receiving shared savings payments under the ENHANCED track will receive a shared savings payment of 75 percent of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (e)(2) of this section).

* * * * *

(f) *Shared loss rate*—(1) *For performance years (or a performance period) beginning on or before January 1, 2020.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined based on the inverse of its final sharing rate described in paragraph (d)(1) of this section (that is, 1 minus the final shared savings rate determined under paragraph (d)(1) of this section). The shared loss rate—

(i) May not exceed 75 percent; and

(ii) May not be less than 40 percent.

(2) *For performance years beginning on or after January 1, 2021.* For an ACO that is required to share losses with the Medicare program for expenditures over the updated benchmark, the amount of shared losses is determined as follows:

(i) If the ACO meets the quality performance standard established in § 425.512, CMS determines the shared loss rate as follows:

(A) Calculate the quotient of the MIPS Quality performance category points earned divided by the total MIPS Quality performance category points available.

(B) Calculate the product of the quotient determined in paragraph (f)(2)(i)(A) of this section, and 75 percent.

(C) Calculate the shared loss rate as 1 minus the product determined in paragraph (f)(2)(i)(B) of this section. The shared loss rate—

(*1*) May not exceed 75 percent; and

(*2*) May not be less than 40 percent.

(ii) If the ACO fails to meet the quality performance standard established in § 425.512, the shared loss rate is 75 percent.

* * * * *

■ 61. Section 425.611 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 425.611 Adjustments to Shared Savings Program calculations to address the COVID–19 pandemic.

* * * * *

(b) * * *

(1) * * *

(ii) Discharges for acute care inpatient services for treatment of COVID–19 from facilities that are not paid under the inpatient prospective payment system, such as CAHs, when the date of discharge occurs within the Public Health Emergency as defined in § 400.200 of this chapter.

* * * * *

§ 425.800 [Amended]

■ 62. Section 425.800 is amended—

■ a. In paragraph (a)(1) by removing the references ''§ 425.500 and § 425.502'' and adding in its place the references ''§§ 425.500, 425.502, 425.510, and 425.512;''

■ b. In paragraph (a)(2) by removing the reference ''§ 425.502'' and adding in its place the references ''§ 425.502 or § 425.512, as applicable''; and

■ c. In paragraph (a)(6) by removing the reference ''§ 425.502'' and adding in its place the references ''§ 425.502 or § 425.512, as applicable''.

Dated: November 18, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: November 23, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

BILLING CODE 4120–01–P

APPENDIX 1: MIPS QUALITY MEASURES

NOTE: Except as otherwise noted in this final rule, previously finalized measures and specialty measure sets will continue to apply for the 2023 MIPS payment year and future years. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table A as follows: NQF # / eCQM NQF #.

TABLE Group A: New Quality Measures Finalized for the 2023 MIPS Payment Year and Future Years

A.1. Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	479
Description:	This measure is a re-specified version of the measure, "Risk-adjusted readmission rate (RARR) of unplanned readmission within 30 days of hospital discharge for any condition" (NQF 1789), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to MIPS participating clinician groups and assesses each group's readmission rate. The measure comprises a single summary score, derived from the results of five models, one for each of the following specialty cohorts (groups of discharge condition categories or procedure categories): medicine, surgery/gynecology, cardio-respiratory, cardiovascular, and neurology.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is unplanned all-cause 30-day readmission. Readmission is defined as a subsequent inpatient admission to any acute care facility which occurs within 30 days of the discharge date of an eligible index admission. Any readmission is eligible to be counted as an outcome, except those that are considered planned. To align with data years used, the planned readmission algorithm version 4.0 was used to classify readmissions as planned or unplanned.
Denominator:	Patients eligible for inclusion in the measure have an index admission hospitalization to which the readmission outcome is attributed and includes admissions for patients: Enrolled in Medicare Fee-For-Service (FFS) Part A for the 12 months prior to the date of admission; Aged 65 or over; Discharged alive from a non-federal short-term acute care hospital; and, Not transferred to another acute care facility.
Exclusions:	1. Patients discharged against medical advice (AMA) are excluded. 2. Admissions for patients to a PPS-exempt cancer hospital are excluded. 3. Admissions primarily for medical treatment of cancer are excluded. 4. Admissions primarily for psychiatric disease are excluded. 5. Admissions for "rehabilitation care; fitting of prostheses and adjustment devices" (CCS 254) are excluded. 6. Admissions where patient cannot be attributed to a clinician group.
Measure Type:	Outcome
Measure Domain:	Communication and Care Coordination (section 1848(s)(1)(B)(iii) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Measure Implementation:	MIPS eligible groups with at least 16 clinicians / 200 case minimum / 1 year performance period (January 1st – December 31st)
Rationale:	This risk-adjusted administrative claims measure was proposed to address unplanned readmissions at the physician group level of Medicare aged > 65 patients. This measure is a re-specified version of the hospital-level measure, "Hospital-Wide All-Cause, Unplanned Readmission Measure" (NQF #1789), which has been in the MIPS program since 2017. In the event we did not finalize this measure, we would have maintained the current measure Q458: All-Cause Hospital Readmission. The re-specification of this measure promotes a systems-level approach by clinicians and focus on high-risk conditions, such as COPD and heart failure. The measure was evaluated by the MAP and was conditionally supported pending NQF endorsement. While we agreed with the MAP that NQF endorsement of measures is preferred, NQF endorsement is not a requirement for measures to be considered for MIPS if the measure has an evidence-based focus as required in section 1848(q)(2)(D)(v) of the Act. A risk-adjusted readmission rate of 15.3 percent at the physician group level was provided by the measure developer. The readmission rate indicates a substantial need to reduce the expected rate and variation of rates across eligible physician groups. Physician groups have the capability to influence unplanned readmission outcomes by appropriate medication reconciliation at discharge, reduction of infection risk, and ensuring proper outpatient follow-up. As an administrative claims measure, there is no separate reporting burden. To maintain continuity with the existing measure Q458: All-Cause Hospital Readmission, the case minimum will remain at 200 cases for consistency in implementation. For 2023 payment determination, the performance period will include administrative claims from January 1, 2021 to December 31, 2021. For further information regarding the implementation of this measure, please see section IV.A.3.c.(1)(e)(i) of this final rule. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.
Comment: One commenter appreciated this measure as a change to the All-Cause Readmissions measure (Q458) to better align with a system-level approach so that patient care can be focused more on high risk conditions. A second commenter supported this new measure, stating that it improves upon the existing readmissions measure as it targets unplanned readmissions to the hospital.	

Category	Description

Response: We thank the commenters for supporting the new HWR measure in the MIPS program.

Comment: One commenter appreciated the measure steward's efforts to provide additional justification for attribution of the Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) measure to the three types of clinician groups, but believed the evidence falls short of demonstrating clear attribution to decreased readmission rates. In addition, the commenter believed the reliability levels for the cardiorespiratory and cardiovascular cohorts continue to be too low for acceptable use. In addition, prior attempts to reduce readmission rates for the heart failure population was associated with a reduction in the rate of readmissions, but also an increase in the rate of death among Medicare patients hospitalized with heart failure. The commenter requested that CMS ensure these issues are considered as the measure continues through development and the endorsement process at NQF.

Response: While the existing literature on the association between clinicians and patient outcomes may be sparse, the Technical Expert Panel (TEP) and clinical consultants, most of whom are clinicians themselves, strongly supported the attribution model and identified the primary inpatient clinician, discharge clinician, and primary outpatient clinician as important roles in providing appropriate care, practical recommendations, and care transitions; and therefore, together, can reduce the risk of readmission. Clinicians are critical contributors to quality improvement, whether as change agents and influencers of health systems or key stakeholders whose acceptance is required for successful or long-lasting improvements. The case minimum will align with that of measure Q458 for consistency in implementation so that only eligible clinician groups with at least 200 cases will receive a measure score. This aligns with feedback received from the public and NQF Admissions/Readmissions committee as well as empiric analyses demonstrating that the minimum case count of 200 cases produces exceptionally reliable measure scores for eligible clinician groups. Using a minimum case count of 200 cases, measure reliability testing conducted by the developers indicated substantial signal to noise reliability across all five specialty cohorts, ranging from 0.82 for surgical to 0.92 for neurology (Adams et al, 2010). Specifically, when limiting to clinician groups with at least 200 cases, the cardiorespiratory and cardiovascular specialty cohorts in question had mean signal to noise reliability scores of 0.89 and 0.88, respectively, indicating substantial reliability (Adams et al, 2010).

We are aware of the literature that suggested an inverse association between 30-day readmission and 30-day mortality for heart failure admissions (Gupta et al. 2018). However, the paper was based on 416 hospitals, which is a small proportion of hospitals participating in the Hospital Readmission Reduction Program (HRRP), and focuses on the temporal association between the HRRP's introduction and an increase in 30-day and one-year mortality rates for heart failure discharges. We continuously monitor the literature related to the impact and unintended consequences of measurement and CMS programs and found the evidence that readmission measurement has increased heart failure mortality as inconclusive. The Medicare Payment Advisory Commission (MedPAC 2018) completed an analysis on readmission measurement within the HRRP and found no negative effect on mortality. Furthermore, literature using the complete sample of over 4,000 hospitals participating in HRRP found that the decline in readmission was not associated with an increase in heart failure mortality and that lowering readmissions actually tends to also lower mortality (Kera et al 2018 and Dharmarajan et al. 2017). The observed increase in mortality in Gupta et al. (2018) may be due to a decline in admission rates, resulting in patients that are admitted presenting with complex comorbidities and a higher risk of death (Dharmarajan et al. 2017, Krumholz et al. 2015, MedPAC 2018). Given the importance of this potential issue on patient outcomes, we also commissioned an independent group to investigate whether there have been increases in mortality rates after HRRP implementation. We found through this investigation that no sufficient evidence exists to suggest that mortality has increased because of HRRP measurement. We are committed to continuing to monitor trends in readmission and mortality rates through annual measure reevaluation and surveillance tasks.

Comment: One commenter stated that though unlikely, based on the case minimum, this new measure could apply to large radiation oncology or multidisciplinary groups. However, the commenter worried that the attribution methodology will unfairly target radiation oncologists, who do not perform primary care services. CMS finalized specialty exclusions under the Total Per Capita Cost (TPCC) Measure in the 2020 PFS final rule that the TPCC measure is more accurately applied to clinicians who provide primary care services. Under the TPCC, attributed episodes of care are excluded if they are performed by clinicians who (i) frequently perform non-primary care services (for example, global surgery, chemotherapy, anesthesia, radiation therapy) or (ii) are in specialties unlikely to be responsible for providing primary care to a beneficiary (for example, podiatry, dermatology, optometry, ophthalmology). The commenter recommended that CMS apply the same specialty exclusions to the Hospital-Wide, All-Cause Unplanned Readmission claims measure.

Response: There are several exclusion criteria applied to the measure population ("starting cohort"), which include: (1) Admissions for patients to a PPS-exempt cancer hospital; (2) Admissions primarily for medical treatment of cancer; (3) Admissions for "rehabilitation care; fitting of prostheses and adjustment devices;" and (4) Admissions where patient cannot be attributed to a clinician group. Additionally, the measure is risk adjusted to account for differences in patient demographics and clinical characteristics across hospitals. These clinical characteristics may not be related to the quality of care; however, they could impact outcomes for patients. Given the wide variety of discharge diagnosis condition categories, the measure is adjusted for both case mix differences (clinical status of the patient, accounted for by adjusting for comorbidities), as well as service mix differences (the types of conditions/procedures, accounted for by adjusting for the principal discharge diagnosis condition category). Adjustments for case mix differences among clinicians are made by risk-adjusting for patients' comorbid conditions that are identified during inpatient episodes of care for the 12 months prior to the index admission in addition to those present at the index admission. Finally, the intent of the measure is to incentivize coordinated and collaborative care across specialties for a wide variety of patients to reduce unplanned readmissions; radiation oncologists may be able to contribute to optimal care. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

Comment: One commenter opposed inclusion of this measure in MIPS, citing their primary concern is the risk of unintended consequences because it does not adequately consider the competing risk of mortality. Providers with higher mortality rates for more severely ill patients could appear to be providing better quality care. Concerns have been raised in multiple peer reviewed publications about the possible association between incentives to reduce admission and increased mortality rates. It is also unclear whether hospital readmission rates truly reflect the quality of care for all patient populations and whether incentivizing lower readmissions could potentially exacerbate disparities in care.

The commenter suggested that CMS consider a measure such as risk-adjusted home time, which, if carefully designed, might better balance the competing risks of readmission and mortality, and mitigate some of these concerns. CMS may also want to consider the additional recommendations for improving on readmission measures and reducing the risk of potential inequities and unintended consequences. Lastly, the commenter noted this measure was more appropriate to attribute at the ACO level only due to better oversight and care coordination to influence performance.

Response: Researchers have conducted considerable investigation of potential unintended consequences since the implementation of the readmission measures within HRRP. More specifically, the relationship between the implementation of the AMI, heart failure, and pneumonia readmission measures in the HRRP and subsequent trends in their respective AMI, heart failure, and pneumonia mortality rates has been studied. We continuously monitor the literature related to the impact and unintended consequences of measurement and CMS programs and found the evidence that readmission measurement has increased mortality rates as inconclusive. The Medicare Payment Advisory Commission (MedPAC 2018) completed an analysis on readmission measurement within the HRRP and found no negative effect on mortality. MedPAC's 2018 report confirms that the readmission declines have occurred without clear adverse consequences and concluded that mortality rates do not seem to be increasing in relation to HRRP. In fact, for most HRRP conditions, observed mortality declined after HRRP was implemented, while mortality increased for non-HRRP measured conditions. Risk-adjusted mortality rates

Category	Description
	declined for AMI, pneumonia, and heart failure from 2010 to 2016. Furthermore, the literature demonstrates that there is no evidence for increased inpatient or post-discharge mortality that is directly associated with the timing of the HRRP. In one study, authors examined the rates of readmission and mortality for Medicare patients with heart failure and found that the decline in readmission associated with HRRP was not associated with increase in mortality (Khera et al, 2018). In a second study, the authors found that hospitals lowering readmissions tended to lower mortality (Dharmarajan et al, 2017). Given the importance of this potential issue on patient outcomes, we also commissioned an independent group to investigate whether there have been increases in mortality rates after HRRP implementation. We found through this investigation that no sufficient evidence exists to suggest that mortality has increased because of HRRP measurement. We are committed to continuing to monitor trends in readmission and mortality rates through annual measure reevaluation and surveillance tasks. The measure is risk adjusted to account for differences in patient demographics and clinical characteristics across hospitals. These clinical characteristics may not be related to the quality of care; however, they could impact outcomes for patients. Given the wide variety of discharge diagnosis condition categories, the measure is adjusted for both case mix differences (clinical status of the patient, accounted for by adjusting for comorbidities), as well as service mix differences (the types of conditions/procedures, accounted for by adjusting for the principal discharge diagnosis condition category). Adjustments for case mix differences among clinicians are made by risk-adjusting for patients' comorbid conditions that are identified during inpatient episodes of care for the 12 months prior to the index admission in addition to those present at the index admission. The measure is not risk-adjusted for social risk factors. Measure testing that evaluated the effects of adjusting for social risk factors revealed, after adjustment for clinical factors, a high correlation of 0.99 between unadjusted and adjusted scores as well as a minimal impact on measure scores. There is, in fact, a risk-standardized all-condition readmission measure for accountable care organizations (ACOs) with specifications that are also re-specified from and harmonized with the Hospital-Wide All-Condition 30-Day Risk-Standardized Readmission measure within the Inpatient Quality Reporting (IQR) Program. Introducing hospital-wide readmission measurement within MIPS fills an important gap by creating a mechanism for shared accountability across health providers for readmitted patients and the testing demonstrated meaningful variation in performance across MIPS eligible clinician groups. Additionally, this measure provides greater information and transparency for clinicians and patients to continue to drive improved patient care quality and positive outcomes. **Comment:** Several commenters opposed the addition of this measure for the 2021 performance year. Clinicians and group practices need stability now more than ever, and noted this is not the time to add new metrics, particularly to a category that groups are familiar with already. The commenter expressed significant concerns around administrative claims measures. While CMS asserts these measures do not increase reporting burden since they are calculated on clinicians' behalf, it takes time to study the measures themselves, understand how clinicians are evaluated, and determine how (or if) clinicians can influence performance. With registry or EHR reporting, clinicians can receive real time feedback on measure performance and evaluate whether changes are needed to facilitate improvement. Claims-based measures do not offer the same opportunity, which makes it difficult to improve performance or drive meaningful change. **Response:** For over a decade, readmission after discharge has been a concern both from an aspect of quality and resources, culminating in a national effort to address rates of readmissions for all patients, regardless of age and condition. While we can appreciate the desire for stability, we believe that the Hospital-Wide Readmission measure is a more robust measure as it is based upon the original hospital-level measure has been most rigorously tested and vetted. As an Administrative Claims measure, there is no burden to the clinician regarding collection and scoring. Real-time feedback is not a guaranteed aspect of the eCQMs Specifications or the MIPS CQMs Specifications collection type, but may be a service provided, for example, by a vendor. While this collection type does not provide real-time feedback, CMS supplies eligible clinicians and eligible clinician groups with confidential reports that provide information on measure performance, including patient-level data, to help drive quality improvement. In addition, since they utilize claims data submitted for payment purposes, they provide data elements that are validated through our monitoring and auditing processes and introduce no burden collection of vital information to help drive quality care. **Comment:** One commenter did not support the All-Cause Readmission measure, Q458, because it said it was not suitable for attribution at the clinician or group level. When the newer version of the measure was submitted for NQF consideration (HWR measure), a number of professional organizations disapproved of applying the measure at either the individual clinician level or group practice level. **Response:** This measure is a re-specification of measure Q458 currently within the MIPS program, which attributes outcomes solely to the primary care physician that provides the plurality of care during the measurement period. However, the primary care physician may not be the clinician with opportunity to impact readmissions. The intent of this measure is to improve upon the attribution of the current ACR measure and incentivize collaboration of care across inpatient and outpatient settings by considering shared attribution to up to three eligible clinician groups that provide care for patients inside and outside of the hospital and are therefore in position to influence patient risk of readmission. The TEP and clinical consultants, most of whom are clinicians themselves, supported the attribution model and identified the primary inpatient clinician, discharge clinician, and primary outpatient clinician as important roles in providing appropriate care, practical recommendations, and care transitions. The primary inpatient clinician is responsible for the medical care provided during the admission, referring patients to inpatient specialists and prescribing medications. The delivery of their care during the hospital admission can influence whether the patient returns with unresolved medical issues or side effects from inappropriate medication or dosage. The discharge clinician is responsible for preparing the patient for discharge, including determining the patient is well enough to leave the hospital, understands their condition and treatments, and has been referred to outpatient specialists or therapy, as needed. Providing clear instructions and arrangements help ensure that the patient adheres to care, medication, and lifestyle changes outside of the hospital (Bowles et al, 2014, Philips et al, 2004, DeCaporale-Ryan et al, 2017, and Verhaegh et al, 2014). The primary outpatient clinician is responsible for the care of the patient outside of the hospital and can prevent readmissions by ensuring accessibility to care and availability for consultations within 30 days after discharge. Through their individual roles and together through coordinated care, these clinicians can reduce the risk of readmission. NQF panel and committee members have voted on this measure several times, all of which concluded in favor of endorsing the measure. Final endorsement of the measure was deferred to the Spring 2020 Consensus Standards Approval Committee (CSAC) due to efforts to reduce burden for committee members who may need to prioritize COVID-19 in their communities. **Comment:** One commenter stated that HWR measure lacks transparent evaluation on whether it is appropriate to apply the readmission of one patient to multiple physicians since no evidence or testing was provided to support the attribution of this measure to the three distinct groups (discharge physician, primary inpatient care provider, and outpatient primary care provider) during NQF endorsement review. In addition, most of the evidence used to support attribution to physicians involves multiple partners and clinicians such as the health system, hospital, nurse, and/or pharmacist, and there was insufficient evidence provided to support that physicians and practices using the proposed attribution approach. The commenter questioned the ability of the HWR to meaningfully distinguish better or worse performers based on the available benchmarks from the 2017 performance period.

Category	Description
Commenters noted there is also a need to determine if additional reductions in scores can be made because readmission rates now somewhat stable. The commenter stated that they did not believe that assignment of responsibility of the reduction of readmissions to multiple physicians and practices in MIPS is appropriate. Lastly, the impact that social risk factors in the risk adjustment model on performance rates has not been fully explored. Due to all of these concerns, the commenter stated that physicians should not be held accountable for the HWR measure and the measure should be removed from the program. **Response:** While the existing literature on the association between clinicians and patient outcomes may be sparse, the TEP and clinical consultants, most of whom are clinicians themselves, supported the attribution model and identified the primary inpatient clinician, discharge clinician, and primary outpatient clinician as important roles in providing appropriate care, practical recommendations, and care transitions; and therefore, together, can reduce the risk of readmission. Clinicians are critical contributors to quality improvement, whether as change agents and influencers of health systems or key stakeholders whose acceptance is required for successful or long-lasting improvements. The measure is intended to improve upon the current ACR measure within MIPS, which unduly attributes readmissions to the clinician that provide the plurality of care during the measurement period, to more appropriately attribute readmissions to up to three clinician groups with the ability to influence the risk of readmission. The shared attribution is meant to reflect the reality that multiple factors and clinicians contribute to patient care and influence outcomes as well as promote a system change towards coordination of care for the benefit of patients. Implementation and reporting of the measure will provide further data and inform the practicality of the attribution model. As done with all measures publicly reported as part of payment programs, we will monitor use of the measure and test the measure on an annual basis. Using data from July 2015 to June 2016, the median risk-standardized readmission rate was 15.3 percent and range was 7.0 percent to 25.1 percent. In other words, patients can expect to have a readmission within 30 days of discharge on an overage of 15.3 percent of the time. The best performing clinician groups (7.0 percent) are performing 54.2 percent better than an average performer, while the worse performing clinician groups (25.1 percent) are performing 64.1 percent worse than an average performer. This variation in performance indicates a clear quality gap in which some clinician groups are able to achieve substantially lower than average rates, while up to a quarter of patients for other clinician groups are being readmitted, possibly without clinician group awareness. Recent studies examining trends in readmissions following specific conditions and procedures indicate that similar quality measures and policies have effectively decreased readmission rates and remain important metrics (Blecker et al, 2019, Carey et al, 2015, Mellor et al, 2017, Wasfy et al, 2017). The developer conducted social risk factor testing using two variables that are available and reliably measured, including dual-eligible status and Agency for Healthcare Research and Quality (AHRQ) SES index score. For both social risk factors, the correlation between the adjusted and unadjusted scores was 0.99, indicating extremely high agreement. In addition, they also tested the absolute change in risk-adjusted readmission rates. When incorporating the dual eligible risk factor, the largest change in a hospital-level risk-adjusted readmission rate was 1.74 percent for clinician groups. When incorporating low AHRQ SES, the largest change in a hospital-level risk-adjusted readmission rate was 2.45 percent. Both analyses support the notion that adding these social risk factors would have minimal impact on measure scores. Ongoing research aims to identify valid patient-level social risk factors and highlight disparities related to social risk, and as additional variables become available, they will be considered for testing and inclusion within the measure. **Comment**: One commenter opposed this measure, citing broad-based concerns about the 30-day window for readmissions in CMS measures. Those concerns are heightened with the re-specification of the measure to apply to physician groups in the MIPS. There are numerous social, economic and logistical hurdles that can occur during a 30-day readmission window, many of which are independent of a physician's or group's behavior. If the measure window were shortened to 7 days, attribution would improve. **Response:** We thank the commenter for their comment. The measure is a re-specified version of the hospital-level measure, "Hospital-Wide All-Cause, Unplanned Readmission Measure" (NQF #1789), which is currently reported within IQR, and the "All-Cause Readmission" measure, Q458, which has been in the MIPS program since 2017, both of which also use a 30-day outcome timeframe. The 30-day timeframe is consistent with other CMS readmission measures endorsed by NQF and publicly reported. The literature demonstrates that older adults are more vulnerable to adverse health outcomes for 30 days post discharge, readmissions occurring within 30 days of discharge can be influenced by care and early transition to the non-acute care setting, and that the 30-day timeframe is a clinically meaningful period for providers to communicate with each other and their patients to reduce readmissions. Furthermore, during development of the hospital-level HWR measure, the developer reviewed time to readmission curves over time, which illustrated that rapid early accrual of readmissions, followed by a stable readmission rate, eventually stabilizing by 30 days. The 30-day readmission timeframe is based upon numerous studies that have been completed assessing the association between quality of inpatient or transitional care and early readmission rates (typically 30 days). We believe that a 7-day readmission timeframe may not provide a complete representation of post-discharge observation and follow-up periods that may influence readmissions. As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years. **Comment:** One commenter stated that comparing to the 30-Day All-Cause Hospital Readmission measure, many exclusions have been dropped from the measure, thereby increasing the denominator. **Response:** We thank the commenter for their comment. The goal is not to compare the data from the All-Cause Hospital Readmission measure to the Hospital-Wide, 30 Day, All-Cause Unplanned Readmission (HWR), but to replace the All-Cause Hospital Readmission measure with a more robust measure as it is based upon the original hospital-level measure has been most rigorously tested and vetted. The measure is intended to improve upon the current ACR measure within MIPS, which unduly attributes readmissions to the clinician that provide the plurality of care during the measurement period, to more appropriately attribute readmissions to up to three clinician groups with the ability to influence the risk of readmission. There are several exclusion criteria applied to the measure population ("starting cohort"), in order to identify the appropriate denominator patient population. Additionally, the measure is risk adjusted to account for differences in patient demographics and clinical characteristics across hospitals. After consideration of public comments, we are finalizing the *Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups* measure as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

A.2. Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

Category	Description
NQF #: / eCQM NQF #:	3493 / N/A
Quality #:	480
Description:	This measure is a re-specified version of the measure, "Hospital-level Risk-standardized Complication rate (RSCR) following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)" (National Quality Forum 1550), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to Merit-based Incentive Payment System participating clinicians and/or clinician groups ("provider") and assesses each provider's complication rate, defined as any one of the specified complications occurring from the date of index admission to up to 90 days post date of the index procedure.
Measure Steward:	Centers for Medicare & Medicaid Services
Numerator:	The outcome for this measure is complication defined as acute myocardial infarction (AMI), pneumonia, and sepsis/septicemia/shock complications within seven days from the index admission date; death, surgical site bleeding, and pulmonary embolism within 30 days from the index admission; mechanical complications and periprosthetic joint infection/wound infection within 90 days of the index admission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a "yes".
Denominator:	Patients eligible for inclusion in the measure are those age 65 years and older admitted to non-federal acute care hospitals. An index admission is the hospitalization during which an elective Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) procedure was performed and to which the complication outcome is attributed. Eligible index admissions are identified using International Classification of Diseases-Tenth Revision-Procedure Coding System (ICD-10-PCS) procedure codes in Medicare inpatient claims data. For risk adjustment and outcome assessment, patients must have continuous enrollment in Medicare fee-for-service (FFS) for 12 months prior to the procedure and 90 days after it. The measure cohort is fully harmonized with the existing hospital-level measure.
Exclusions:	This measure excludes from the denominator admissions for patients: 1. With a femur, hip or pelvic fracture coded in the principal discharge diagnosis field for the index admission. 2. Undergoing partial hip arthroplasty (PHA) procedures (with a concurrent Total Hip Arthroplasty or Total Knee Arthroplasty [THA/TKA]). 3. Undergoing revision procedures (with a concurrent THA/TKA). 4. Undergoing resurfacing procedures (with a concurrent THA/TKA). 5. With a mechanical complication coded in the principal discharge diagnosis field for the index admission. 6. With a malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field for the index admission. 7. With a procedure code for removal of implanted devices/prostheses. After excluding the above admissions to identify elective primary THA/TKA procedures, the measure also excludes admissions for patients: 8. Who were transferred to the index hospital. 9. Who leave the hospital against medical advice (AMA). 10. With more than two THA/TKA procedure codes during the index hospitalization. Note: The measure does not count complications that occur in the outpatient setting and do not require a readmission.
Measure Type:	Outcome
Measure Domain:	Patient Safety (section 1848(s)(1)(B)(ii) of the Act)
High Priority Measure:	Yes (Outcome)
Collection Type:	Administrative Claims
Measure Implementation:	MIPS eligible clinicians and groups / 25 case minimum / 3 year performance period (October 1st – September 30th)
Rationale:	This risk-standardized complication rate administrative claims measure was proposed to incentivize improved coordination of care, thereby reducing the number of hospitalizations and days hospitalized for patients, reducing rates of complications, and promoting cost savings resulting from fewer hospitalizations. This measure can improve the quality of surgical care delivery and follow-up care for a common and costly surgical procedure performed for Medicare patients. This measure is a re-specified version of an existing, publicly reported hospital measure, NQF #1550, located at https://innovation.cms.gov/files/fact-sheet/bpciadvanced-fs-nqf1550.pdf. Additionally, as an administrative claims measure, there is no separate reporting burden. The measure was evaluated by the MAP and is supported for rulemaking and is NQF endorsed (NQF #3493). The measure steward indicated variability among providers and groups with the risk standardized complication rates (RSCR) ranging from 1.2 percent to 7.2 percent across the groups. In adapting the measure for MIPS eligible clinicians, it will assess the same cohort of patients as the hospital measure, but attribute complications to a larger number of entities with a typically lower volume. Thus, we anticipate that the MIPS THA/TKA complication measure will reflect meaningful variation across MIPS eligible clinicians. The median RSCR for MIPS eligible clinicians with more than 25 cases was 2.7 percent with a minimum interquartile range (IQR) of 2.4 percent - 3.2 percent. The median RSCR for MIPS eligible clinician groups with more than 25 cases was 2.8 percent, with a minimum IQR of 2.4 percent - 3.1 percent. This indicates that 50 percent of clinicians have a complication rate of 2.7 percent or more after adjusting for patient age and comorbidities. The best performing clinicians (1.2 percent) are performing 55.6 percent better than an average performer, while the worst performing clinicians (7.2 percent) are performing 166.7 percent worse than an average performer. The best performing clinician groups (1.4 percent) are performing 50 percent better than an average performer, while the worst performing clinicians (5.7 percent) are performing 103.6 percent worse than an average performer. The measure steward believes these results support meaningful variation in rates across clinician and clinician groups with room for improvement. This measure is a re-specification of the existing, publicly reported hospital-level total hip/knee arthroplasty (THA/TKA) 90-day complication measure and has been designed to align with the cohort and methods of that measure. This measure uses 36 months of administrative claims data to calculate risk-standardized complication rates (RSCRs) for MIPS eligible clinicians and MIPS eligible clinician groups with 25 or more cases within the 3-year performance period. This approach balances measure reliability with maximizing the number of clinicians or clinician groups measured. For 2023 payment determination, the performance period will include administrative claims from October 1, 2018 to September 30, 2021. The measure's numerator assesses the occurrence of complications in the 90 days following the index admission date; therefore, ending the 3-year performance period on September 30th of the calendar year will allow time for numerator assessment. Based on the information provided by the measures steward, we believe this measure is evidence-based and represents an important clinical outcome. For further information regarding the implementation of this measure, please see IV.A.3.c.(1)(e)(i) of this final rule. Note: Refer to the MAP Spreadsheet of Final Recommendations to CMS and HHS at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=91911.

Category	Description
	Comment: One commenter supported this new measure, citing that that there is no data submission requirement from clinicians. The commenter requested that consideration be given to fast-tracking this measure for reporting on Physician Compare, as a complement to measure already available on Hospital Compare, so that beneficiaries potentially could access information about the quality and clinical outcomes of joint replacement surgeons. A second commenter stated that orthopedic surgeons would choose to report this measure and also asked for the measure to be included on Physician Compare, or other CMS site. **Response:** We thank the commenter for supporting this new measure for inclusion in the MIPS program. **Comment:** One commenter indicated that it has urged CMS to consider measure reliability on a measure-by-measure basis and applauds CMS for incorporating a 3-year window to increase the integrity of this measure. The commenter has expressed concerns to CMS about the difficulty of calculating a high level of reliability and validity with 12 months of data for an individual clinician, and has urged CMS to measure surgical care at the group or facility level in order to increase statistical power. This is especially important for procedures with a low complication rate. The commenter supported the direction of this measure since it evaluates individuals and groups over a longer time period for increased reliability, and also aligns with the hospital measure. The commenter recommended that CMS allow for a longer look back period for other MIPS measures, where appropriate. Although risk-adjusted clinical data from a high-fidelity registry is often preferred to claims data, a 36-month collection period of claims data can be used as a proxy for quality outcomes with low event rates. **Response:** We thank the commenter for supporting this new measure for inclusion in the MIPS program. **Comment:** Several commenters opposed the addition of this measure for the 2021 performance year. Clinicians and group practices need stability now more than ever, and this is not the time to add new metrics, particularly to a category that groups are familiar with already. The commenter expressed significant concerns around administrative claims measures. While CMS asserts these measures do not increase reporting burden since they are calculated on clinicians' behalf, it takes time to study the measures themselves, understand how clinicians are evaluated, and determine how (or if) clinicians can influence performance. With registry or EHR reporting, clinicians can receive real time feedback on measure performance and evaluate whether changes are needed to facilitate improvement. Claims-based measures do not offer the same opportunity, which makes it difficult to improve performance or drive meaningful change. Another commenter said this measure should be delayed and implemented as part of an Orthopedic MVP instead of being implemented as a category-wide population health measure. **Response:** We believe that it is important to capture patient outcomes, that is, complication rates, for these procedures to allow for a more comprehensive view of quality of care, patient safety, prevention of and response to complications, and coordination of care. We believe this measure has the potential to illustrate variations seen in quality, help to inform patient choice, be a driver of quality improvement while enhancing care coordination. While we can appreciate the desire for stability, we believe the addition of an Administrative Claims based measure has low burden on clinicians, covers a gap within MIPS, and is important in driving quality care. Real-time feedback is not a guaranteed aspect of the eCQMs Specifications or the MIPS CQMs Specifications collection type, but may be a service provided, for example, by a vendor. While the administrative claims does not provide real-time feedback, CMS supplies eligible clinicians and eligible clinician groups with confidential reports that provide information on measure performance, including patient-level data, to help drive quality improvement. In addition, since they utilize claims data submitted for payment purposes, they provide data elements that are validated through CMS monitoring and auditing processes and introduce no burden collection of vital information related to decreasing complications from elective primary THA and/or TKA therefore improving patient outcomes. **Comment:** One commenter did not support including this new measure and requested that if CMS finalizes the measure, it must delay implementation of the measure, not include 2020 data, and provide advance notice given the measure utilizes retrospective data. The commenter was concerned that there is insufficient evidence on how an individual physician or practice could reduce complication rates in these patients and the scientific acceptability of this measure is questionable. In addition, the reliability scores when applying this measure to eligible clinicians with more than 25 admissions was below the minimum acceptable threshold. The commenter was also concerned about the impact COVID-19 may have on volume and outcomes, and did not believe any physician should be evaluated on outcomes that includes 2020 data. Finally, information on how the measure would perform using the MIPS benchmark methodology and Physician Compare Star Ratings has not been provided. In addition, two commenters opposed having a 3-year performance period for this measure. The commenter thought that it would be operationally difficult and would delay actionable feedback and payment adjustments for years. The data received and scored across two years would not reflect true performance during the performance year and would impact scoring on an episode that they treat fewer than 25 times per year. Two commenters thought that a 3-year performance period is far too long to provide meaningful, timely data that would help to inform quality improvement activities and convert it to a data reporting exercise. **Response:** THA/TKA elective procedures dramatically improve quality of life and function but can result in serious complications. The associated risk and performance of surgeons are important factors for patients to consider when deciding whether to undergo the elective operation. Current clinician-level THA/TKA quality improvement measures are generally limited to evidence-based processes of care. Measurement of patient outcomes, such as complications, allows for a more comprehensive view of quality of care, capturing complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment. During the NQF initial endorsement review process, the measure specifications and testing was reviewed by a scientific methods panel, which concluded that the measure was scientifically acceptable, contributing to the ultimate endorsement of the measure. Measure reliability testing conducted by the developer consisted of two approaches, one of which demonstrated acceptable reliability with mean signal to noise reliability scores of 0.786 and 0.769 for eligible clinicians and eligible clinician groups, respectively (Adams et al, 2010). While the other approach, test-retest reliability, yielded lower but still fair reliability scores of 0.35 and 0.47 for eligible clinicians and eligible clinician groups, respectively, the reliability results are consistent with MIPS requirements (Landis and Koch, 1977). During TEP meetings and the NQF initial endorsement review process, stakeholders argued that eligible clinicians and eligible clinician groups with less than 25 cases should also be measured since those surgeons perform fewer procedures and may benefit from quality measurement. A minimum case count of 25 ensures that a measure result is available for most eligible clinicians and eligible clinician groups while maintaining measure reliability. This ensures that we are capturing a more complete patient population by including a broadened performance period. With regard to the 3-year performance period, specifically the COVID-19 Public Health Emergency (PHE) impact, this approach supports clinicians or clinicians groups by assuring an adequately sized cohort of THA/TKA elective procedures for the assessment of complications post procedure. An adequate cohort is necessary to demonstrate reliability of results. We expect a decline in elective procedures during the PHE; however, the threshold will protect those clinicians or clinician groups that did not meet the 25 case requirement to ensure reliability. This reporting period approach balances measure reliability with maximizing the number of clinicians or clinician groups measured and quantifies the outcome derived from the data. For 2023 payment determination, the performance period will include administrative claims from October 1, 2018 to September 30, 2021. Though the performance period will span three years, performance data will be provided each year to reflect the corresponding performance period. This will ensure meaningful and timely data is available. **Comment:** One commenter stated it would be beneficial to understand why the claims-based measures differ between the two programs as the ACO has a Risk Standardized, All-Cause Unplanned Admissions for Multiple Chronic Conditions measure rather than the Risk-Standardized measure proposed here. The commenter asked that measures be aligned between programs where it makes sense to do so. **Response:** We thank the commenter for their comment. The "Risk-Standardized Acute Admission Rates for Patients with Multiple Chronic Conditions" measure was specifically developed to fulfill a measurement gap, as identified by NQF, for the ambulatory setting, which the literature demonstrates may lower readmissions for

Category	Description
	patients with multiple chronic conditions through improving access to care, supporting self-care at home, coordinating care across providers, and integrating social work, nursing, and medical services. We previously proposed but did not finalize the All-Cause Unplanned Admissions for Multiple Chronic Conditions measure for the 2021 MIPS performance period/2023 MIPS payment year to allow more time for considering feedback from the MAP on the measure (84 FR 62956). We endeavor to align with other reporting programs when able and will consider inclusion of All-Cause Unplanned Admissions for Multiple Chronic Conditions for future program years through future rulemaking. After consideration of public comments, we are finalizing the *Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)* measure as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

TABLE Group B: New Specialty Measures Sets and Modifications to Previously Finalized Specialty Measure Sets Finalized for the 2023 MIPS Payment Year and Future Years

We proposed to modify the previously finalized specialty measures sets below based upon review of updates made to existing quality measure specifications, proposed the addition of new measures for inclusion in MIPS, and considered the feedback provided by specialty societies. There may be instances where the quality measures within a specialty set remained static, but the individual measures had proposed substantive changes in Table Group D. In the first column, existing measures with substantive changes described in Table Group D are noted with an asterisk (*), core measures that align with Core Quality Measure Collaborative (CQMC) core measure set(s) are noted with the symbol (§), and high priority measures are noted with an exclamation point (!). In addition, the Indicator column includes a "high priority type" in parentheses after each high priority indicator (!) to represent fully the regulatory definition of high priority measures. In addition, electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table B as follows: NQF # / eCQM NQF #.

NOTE:

- In the instance a title and/or measure description had a substantive change finalized in Table Group D, the revised title and/or measure description is reflected in the specialty measure sets located in Table Group B.
- Under Table Group B, we respond to comments that are related to new measures that were proposed for addition to measure sets, and measures that were proposed for removal. Any comments received on previously finalized measures are out of scope and not included in this final rule.
- Measures that were not finalized for removal in this final rule have been added back into the applicable previously finalized specialty set(s) under Table Group B and the reason for their retention is addressed under Table Group C.

The definition of high priority at § 414.1305 includes an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure.

The following specialty measure set was excluded from this group because we did not propose any changes to this specialty measure set: Anesthesiology. Therefore, we refer readers to the CY 2020 Quality Payment Program final rule for the previously finalized Anesthesiology specialty measure set (84 FR 63218 through 63219).

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.1. Allergy/Immunology

PREVIOUSLY FINALIZED MEASURES IN THE ALLERGY/IMMUNOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation	This measure was proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage sinusitis. As such, we agreed with the stakeholder and proposed to add to the Allergy/Immunology specialty set.
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation	This measure was proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage sinusitis. As such, we agreed with the stakeholder and proposed to add to the Allergy/Immunology specialty set.
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement	This measure was proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/immunologists treat and frequently manage asthma. As such, we agreed with the stakeholder and proposed to add to the Allergy/Immunology specialty set.

B.1. Allergy/Immunology

MEASURES FINALIZED FOR **ADDITION** TO THE ALLERGY/IMMUNOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Efficiency)	N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma**: The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance	This measure was proposed for inclusion into the Allergy/Immunology specialty set based on previous stakeholder feedback during previous comment period. Allergists/Immunologists treat and frequently manage asthma. As such, we agreed with the stakeholder and proposed to add to the Allergy/Immunology specialty set.

Comment: One commenter thanked CMS for the addition of measures Q331, Q332, Q398, and Q444 to the Allergy/Immunology set that it had requested in prior years comments.

Response: We thank the commenter for supporting the addition of the four measures to this specialty set.

After consideration of public comments, we are finalizing the measures for addition to the *Allergy/Immunology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.2. Audiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.2. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ *	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.2. Audiology

PREVIOUSLY FINALIZED MEASURES IN THE AUDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	261	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness.	Audiology Quality Consortium
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.3a. Cardiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Efficiency)	N/A / N/A	322	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low-risk surgery patients 18 years or older for preoperative evaluation during the 12-month submission period.	American College of Cardiology Foundation
§ ! (Efficiency)	N/A / N/A	323	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status.	American College of Cardiology Foundation
! (Efficiency)	N/A / N/A	324	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment.	American College of Cardiology Foundation
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.3a. Cardiology

PREVIOUSLY FINALIZED MEASURES IN THE CARDIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347 v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- And □ Most recent tobacco status is Tobacco Free -- And □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- And □ Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)

B.3a. Cardiology

MEASURES FINALIZED FOR **ADDITION** TO THE CARDIOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	We proposed to include this measure in the Cardiology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We proposed to include this measure in the Cardiology specialty set as it is clinically relevant to this clinician type.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Cardiology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.3b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.3b. Electrophysiology Cardiac Specialist

PREVIOUSLY FINALIZED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2474 / N/A	392	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and gender: • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older	American College of Cardiology Foundation
! (Outcome)	N/A / N/A	393	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision.	American College of Cardiology Foundation

B.3b. Electrophysiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ELECTROPHYSIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	348	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.	American College of Cardiology Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Electrophysiology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.4. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.4. Chiropractic Medicine

PREVIOUSLY FINALIZED MEASURES IN THE CHIROPRACTIC MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.5. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology

B.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association / American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association /American Academy of Neurology
* ! (Outcome)	0710 / 0710e	370	CMS159v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Patient Safety)	N/A / 1365e	382	CMS177v9	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services

B.5. Clinical Social Work

MEASURES FINALIZED FOR ADDITION TO THE CLINICAL SOCIAL WORK SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan**: Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance	We proposed in Table D.9 to expand the measure's applicability to include coding that would include clinical social worker clinician type. With the expanded patient population and the clinically relevance to this clinician type, we proposed to add to the Clinical Social Work specialty set.

Comment: One commenter stated that in the palliative care setting, clinical social workers are trained to provide counseling services and play an important role in goals of care discussions, naming a surrogate decision maker and developing an advance care plan. The commenter's members regularly hold these discussions with patients and families during the course of care. As this measure is added to the Clinical Social Work set, the commenter strongly recommended that clinical social workers be added to the list of providers who can use CPT code 99497 and the add-on code 99498 and bill for advance care planning services. A second commenter supported the addition of measure Q047 to the Clinical Social Work set.

Response: We thank the commenters for their support of the addition of clinical social worker clinician type. In regards to the comment requesting updates to CPT codes 99497 and 99498, these codes are not necessary for the utilization of measure Q047, as they are included within the measure to show examples as to what services would typically satisfy the quality action. As noted in the measure specification, the quality-data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third party intermediaries that utilize Medicare Part B claims data and submit data to CMS on the clinicians behalf. However, for Medicare Part B claims, adding these codes to the numerator could potentially skew performance calculations and not allow proper distribution of numerator outcomes that reflect accurate performance.

After consideration of public comments, we are finalizing the measures for addition to the *Clinical Social Work Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.5. Clinical Social Work

PREVIOUSLY FINALIZED MEASURES IN THE CLINICAL SOCIAL WORK SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803 / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.6. Dentistry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.6. Dentistry

PREVIOUSLY FINALIZED MEASURES IN THE DENTISTRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	378	CMS75v9	eCQM Specifications	Outcome	Community/ Population Health	**Children Who Have Dental Decay or Cavities:** Percentage of children, 6 months - 20 years of age, who have had tooth decay or cavities during the measurement period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	379	CMS74v10	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services

B.7. Dermatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.7. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	137	N/A	MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	138	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma that have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis.	American Academy of Dermatology
* §	0028 / 0028e	226	CMS13 8v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology

B.7. Dermatology

PREVIOUSLY FINALIZED MEASURES IN THE DERMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	410	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Systemic Medications:** Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician- or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.	American Academy of Dermatology
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.8. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.8. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
* ! (Care Coordination)	N/A / N/A	147	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.	Society of Nuclear Medicine and Molecular Imaging
*	0507 / N/A	195	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.	American College of Radiology
! (Care Coordination)	0509 / N/A	225	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Structure	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram.	American College of Radiology
! (Appropriate Use)	N/A / N/A	360	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study.	American College of Radiology
* ! (Appropriate Use)	N/A / N/A	364	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).	American College of Radiology

B.8. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	405	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-up Imaging for Incidental Abdominal Lesions:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols	American College of Radiology
! (Appropriate Use)	N/A / N/A	406	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT), CT angiography (CTA) or magnetic resonance imaging (MRI) or magnetic resonance angiogram (MRA) studies of the chest or neck for patients aged 18 years and older with no known thyroid disease with a thyroid nodule < 1.0 cm noted incidentally with follow-up imaging recommended.	American College of Radiology
	N/A / N/A	436	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:** Percentage of final reports for patients aged 18 years and older undergoing computed tomography (CT) with documentation that one or more of the following dose reduction techniques were used: • Automated exposure control. • Adjustment of the mA and/or kV according to patient size. • Use of iterative reconstruction technique.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance

B.8. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE DIAGNOSTIC RADIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
0508 / N/A	146	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms:** Percentage of final reports for screening mammograms that are classified as "probably benign".	American College of Radiology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Diagnostic Radiology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.9. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.9. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS161 v9	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
	N/A / N/A	254	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location.	American College of Emergency Physicians
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.9. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES IN THE EMERGENCY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* ! (Efficiency)	N/A / N/A	415	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	American College of Emergency Physicians
* ! (Efficiency)	N/A / N/A	416	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.	American College of Emergency Physicians

B.9. Emergency Medicine

MEASURES NOT FINALIZED FOR **ADDITION** TO THE EMERGENCY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0053 / N/A	418	N/A	Medicare Part B Claims Specifications, MIPS CQM Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture**: The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance	We proposed in Table D.89 to expand the clinical setting to include Emergency Medicine. With the expanded patient population and the clinically relevance to this clinician type, we proposed to add to the Emergency Medicine specialty set.

Comment: One commenter opposed the addition of measure Q418 to the emergency department as an appropriate setting for this measure, stating that emergency department physicians do not manage these types of services. Furthermore, bone density tests often require a prior authorization, which would make this measure infeasible for an emergency medicine physician who does not oversee the ongoing care of a patient outside of the emergency department. A second commenter was also in opposition, stating that osteoporosis management is a chronic condition measure that requires longitudinal care and retrospective data. It is not an accurate reflection of emergency care and should not be attributable to the emergency physician, who only provides acute care management.

Response: We agree that this measure may not fit into the emergency department workflow and that these quality actions may not be feasible for the emergency medicine clinician. We will not finalize the addition of measure Q418 to the Emergency Medicine set.

After consideration of public comments, we are not finalizing measure Q418 for addition to the *Emergency Medicine Specialty Measure Set* as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.9. Emergency Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE EMERGENCY MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQM Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Emergency Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.10. Endocrinology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.10. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.10. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.10. Endocrinology

PREVIOUSLY FINALIZED MEASURES IN THE ENDOCRINOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347 v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
*	N/A / N/A	462	CMS645 v4	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.10. Endocrinology

MEASURES FINALIZED FOR **ADDITION** TO THE ENDOCRINOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We proposed to include this measure in the Endocrinology specialty set as it is clinically relevant to this clinician type.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Endocrinology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.11. Family Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128 v9	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	N/A / 0104e	107	CMS161 v9	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0055 / N/A	117	CMS131 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v1 0	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communicati on and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Opioid)	N/A / N/A	305	CMS137 v9	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. □ Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. □□□□□□Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124 v9	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139 v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
	N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
! (Outcome)	0209 / N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* ! (Outcome)	0710 / 0710e	370	CMS159 v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v 9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
* §	1407 / N/A	394	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347 v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	Centers for Medicare & Medicaid Services

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PREVIOUSLY FINALIZED MEASURES IN THE FAMILY MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND □ Most recent tobacco status is Tobacco Free -- AND □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND □ Statin Use Unless Contraindicated	Wisconsin Collaborative for Healthcare Quality (WCHQ)
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
* ! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249 v3	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349 v3	eCQM Specifications	Process	Community /Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

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MEASURES NOT FINALIZED FOR **ADDITION** TO THE FAMILY MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQM Specifications	Process	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	We proposed to add this measure to the Family Medicine specialty set. Stakeholders commented, as we agreed, that the Family Medicine set includes several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Family Medicine specialty set.

Comment: Two commenters opposed the addition of measure Q391 to the Family Medicine set, and noted that the measure specifications require a visit with a mental health professional to satisfy the measure (i.e., a visit with a family physician does not satisfy the measure); therefore application to family medicine is inappropriate.

Response: We thank the commenters for their comments. We believe that measure Q391 supports the facilitation of follow up care for patients that have been hospitalized with mental illness and represents a meaningful measure within MIPS. However, we understand the concern provided by the commenters and recognize that the quality action of the measure indicates the follow up is with a mental health practitioner. Therefore, we agree that this measure should not be added to the Family Medicine set.

After consideration of public comments, we are not finalizing measure Q391 for addition to the *Family Medicine Specialty Measure Set* as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.11. Family Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE FAMILY MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Family Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.12. Gastroenterology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	N/A / N/A	185	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of prior adenomatous polyp(s) in previous colonoscopy findings, which had an interval of 3 or more years since their last colonoscopy.	American Gastroenterological Association
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	275	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted prior to initiating anti-TNF (tumor necrosis factor) therapy.	American Gastroenterological Association
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Care Coordination)	0658 / N/A	320	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.	American Gastroenterological Association
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis**: Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastroenterological Association
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	425	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of at least two landmarks of cecal intubation is performed to establish a complete examination.	American Society for Gastrointestinal Endoscopy

B.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES IN THE GASTROENTEROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Efficiency)	N/A / N/A	439	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31.	American Gastroenterological Association

B.12. Gastroenterology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GASTROENTEROLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	390	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.	American Gastroenterological Association	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Gastroenterology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.13 General Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.13. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.13. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	264	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer**: The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients before or after neoadjuvant systemic therapy, who undergo a sentinel lymph node (SLN) procedure.	American Society of Breast Surgeons
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	354	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Anastomotic Leak Intervention**: Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.13. General Surgery

PREVIOUSLY FINALIZED MEASURES IN THE GENERAL SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

Comment: One commenter indicated that measures Q047, Q128, Q130, Q226, Q317, and Q374, included in the General Surgery set, have substantive changes proposed under the applicable D Tables (D.9, D.24, D.25, D.46, D.64, and D.73) that measure preventive care services, which do not directly align with most surgical workflows. The commenter believes that administering and measuring population health and preventive care activities are important, but these measures should not make up the majority of the General Surgery set as they offer little support in understanding the quality of surgical care.

Response: We did not propose any changes to the General Surgery set. Of note, the substantive changes finalized for the aforementioned measures do not change the intent of the measures. We encourage the commenter to submit this comment during the Solicitation for Specialty Sets for potential implementation in future years.

B.14. Geriatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0022 / N/A	238	CMS156v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES IN THE GERIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0710 / 0710e	370	CMS159v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* § ! (Outcome)	0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
* ! (Outcome)	N/A / N/A	476	CMS159v9	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE GERIATRICS SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than 6 weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

B.14. Geriatrics

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE GERIATRICS SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal

Comment: One commenter supported the removal of measures Q412 and Q414 from the Geriatrics set.

Response: We thank the commenter for supporting the removal of these measures.

After consideration of public comments, we are finalizing the measures for removal from the *Geriatrics Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program. Also note that measure Q408: Opioid Therapy Follow-up Evaluation should have been included in the removal table for the Geriatrics set in the 2021 PFS proposed rule as it is being removed from the MIPS program.

B.15. Hospitalists

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.15. Hospitalists

PREVIOUSLY FINALIZED MEASURES IN THE HOSPITALISTS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0081 / 0081e	005	CMS135 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0083 / 0083e	008	CMS144 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.16. Infectious Disease

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.16. Infectious Disease

PREVIOUSLY FINALIZED MEASURES IN THE INFECTIOUS DISEASE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
§ ! (Efficiency)	2079 / N/A	340	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits.	Health Resources and Services Administration
§	N/A / N/A	475	CMS349 v3	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.17. Internal Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	0081 / 0081e	005	CMS135v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128v9	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0055 / N/A	117	CMS131v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam**: Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0418 / 0418e	134	CMS2v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS13 8v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS16 5v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS15 6v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0643 / N/A	243	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Cardiac Rehabilitation Patient Referral from an Outpatient Setting:** Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.	American Heart Association
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Opioid)	N/A / N/A	305	CMS137v9	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. □ Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. □ Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
* §	N/A / N/A	309	CMS124v9	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years •	National Committee for Quality Assurance

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS13 9v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
§ ! (Patient Experience)	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for MIPS Clinician/Group Survey:** The Consumer Assessment of Healthcare Providers and Systems (CAHPS) for MIPS Clinician/Group Survey is comprised of 10 Summary Survey Measures (SSMs) and measures patient experience of care within a group practice. The NQF endorsement status and endorsement id (if applicable) for each SSM utilized in this measure are as follows: • Getting Timely Care, Appointments, and Information; (Not endorsed by NQF) • How well Providers Communicate; (Not endorsed by NQF) • Patient's Rating of Provider; (NQF endorsed # 0005) • Access to Specialists; (Not endorsed by NQF) • Health Promotion and Education; (Not endorsed by NQF) • Shared Decision-Making; (Not endorsed by NQF) • Health Status and Functional Status; (Not endorsed by NQF) • Courteous and Helpful Office Staff; (NQF endorsed # 0005) • Care Coordination; (Not endorsed by NQF) • Stewardship of Patient Resources. (Not endorsed by NQF)	Agency for Healthcare Research & Quality (AHRQ)
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology -Head and Neck Surgery Foundation
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology -Head and Neck Surgery Foundation

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	337	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier:** Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.	American Academy of Dermatology
§ ! (Outcome)	2082 / N/A	338	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year.	Health Resources and Services Administration
! (Outcome)	0209 / N/A	342	N/A	MIPS CQMs Specifications	Outcome	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours.	National Hospice and Palliative Care Organization
* ! (Outcome)	0710 / 0710e	370	CMS159v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	377	CMS90v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessments for Congestive Heart Failure:** Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.	Centers for Medicare & Medicaid Services
* ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
*	N/A / N/A	387	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.	American Gastroenterological Association
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association
§	N/A / N/A	401	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12-month submission period.	American Gastro-enterological Association
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* §	N/A / N/A	438	CMS347v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES IN THE INTERNAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND □ Most recent tobacco status is Tobacco Free -- AND □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND □ Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	444	NA	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249v3	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v3	eCQM Specifications	Process	Community/Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.17. Internal Medicine

MEASURES FINALIZED FOR **ADDITION** TO THE INTERNAL MEDICINE SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / 0104e	107	CMS161 v9	eCQM Measure Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica	We proposed to add this measure to the Internal Medicine specialty set. Stakeholders commented, and we agreed, that the Internal Medicine set include several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Internal Medicine specialty set.
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQM Specifications	Process	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH)**: The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance	We proposed to add this measure to the Internal Medicine specialty set. Stakeholders commented, and we agreed, that the Family Medicine set include several quality measures that address mental health and substance use disorders. Given the high rates that patients are assessed or treated for these conditions within this specialty, they recommended the inclusion of this measure within the Internal Medicine specialty set.
We received no comments on the measures for proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Internal Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.17. Internal Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE INTERNAL MEDICINE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Internal Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.18. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.18. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES IN THE INTERVENTIONAL RADIOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	2726 / N/A	076	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Prevention of Central Venous Catheter (CVC) - Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed.	American Society of Anesthesiologists
* ! (Patient Safety)	N/A / N/A	145	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).	American College of Radiology
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	MIPS CQMs Specifications, eCQM Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	Society of Interventional Radiology
! (Patient Safety)	N/A / N/A	465	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries:** The percentage of patients with documentation of angiographic endpoints of embolization AND the documentation of embolization strategies in the presence of unilateral or bilateral absent uterine arteries.	Society of Interventional Radiology

B.18. Interventional Radiology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE INTERVENTIONAL RADIOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	437	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure:** Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.	Society of Interventional Radiology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Interventional Radiology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.19. Mental/Behavioral Health

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Mental/Behavioral Health specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	009	CMS128 v9	eCQM Specifications	Process	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were treated with antidepressant medication, had a diagnosis of major depression, and who remained on an antidepressant medication treatment. Two rates are reported. a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months).	National Committee for Quality Assurance
*	N/A/ / 0104e	107	CMS161 v9	eCQM Specifications	Process	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit.	Mathematica
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/P opulation Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v1 0	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / 2872e	281	CMS149 v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	366	CMS136 v10	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* ! (Outcome)	0710 / 0710e	370	CMS159 v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / 1365e	382	CMS177 v9	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* ! (Outcome)	1879 / N/A	383	N/A	MIPS CQMs Specifications	Intermediate Outcome	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication/ Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: ● The percentage of discharges for which the patient received follow-up within 30 days after discharge. ● The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
	2803 / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.19. Mental/Behavioral Health

PREVIOUSLY FINALIZED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.20. Nephrology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.20. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.20. Nephrology

PREVIOUSLY FINALIZED MEASURES IN THE NEPHROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	400	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.	American Gastroenterological Association

B.21. Neurology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	268	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.	American Academy of Neurology
*	N/A / 2872e	281	CMS149 v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
*	N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Psychiatric Association/ American Academy of Neurology

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	290	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms once in the past 12 months.	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once in the past 12 months.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	293	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months.	American Academy of Neurology
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
* ! (Patient Experience)	N/A / N/A	386	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.	American Academy of Neurology
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	419	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Overuse of Imaging for the Evaluation of Primary Headache:** Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.	American Academy of Neurology

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES IN THE NEUROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.21. Neurology

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine	We proposed to include this measure in the Neurology specialty set based upon stakeholder feedback, as it is clinically relevant to this clinician type.
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine	We proposed to include this measure in the Neurology specialty set based upon stakeholder feedback, as it is clinically relevant to this clinician type.

Comment: One commenter supported the addition of measures Q277 and Q279 to the Neurology set.

Response: We thank the commenter for supporting the addition of these measures to the Neurology set.

After consideration of public comments, we are finalizing the measures for addition to the *Neurology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.21. Neurology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE NEUROLOGY SET

Note: In this final, we proposed the removal of the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	435	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Quality Of Life Assessment For Patients With Primary Headache Disorders:** Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12-month measurement period AND whose health related quality of life score stayed the same or improved.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

Comment: One commenter supported the removal of the three retired opioid measures, Q408, Q412, and Q414 from the Neurology set.

Response: We thank the commenter for supporting the removal of measures Q408, Q412, and Q414 from the Neurology set, as they are being removed from the MIPS program.

After consideration of public comments, we are finalizing the measures for removal from the *Neurology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.22. Neurosurgical

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.22. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications fo a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated i all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis t be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
	N/A / N/A	187	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV alteplase was initiated within three hours of time last known well.	American Heart Association
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.22. Neurosurgical

PREVIOUSLY FINALIZED MEASURES IN THE NEUROSURGICAL SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	409	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	413	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	Society of Interventional Radiology
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement

B.22. Neurosurgical

MEASURES FINALIZED FOR **ADDITION** TO THE NEUROSURGICAL SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
! (Outcome)	N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	We proposed to include this measure in the Neurosurgical specialty set as we received previous stakeholder feedback to include this measure within the specialty set. We agreed with that stakeholder that it is clinically relevant to this clinician type.
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons	We proposed to include this measure in the Neurosurgical specialty set as we received previous stakeholder feedback to include this measure within the specialty set. We agreed with that stakeholder that it is clinically relevant to this clinician type.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Neurosurgical Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.23. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.23. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services

B.23. Nutrition/Dietician

PREVIOUSLY FINALIZED MEASURES IN THE NUTRITION/DIETICIAN SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	239	CMS155v9	eCQM Specifications	Process	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. □ Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. □ Percentage of patients with counseling for nutrition. □ Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.24. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	.	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	2372 / N/A	112	CMS125v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
* §	N/A / N/A	309	CMS124v9	eCQM Specifications	Process	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v9	eCQM Specifications	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	335	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse):** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries by cesarean section (C-section), or early inductions of labor, without medical indication.	Centers for Medicare & Medicaid Services

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Care Coordination)	N/A / N/A	336	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Maternity Care: Postpartum Follow-up and Care Coordination**: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
! (Patient Safety)	2063 / N/A	422	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury:** Percentage of patients who undergo cystoscopy to evaluate for lower urinary tract injury at the time of hysterectomy for pelvic organ prolapse.	American Urogynecologic Society
! (Patient Safety)	N/A / N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.24. Obstetrics/Gynecology

PREVIOUSLY FINALIZED MEASURES IN THE OBSTETRICS/GYNECOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A / N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Appropriate Use)	N/A / N/A	443	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Non-Recommended Cervical Cancer Screening in Adolescent Females:** The percentage of adolescent females 16–20 years of age who were screened unnecessarily for cervical cancer.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	448	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Appropriate Workup Prior to Endometrial Ablation:** Percentage of patients, aged 18 years and older, who undergo endometrial sampling or hysteroscopy with biopsy and results are documented before undergoing an endometrial ablation.	Centers for Medicare & Medicaid Services
§ ! (Appropriate Use)	N/A / 3475e	472	CMS249v3	eCQM Specifications	Process	Efficiency and Cost Reduction	**Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture:** Percentage of female patients 50 to 64 years of age without select risk factors for osteoporotic fracture who received an order for a dual-energy x-ray absorptiometry (DXA) scan during the measurement period.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349v3	eCQM Specifications	Process	Community /Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.25a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
	N/A / N/A	067	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemias: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow.	American Society of Hematology
	N/A / N/A	070	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry**: Percentage of patients aged 18 years and older, seen within a 12-month reporting period, with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart.	American Society of Hematology
§ ! (Appropriate Use)	0389 / 0389e	102	CMS129 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
*	0041 / 0041e	.	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
* ! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* § ! (Appropriate Use)	1858 / N/A	450	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer:** Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated.	American Society of Clinical Oncology
* §	1859 / N/A	451	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed	American Society of Clinical Oncology

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES IN THE ONCOLOGY/HEMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	1860 / N/A	452	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies:** Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.	American Society of Clinical Oncology
* § ! (Appropriate Use)	0210 / N/A	453	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Percentage of Patients who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better):** Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.	American Society of Clinical Oncology
* § ! (Outcome)	0213 / N/A	455	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better):** Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.	American Society of Clinical Oncology
* § ! (Outcome)	0216 / N/A	457	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better):** Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.	American Society of Clinical Oncology
*	N/A / N/A	462	CMS645 v4	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.25a. Oncology/Hematology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ONCOLOGY/HEMATOLOGY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	069	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.	American Society of Hematology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Oncology/Hematology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.25b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.25b. Radiation Oncology

PREVIOUSLY FINALIZED MEASURES IN THE RADIATION ONCOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Appropriate Use)	0389 / 0389e	102	CMS129 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
* § ! (Patient Experience)	0384 / 0384e	143	CMS157 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.	American Society of Clinical Oncology
* ! (Patient Experience)	0383 / N/A	144	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcome	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.	American Society of Clinical Oncology

B.26. Ophthalmology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.26. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0086 / 0086e	012	CMS143v9	eCQM Specifications	Process	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.	American Academy of Ophthalmology
*	0087 / N/A	014	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.	American Academy of Ophthalmology
* ! (Care Coordination)	N/A / N/A	019	CMS142v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.	American Academy of Ophthalmology
* §	0055 / N/A	117	CMS131v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.26. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	0563 / N/A	141	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Outcome	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.	American Academy of Ophthalmology
* ! (Outcome)	0565 / 0565e	191	CMS133v9	eCQM Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.	American Academy of Ophthalmology
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	303	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey.	American Academy of Ophthalmology
! (Patient Experience)	N/A / N/A	304	N/A	MIPS CQMs Specifications	Patient Engagement/Experience	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey.	American Academy of Ophthalmology

B.26. Ophthalmology

PREVIOUSLY FINALIZED MEASURES IN THE OPHTHALMOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	384	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	385	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye.	American Academy of Ophthalmology
! (Outcome)	N/A / N/A	389	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction.	American Academy of Ophthalmology

B.26. Ophthalmology

MEASURES FINALIZED FOR **ADDITION** TO THE OPHTHALMOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance	We proposed in Table D.48 to expand the measure's applicability to include the ophthalmology patient population. With the expanded patient population and the clinical relevance to this clinician type, we proposed to add to the Ophthalmology specialty set.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Ophthalmology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.27. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69 v9	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68 v10	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v 10	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Specifications, MIPS CQMs Specifications	Process	Communicat ion and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
*	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communicat ion and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments**: A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	350	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.	American Association of Hip and Knee Surgeons
! (Patient Safety)	N/A / N/A	351	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g., History of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke).	American Association of Hip and Knee Surgeons

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	375	CMS66 v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Knee Replacement:** Percentage of patients 18 years of age and older who received an elective primary total knee arthroplasty (TKA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
§ ! (Patient Experience)	N/A / N/A	376	CMS56 v9	eCQM Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Total Hip Replacement:** Percentage of patients 18 years of age and older who received an elective primary total hip arthroplasty (THA) and completed a functional status assessment within 90 days prior to the surgery and in the 270-365 days after the surgery.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
*	0053 / N/A	418	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	459	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	460	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Back Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	461	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Discectomy/Laminectomy:** For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	469	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Fusion:** For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	470	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Primary Total Knee Replacement:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	471	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status After Lumbar Discectomy/Laminectomy:** For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively.	Minnesota Community Measurement
* § ! (Outcome)	N/A / N/A	473	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Leg Pain After Lumbar Fusion:** For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain	Minnesota Community Measurement

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE ORTHOPEDIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patien characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, a the individual clinician level, and at the clinic level to assess quality. The measure i available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.27. Orthopedic Surgery

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE ORTHOPEDIC SURGERY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.		This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Orthopedic Surgery Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.28. Otolaryngology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	111	CMS127v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0101 / N/A	318	CMS139v9	eCQM Specifications. CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
* ! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without Clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology-Head and Neck Surgery Foundation
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES IN THE OTOLARYNGOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.28. Otolaryngology

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE OTOLARYNGOLOGY SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Otolaryngology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.29. Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.29. Pathology

PREVIOUSLY FNALIZED MEASURES IN THE PATHOLOGY SET								
Indicator	**NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	1854 / N/A	249	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia.	College of American Pathologists
	N/A / N/A	250	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists
* ! (Care Coordination)	N/A / N/A	395	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.	College of American Pathologists
! (Care Coordination)	N/A / N/A	396	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.	College of American Pathologists
! (Care Coordination)	N/A / N/A	397	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness, ulceration and mitotic rate.	College of American Pathologists
! (Care Coordination)	N/A / N/A	440	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician:** Percentage of biopsies with a diagnosis of cutaneous Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.	American Academy of Dermatology

B.30. Pediatrics

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.30. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology-Head and Neck Surgery
*	0041 / 0041e	110	CMS147v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
§	0409 / N/A	205	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea, and syphilis screenings were performed at least once since the diagnosis of HIV infection.	Health Resources and Services Administration

B.30. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§	N/A / N/A	239	CMS155v9	eCQM Specifications	Process	Community / Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. □ Percentage of patients with height, weight, and body mass index (BMI) percentile documentation. □ Percentage of patients with counseling for nutrition. □ Percentage of patients with counseling for physical activity.	National Committee for Quality Assurance
§	N/A / N/A	240	CMS117v9	eCQM Specifications	Process	Community / Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three or four H influenza type B (Hib); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	305	CMS137v9	eCQM Specifications	Process	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol or other drug abuse or (AOD) dependence who received the following. Two rates are reported. □ Percentage of patients who initiated treatment including either an intervention or medication for the treatment of AOD abuse or dependence within 14 days of the diagnosis. □ Percentage of patients who engaged in ongoing treatment including two additional interventions or a medication for the treatment of AOD abuse or dependence within 34 days of the initiation visit. For patients who initiated treatment with a medication, at least one of the two engagement events must be a treatment intervention.	National Committee for Quality Assurance
§	N/A / N/A	310	CMS153v9	eCQM Specifications	Process	Community / Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period.	National Committee for Quality Assurance

B.30. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	366	CMS136v10	eCQM Specifications	Process	Effective Clinical Care	**Follow-Up Care for Children Prescribed ADHD Medication (ADD):** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a) Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b) Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended.	National Committee for Quality Assurance
* ! (Outcome)	0710 / 0710e	370	CMS159v9	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Depression Remission at Twelve Months:** The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.	Minnesota Community Measurement
*	N/A / N/A	379	CMS74v10	eCQM Specifications	Process	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / 1365e	382	CMS177v9	eCQM Specifications	Process	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.	Mathematica
* ! (Care Coordination)	0576 / N/A	391	N/A	MIPS CQMs Specifications	Process	Communication/Care Coordination	**Follow-up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.	National Committee for Quality Assurance
* §	1407 / N/A	394	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.	National Committee for Quality Assurance

B.30. Pediatrics

PREVIOUSLY FNALIZED MEASURES IN THE PEDIATRICS SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
	2803 / N/A	402	NA	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.30. Pediatrics

MEASURES FINALIZED FOR **ADDITION** TO THE PEDIATRICS SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance	We proposed in Table D.18 to expand the measure's applicability to include the pediatric patient population. With the expanded patient population and the clinical relevance to this clinician type, we proposed to add to the Pediatric specialty set.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Pediatrics Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.31. Physical Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.31. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419 e	130	CMS68 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.31. Physical Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028 e	226	CMS13 8v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Opioid)	N/A / N/A	468	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Continuity of Pharmacotherapy for Opioid Use Disorder (OUD):** Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.	University of Southern California

B.31. Physical Medicine

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PHYSICAL MEDICINE SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	408	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	412	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Documentation of Signed Opioid Treatment Agreement:** All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.	American Academy of Neurology	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
N/A / N/A	414	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Evaluation or Interview for Risk of Opioid Misuse:** All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.		This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.

After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Physical Medicine Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.32. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association
*	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v 10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v1 0	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient	N/A / N/A	181	N/A	Medicare Part B Claims Measure	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older	Centers for Medicare & Medicaid

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
Safety)				Specifications, MIPS CQMs Specifications			with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Services
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* ! (Outcome)	N/A / N/A	217	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Knee Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	218	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Hip Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	219	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	220	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Low Back Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients	Focus on Therapeutic Outcomes, Inc.

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
							14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	
* ! (Outcome)	N/A / N/A	221	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Shoulder Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* ! (Outcome)	N/A / N/A	222	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Communication and Care Coordination	**Functional Status Change for Patients with Elbow, Wrist or Hand Impairments:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).	Focus on Therapeutic Outcomes, Inc.
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / 2872e	281	CMS149 v9	eCQM Specifications	Process	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.	American Academy of Neurology
* ! (Care Coordination)	N/A / N/A	288	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Dementia: Education and Support of Caregivers for Patients with Dementia:** Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.	American Psychiatric Association/ American Academy of Neurology
* ! (Patient Safety)	0101 / N/A	318	CMS139 v9	eCQM Specifications. CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance
* ! (Outcome)	N/A / N/A	478	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Change for Patients with Neck Impairments:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil).	Focus on Therapeutic Outcomes, Inc.

B.32. Physical Therapy/Occupational Therapy

MEASURES FINALIZED FOR ADDITION TO THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	N/A / N/A	283	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management:** Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.	American Academy of Neurology	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	N/A / N/A	286	N/A	MIPS CQMs Specifications	Process	Patient Safety	**Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia:** Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.	American Academy of Neurology	We proposed to include this measure in the Physical Therapy/Occupational Therapy specialty set as it is clinically relevant to this clinician type.

Comment: Once commenter was supportive of adding measures Q283 and Q286 to the Physical Therapy/Occupational Therapy set.

Response: We thank the commenter for supporting the addition of measures Q283 and Q286 to this specialty set.

After consideration of public comments, we are finalizing the measures for addition to the *Physical Therapy/Occupational Therapy Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

B.32. Physical Therapy/Occupational Therapy

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR REMOVAL FROM THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SET

Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.

NQF # / eCQM NQF #	Quality #	CMS eCQM ID	Collection Type	Measure Type	National Quality Strategy Domain	Measure Title and Description	Measure Steward	Rationale for Removal
N/A / N/A	282	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.	American Psychiatric Association/ American Academy of Neurology	We proposed to remove this measure from the Physical Therapy/Occupational Therapy set as it is duplicative of measure Q182: Functional Outcome Assessment. Measure Q182 includes much of the patient population in measure Q282, but is more robust in that is requires more frequent assessments and a plan of care.

Comment: One commenter supported the removal of measure Q282 from the Physical Therapy/Occupational Therapy set and agreed with the rationale that the measure is duplicative to measure Q182.

Response: We thank the commenter for supporting the removal of measure Q282 from this specialty set.

After consideration of public comments, we are finalizing the measures for removal from the *Physical Therapy/Occupational Therapy Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.

B.33. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.33. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.33. Plastic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE PLASTIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v9	Medicare Part B Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
§ ! (Outcome)	N/A / N/A	355	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period.	American College of Surgeons
! (Outcome)	N/A / N/A	356	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure.	American College of Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons

B.34. Podiatry

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.34. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.34. Podiatry

PREVIOUSLY FINALIZED MEASURES IN THE PODIATRY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0416 / N/A	127	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.	American Podiatric Medical Association
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Patient Safety)	0101 / N/A	318	CMS139 v9	eCQM Specifications, CMS Web Interface Measure Specifications,	Process	Patient Safety	**Falls: Screening for Future Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.	National Committee for Quality Assurance

B.35. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	0059 / N/A	001	CMS122 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%):** Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
	0046 / N/A	039	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	2372 / N/A	112	CMS125 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.	National Committee for Quality Assurance
* §	0034 / N/A	113	CMS130 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
*	0417 / N/A	126	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.	American Podiatric Medical Association

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	NA	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance

B.35. Preventive Medicine

PREVIOUSLY FINALIZED MEASURES IN THE PREVENTIVE MEDICINE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	N/A / N/A	438	CMS347 v4	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease**: Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.	Centers for Medicare & Medicaid Services
§	N/A / N/A	475	CMS349 v3	eCQM Specifications	Process	Community/ Population Health	**HIV Screening:** Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for HIV.	Centers for Disease Control and Prevention

B.36. Pulmonology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.36. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0102 / N/A	052	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy**: Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.	American Thoracic Society
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.36. Pulmonology

PREVIOUSLY FINALIZED MEASURES IN THE PULMONOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Outcome)	N/A / N/A	236	CMS165 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / N/A	277	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.	American Academy of Sleep Medicine
*	N/A / N/A	279	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.	American Academy of Sleep Medicine
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	398	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Optimal Asthma Control:** Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.	Minnesota Community Measurement
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Efficiency)	N/A / N/A	444	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Medication Management for People with Asthma:** The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.	National Committee for Quality Assurance

B.36. Pulmonology

MEASURES FINALIZED FOR **ADDITION** TO THE PULMONOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We proposed to include this measure in the Pulmonology specialty set as it is clinically relevant to this clinician type.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Pulmonology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.37. Rheumatology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.37. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
	0046 / N/A	039	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis.	National Committee for Quality Assurance
! (Care Coordination)	N/A / N/A	024	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.	National Committee for Quality Assurance
* ! (Care Coordination)	0326 / N/A	047	N/A	Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e	110	CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services

B.37. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
*	N/A / N/A	176	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Tuberculosis Screening Prior to First Course Biologic Therapy:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period.	American College of Rheumatology
	2523 / N/A	177	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment of disease activity using an ACR-preferred RA disease activity assessment tool at ≥50% of encounters for RA for each patient during the measurement year.	American College of Rheumatology
*	N/A / N/A	178	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.	American College of Rheumatology
*	N/A / N/A	180	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.	American College of Rheumatology
* §	0028 / 0028e	226	CMS138v9	Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165v9	Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance

B.37. Rheumatology

PREVIOUSLY FINALIZED MEASURES IN THE RHEUMATOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v 9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	374	CMS50v 9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.38. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.38. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0067 / N/A	006	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.	American Heart Association
* §	0070 / 0070e	007	CMS145 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.	American Heart Association
* §	0083 / 0083e	008	CMS144 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.	American Heart Association
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	0041 / 0041e		CMS147 v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.	National Committee for Quality Assurance
* §	0066 / N/A	118	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.	American Heart Association

B.38. Skilled Nursing Facility

PREVIOUSLY FINALIZED MEASURES IN THE SKILLED NURSING FACILITY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	0101 / N/A	154	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Falls: Risk Assessment:** Percentage of patients aged 65 years and older with a history of falls that had a risk assessment for falls completed within 12 months.	National Committee for Quality Assurance
! (Care Coordination)	0101 / N/A	155	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Falls: Plan of Care:** Percentage of patients aged 65 years and older with a history of falls that had a plan of care for falls documented within 12 months.	National Committee for Quality Assurance
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
* §	1525 / N/A	326	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.	American Heart Association

B.38. Skilled Nursing Facility

MEASURES FOR ADDITION TO THE SKILLED NURSING FACILITY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	N/A / N/A	111	CMS127 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Pneumococcal Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine.	National Committee for Quality Assurance	We proposed to include this measure in the Skilled Nursing Facility specialty set as it is clinically relevant to this clinician type.
* ! (Patient Safety)	0022 / N/A	238	CMS156 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Use of High-Risk Medications in Older Adults:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications.	National Committee for Quality Assurance	We proposed in Table D.48 to expand the measure's applicability to include the skilled nursing facility patient population. With the expanded patient population and the clinical relevance to this clinician type, we proposed to add to the Skilled Nursing Facility specialty set.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Skilled Nursing Facility Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.39. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.39. Speech Language Pathology

PREVIOUSLY FINALIZED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	N/A / N/A	181	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.	Centers for Medicare & Medicaid Services
* ! (Care Coordination)	N/A / N/A	182	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance

B.39. Speech Language Pathology

MEASURES FINALIZED FOR **ADDITION** TO THE SPEECH LANGUAGE PATHOLOGY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
* §	0418 / 0418e	134	CMS2v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Screening for Depression and Follow-Up Plan**: Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.	Centers for Medicare & Medicaid Services	We proposed to add this measure to the Speech Language Pathology specialty set as the specific codes were finalized for inclusion in 2020 performance period. We proposed to include this measure in the Speech Language Pathology specialty set as it is clinically relevant to this clinician type.
We received no comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Speech Language Pathology Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.40. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.40. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
! (Outcome)	0129 / N/A	164	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours.	Society of Thoracic Surgeons
! (Outcome)	0114 / N/A	167	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons

B.40. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Outcome)	0115 / N/A	168	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason.	Society of Thoracic Surgeons
* §	0028 / 0028e	226	CMS138v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user .	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance

B.40. Thoracic Surgery

PREVIOUSLY FINALIZED MEASURES IN THE THORACIC SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
§ ! (Outcome)	0119 / N/A	445	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG):** Percent of patients aged 18 years and older undergoing isolated CABG who die, including both all deaths occurring during the hospitalization in which the CABG was performed, even if after 30 days, and those deaths occurring after discharge from the hospital, but within 30 days of the procedure.	Society of Thoracic Surgeons

B.40. Thoracic Surgery

MEASURES FINALIZED FOR **ADDITION** TO THE THORACIC SURGERY SET									
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title And Description**	**Measure Steward**	**Rationale for Inclusion**
	0236 / N/A	044	N/A	MIPS CQM Specifications	Process	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery**: Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision.	Centers for Medicare & Medicaid Services	We proposed to add this measure to the Thoracic Surgery set as it is clinically relevant to this clinician type. This set includes additional CABG quality measures and inclusion of this measure would allow for a complete assessment of quality for this surgical procedure.
We received no public comments on the measures proposed for addition to this specialty set; therefore, we are finalizing the measures for addition to the *Thoracic Surgery Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.									

B.41. Urgent Care

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.41. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* § ! (Appropriate Use)	0069 / N/A	065	CMS154 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Treatment for Upper Respiratory Infection (URI):** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* § ! (Appropriate Use)	N/A / N/A	066	CMS146 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Appropriate Testing for Pharyngitis:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test.	National Committee for Quality Assurance
* ! (Appropriate Use)	0654 / N/A	093	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.	American Academy of Otolaryngology – Head and Neck Surgery
* § ! (Appropriate Use)	0058 / N/A	116	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.	National Committee for Quality Assurance
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.41. Urgent Care

PREVIOUSLY FINALIZED MEASURES IN THE URGENT CARE SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Appropriate Use)	N/A / N/A	331	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
! (Appropriate Use)	N/A / N/A	332	N/A	MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
* ! (Appropriate Use)	0657 / N/A	464	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use:** Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.41. Urgent Care

PREVIOUSLY FINALIZED MEASURES FINALIZED FOR **REMOVAL** FROM THE URGENT CARE SET Note: In this final rule, we are removing the following measure(s) below from this specific specialty measure set based upon review of updates made to existing quality measure specifications, the addition of addition of new measures for inclusion in MIPS, and the feedback provided by specialty societies.								
NQF # / eCQM NQF #	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**	**Rationale for Removal**
N/A / N/A	333	N/A	MIPS CQMs Specifications	Efficiency	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.	American Academy of Otolaryngology - Head and Neck Surgery Foundation	This measure was proposed for removal beginning with the 2023 MIPS payment year. See Table C for rationale.
After consideration of public comments as shown in Table C, we are finalizing the measures for removal from the *Urgent Care Specialty Measure Set* as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years. Note: Where applicable, see Table C for any comments and responses pertaining to measures that were proposed for removal from the MIPS program.								

B.42. Urology

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.42. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
*	N/A / N/A	048	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.	National Committee for Quality Assurance
! (Patient Experience)	N/A / N/A	050	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months.	National Committee for Quality Assurance
§ ! (Appropriate Use)	0389 / 0389e	102	CMS129 v10	eCQM Specifications, MIPS CQMs Specifications	Process	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.	Centers for Medicare & Medicaid Services
	0390 / N/A	104	N/A	MIPS CQMs Specifications	Process	Effective Clinical Care	**Prostate Cancer: Combination Androgen Deprivation Therapy for High Risk or Very High Risk Prostate Cancer**: Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed androgen deprivation therapy in combination with external beam radiotherapy to the prostate.	American Urological Association Education and Research

B.42. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0062 / N/A	119	CMS134 v9	eCQM Specifications, MIPS CQMs Specifications	Process	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* ! (Care Coordination)	N/A / N/A	265	N/A	MIPS CQMs Specifications	Process	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.	American Academy of Dermatology
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community /Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services

B.42. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
! (Patient Safety)	N/A / N/A	429	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to vaginal closure or obliterative surgery for pelvic organ prolapse.	American Urogynecologic Society
* §	2152 / N/A	431	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	432	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bladder Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the bladder recognized either during or within 30 days after surgery.	American Urogynecologic Society
§ ! (Outcome)	N/A / N/A	433	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Bowel Injury at the time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by a bowel injury at the time of index surgery that is recognized intraoperatively or within 30 days after surgery.	American Urogynecologic Society
! (Outcome)	N/A / N/A	434	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Proportion of Patients Sustaining a Ureter Injury at the Time of Pelvic Organ Prolapse Repair:** Percentage of patients undergoing pelvic organ prolapse repairs who sustain an injury to the ureter recognized either during or within 30 days after surgery.	American Urogynecologic Society
*	N/A / N/A	462	CMS645v4	eCQM Specifications	Process	Effective Clinical Care	**Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy:** Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.	Oregon Urology Institute

B.42. Urology

PREVIOUSLY FINALIZED MEASURES IN THE UROLOGY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* ! (Outcome)	N/A / N/A	476	CMS771 v2	eCQM Specifications	Patient Reported Outcome	Person and Caregiver-Centered Experience and Outcomes	**Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia:** Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUS) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.	Large Urology Group Practice Association and Oregon Urology Institute

B.43. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table B of the appendix of this final rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to: whether the measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. Measure tables in this set include previously finalized measures that we are maintaining within the set, measures that were proposed to be added, and measures that were proposed for removal, as applicable.

B.43. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
! (Appropriate Use)	0268 / N/A	021	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second-Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second-generation cephalosporin prophylactic antibiotic who had an order for a first OR second-generation cephalosporin for antimicrobial prophylaxis.	American Society of Plastic Surgeons
! (Patient Safety)	N/A / N/A	023	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which venous thromboembolism (VTE) prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low- Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time.	American Society of Plastic Surgeons
* ! (Care Coordination)	0326 / N/A	047	N/A	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Advance Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.	National Committee for Quality Assurance
* §	N/A / N/A	128	CMS69v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.	Centers for Medicare & Medicaid Services
* ! (Patient Safety)	0419 / 0419e	130	CMS68v10	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.	Centers for Medicare & Medicaid Services

B.43. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
* §	0028 / 0028e	226	CMS138 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Process	Community/ Population Health	**Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention:** Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user.	National Committee for Quality Assurance
* § ! (Outcome)	N/A / N/A	236	CMS165 v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	258	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured infrarenal abdominal aortic aneurysms (AAA) who do not experience a major complication (discharge to home no later than post-operative day #7).	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	259	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured infrarenal abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2).	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	260	N/A	MIPS CQMs Specifications	Outcome	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing Carotid Endarterectomy (CEA) who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons

B.43. Vascular Surgery

PREVIOUSLY FINALIZED MEASURES IN THE VASCULAR SURGERY SET								
Indicator	**NQF # / eCQM NQF #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**National Quality Strategy Domain**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	317	CMS22v9	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications	Process	Community / Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive.	Centers for Medicare & Medicaid Services
! (Outcome)	N/A / N/A	344	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2.	Society for Vascular Surgeons
! (Outcome)	N/A / N/A	357	N/A	MIPS CQMs Specifications	Outcome	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI).	American College of Surgeons
! (Patient Experience)	N/A / N/A	358	N/A	MIPS CQMs Specifications	Process	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon.	American College of Surgeons
* ! (Care Coordination)	N/A / N/A	374	CMS50v9	eCQM Specifications, MIPS CQMs Specifications	Process	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.	Centers for Medicare & Medicaid Services
	2803 / N/A	402	N/A	MIPS CQMs Specifications	Process	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user.	National Committee for Quality Assurance
! (Outcome)	N/A / N/A	420	N/A	MIPS CQMs Specifications	Patient Reported Outcome	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment.	Society of Interventional Radiology
! (Outcome)	N/A / N/A	441	N/A	MIPS CQMs Specifications	Intermediate Outcome	Effective Clinical Care	**Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control):** The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: □ Most recent blood pressure (BP) measurement is less than or equal to 140/90 mm Hg -- AND □ Most recent tobacco status is Tobacco Free -- AND □ Daily Aspirin or Other Antiplatelet Unless Contraindicated -- AND □ Statin Use Unless Contraindicated.	Wisconsin Collaborative for Healthcare Quality (WCHQ)

TABLE Group C: Previously Finalized Quality Measures Finalized for Removal in the 2023 MIPS Payment Year and Future Years

In this final rule, we are removing 11 previously finalized quality measures from the MIPS Program for the 2021 MIPS performance period/2023 MIPS payment year and future years. These measures are discussed in detail below. Our measure removal criteria was discussed in the CY 2019 PFS final rule (83 FR 59763 through 59765).

Further considerations are given in the evaluation of the measure's performance data, to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), additional criteria that we use for the removal of measures also includes extremely topped out measures, which means measures that are topped out with an average (mean) performance rate between 98-100 percent. Beginning with the 2020 MIPS performance period/2022 MIPS payment year, we also refer readers to the CY 2020 PFS final rule (84 FR 62957 through 62959) for additional quality measure removal criteria.

NOTE: Since publication of the measures in Table C in CY 2021 PFS proposed rule, we have determined the following measures will be retained in the 2021 MIPS performance period/2023 MIPS payment year: Q024, Q048 (MIPS CQMs Specifications collection type only), and Q337. As such, these measures have been removed from Table C and integrated back into the relevant previously finalized measure sets under Table B in this final rule. Our decisions not to finalize these measures for removal in this final rule are detailed in our responses to the public comments for these measures in Table Group C.

TABLE Group C: Previously Finalized Quality Measures Finalized and Not Finalized for Removal in the 2023 MIPS Payment Year and Future Years

C.1. Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	024
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is submitted by the physician who treats the fracture and who therefore is held accountable for the communication.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure supports communication between the physician treating the fracture and the clinician managing the patient's on-going care, but does not ensure that the patient receives the appropriate treatment or testing for osteoporosis. We believe measure Q418: Osteoporosis Management in Women Who Had a Fracture represents a more robust quality outcome in the management of patients with osteoporosis who experience a fracture since the clinical focus of this measure is the care of the patient rather than just the communication of the care plan for on-going post fracture care.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter opposed the removal of measure Q024, stating that it does not believe this measure is duplicative of measure Q418 as that measure only focuses on women, and not the entire population of possible concern. While the commenter appreciated the measure is a process measure that does not address appropriate treatment or testing, this measure captures an important aspect of care continuity for a large proportion of Medicare beneficiaries with fractures that is not addressed in any other MIPS quality measures.

Response: We agree that treatment of osteoporosis is important, however, measure Q024 does not ensure treatment of the patient only that the fracture was communicated to the clinician managing the patient's on-going care. Measure Q418 is more robust in that it requires a bone mineral density test or pharmacologic therapy. After careful consideration, we will maintain this measure for consistency and stability as it is not topped out and still in alignment with guidelines, but may consider removal in the future.

After consideration of public comments, we are not finalizing the removal of measure Q024 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.2.Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	048
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.
Measure Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measures initiative. This is a process measure that only requires an assessment for the presence or absence of urinary incontinence, which by itself may not have a meaningful direct impact on patient care as the screening itself does not indicate a plan of care was implemented. Additionally, the Medicare Part B Claims Measure Specifications collection type has reached the end of the topped out lifecycle (82 53640).
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter opposed removal of measure Q048, stating that according to the Women's Preventive Services Initiative, screening for urinary incontinence is important as this condition is underdiagnosed and undertreated in the United States. This practice screens for urinary incontinence in order to provide the appropriate diagnosis and ultimately the plan of care, and screens all women over 65 as it is clinically relevant for its practice.

Response: While we agree that this is an important concept, the measure for assessment alone is low-bar and may not drive quality outcomes meaning completion of a screening does not indicate appropriate treatment was provided to the patient. We believe that measure Q050 allows clinicians to support patients screened positive for urinary incontinence and support the needs of these patients with quality being captured upon providing the patient with a plan of care. After careful consideration, we will maintain the MIPS CQMs Specifications collection type for consistency and stability as it is not topped out and still in alignment with guidelines, but may consider removal in the future. The Medicare Part B Claims Measure Specifications collection type has reached the end of the topped out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File.

Comment: Two commenters opposed removal of measure Q048 from the MIPS program and therefore the Obstetrics/Gynecology and Geriatrics specialty sets because evaluation of incontinence is an important initial evaluative process for female patients 65 or older. While sensible to remove the measure due to the topped out status, it seems reasonable to consider modification to transition this measure to an outcomes measure. The commenter received requests to delay removing this measure until MVPs are implemented and because many TINs using this measure are short of their required six measures for MIPS reporting.

Response: Measure Q048 does not require a quality action (follow up, plan of care, etc.) that links to improved outcomes. The measure does not assess a clinical outcome nor one of the defined MIPS high priority areas. Measure Q050 is a more robust measure that requires a quality action (plan of care) for the appropriate patient population screened and diagnosed with urinary incontinence. We would encourage the commenter to collaborate with the measure to expand the population of Q050 to include all women to be screened for urinary incontinence and if positive, develop a plan of care to create a single comprehensive quality measure. After careful consideration, we will maintain the MIPS CQMs Specifications collection type for consistency and stability as it is not topped out and still in alignment with guidelines, but may consider removal in the future. The Medicare Part B Claims Measure Specifications collection type has reached the end of the topped out life cycle, which does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File.

After consideration of public comments, we are finalizing the removal of measure Q048 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years for the Medicare Part B Claims Specifications collection type only (see Table D.113). Measure Q048 will remain in the MIPS program for 2021 for the MIPS CQMs Specifications collection type.

C.3. Hematology: Multiple Myeloma: Treatment with Bisphosphonates

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	069
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period.
Measure Steward:	American Society of Hematology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because the measure does not align with current treatment guidelines and could inadvertently penalize eligible clinicians who are treating patients appropriately (i.e., Prolia), by excluding those patients instead of being numerator compliant. As currently constructed, the measure may produce misleading results.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.
Comment: One commenter was supportive of removing measure Q069 from the MIPS program. **Response:** We thank the commenter for supporting the removal of this measure. After consideration of public comments, we are finalizing the removal of measure Q069 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

C.4. Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

Category	Description
NQF # / eCQM NQF #:	0508 / N/A
Quality #:	146
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of final reports for screening mammograms that are classified as "probably benign".
Measure Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 0.428 percent for the MIPS CQMs Specifications collection type and 0.253 percent for the Medicare Part B Claims Measure Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs Specifications collection type and the Medicare Part B Claims Measure Specifications collection type are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter did not support the removal of measure Q146 since reporting difficulties created by the COVID-19 pandemic may limit relevancy of some measures due to reduced services provided. The use of performance period benchmarks for the 2021 performance year introduces uncertainty in measure selection. The removal of this measure would also limit the pool of measures available for breast imagers, and many groups carve out mammography services into separate TINs, thus group reporting does not broaden the list of available measures for these specialists. In addition, the measure could be useful as part of a measure set for a breast imaging MVP. A second commenter urged CMS to temporarily halt the removal of topped out measures for the 2021 performance year to provide clinicians with consistency as they recover from the COVID-19 PHE, particularly those that may be aligned with future MVPs. A third commenter said removal of this measure would limit the number of measures for radiologists and wanted this topped out measure to remain. A fourth commenter acknowledged the topped out data but suggested retaining the measure with an increase in the data completeness threshold to 90-95 percent since there have been no new radiology measures since 2017. A fifth commenter recommended maintaining the existing MIPS quality measures to ensure consistency, reduce a burden, and allow options in the future for MVPs.

Response: While we acknowledge the hardships faced due to the COVID-19 PHE and the specializations found within diagnostic radiation, the performance for measure Q146 has an extremely high and unvarying performance rate. This does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File. The policy for data completeness is established for all measures and is not varied between measures. We encourage the commenter to reach out to measure developers/stewards to develop new outcome/high-priority measures for submission to the Call for Measures for possible future implementation. We understand that ensuring there are measure available for future use in MVPs is important, however, we strive to ensure that all measures align with the Meaningful Measures Initiative, including removal of measures that are extremely topped out.

After consideration of public comments, we are finalizing the removal of measure Q146 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.5. Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	333
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older, with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure has reached the end of the topped out lifecycle and has a high performance rate of 2.834 percent for the MIPS CQMs Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. Given this measure's continued topped out status, we believe it has a limited opportunity to improve clinical outcomes. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	We proposed to update the denominator eligible encounters to include telehealth encounters as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter opposed removal of measure Q333, stating that while performance on this measure has historically been high, it is still possible to further improve clinical outcomes. Patients who undergo CT scans are exposed to radiation, which is correlated with an increased risk of cancer. This measure disincentivizes CT scans when diagnosing uncomplicated cases of adult sinusitis, which leads to better clinical outcomes. Removing this measure also reduces wasteful spending incurred by ordering CT scans.

A second commenter stated that the removal of measure Q333 would impact the Emergency Medicine and Urgent Care sets. The commenter recognizes that it is not necessarily productive to keep measures that have demonstrated consistently high performance over time. At the same time, measure removal policies limiting the number of measures available to emergency medicine impact the ability of emergency medicine physicians to participate in the MIPS program. The commenter indicated that CMS must adopt a process that allows specialties to more rapidly test and replace obsolete measures. CMS should also work with clinical experts to consider ways to encourage the long-term tracking of topped out measures and allow for the reintroduction of previously topped out measures if a performance gap is later identified.

A third commenter urged CMS to temporarily halt the removal of topped out measures for the 2021 performance year to provide clinicians with consistency as they recover from the COVID-19 PHE, particularly those that may be aligned with future MVPs. A fourth commenter recommended maintaining the existing MIPS quality measures to ensure consistency, reduce a burden, and allow options in the future for MVPs. A fifth commenter requested that CMS consider extending the life of this measure with an updated denominator that adds telehealth as an eligible encounter, and the commenter also thought this would be an excellent measure to include in a future MVP.

Response: We agree that this is an important concept and we can appreciate the difficulties of the COVID-19 PHE. We understand that ensuring there are measures available for future use in MVPs is important, however, we strive to ensure that all measures align with the Meaningful Measures Initiative, including the removal of measures that are at the end of the topped out lifecycle. Additionally, by removing measures at the end of the topped out lifecycle, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File. The policy for data completeness is established for all measures and is not varied between measures. We appreciate the comment regarding inclusion of telehealth as an eligible encounter of the measure and encourage the commenter to communicate their request to the measure steward for consideration in future years.

We ensure there is an annual review of quality measures with measure stewards to ensure we maintain measures that reflect meaningful measurement. We believe that measures that are submitted to Call for Measures, vetted by CMS, and reviewed by Measure Applicability Partnership ensure that included MIPS measures are robust and fulfill our goal of incorporating meaningful measurement.

After consideration of public comments, we are finalizing the removal of measure Q333 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.6. Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	337
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients, regardless of age, with psoriasis, psoriatic arthritis and/or rheumatoid arthritis on a biological immune response modifier whose providers are ensuring active tuberculosis prevention either through negative standard tuberculosis screening tests or are reviewing the patient's history to determine if they have had appropriate management for a recent or prior positive test.
Measure Steward:	American Academy of Dermatology
High Priority Measure:	No
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure is duplicative to measure Q176: Rheumatoid Arthritis (RA): Tuberculosis Screening because we are proposing in Table D.33 substantive changes to measure Q176 that would broaden the denominator by removing the disease specificity criteria. Therefore, the patient population will overlap between these measures; however, measure Q176 has a broader eligible patient population. In the event the proposed substantive change to measure Q176 was not finalized, we considered maintaining this measure to ensure this patient population is being assessed for appropriate tuberculosis screening.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One specialty dermatology practice said it does not have a broad selection of measures to choose from and opposed the removal of measure Q337, stating that the measure is not duplicative to measure Q176. The practice does not diagnosis rheumatoid arthritis, and there is no mention of psoriasis in measure Q176. The commenter suggested that psoriasis be added to measure Q176, or as an alternative, that measure Q176 be eliminated instead since rheumatoid arthritis is mentioned in measure Q337.

A second commenter opposed the removal of measure Q337, citing that the rationale for removal is the proposed substantive changes under Table D.33 to measure Q176, where the measure population would then overlap with measure Q337. However, if changes to measure Q176 are not finalized, measure Q337 would be retained. The commenter stated that the revision to measure Q176 does not sufficiently cover the patients that dermatologist treat or the medications that are used, as are currently reported under measure Q337. See comments under Table D.33 for further recommendations from this commenter.

Response: We proposed a substantive change to measure Q176 in Table D.33 to broaden the denominator by removing the disease specificity criteria. The denominator will now include all patients aged 18 years and older receiving their first course of therapy using a biologic DMARD, regardless of diagnosis. We encourage the commenter to reach out to the measure stewards for measures Q176 and/or Q337 to discuss revisions for possible implementation of a single all-encompassing measure in future years. However, we agree the changes to measure Q176 do not adequately cover all dermatologic medications seen within measure Q337. For this reason, we will maintain measure Q337 for PY2021.

After consideration of public comments, we are not finalizing the removal of measure Q337 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.7. Implantable Cardioverter-Defibrillator (ICD) Complications Rate

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	348
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	MIPS CQMs Specifications
Measure Description:	Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD.
Measure Steward:	American College of Cardiology Foundation
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because this measure does not align with the meaningful measures initiative. The limited patient population and adoption of the quality measure does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. The limited adoption over multiple performance periods suggests this is not an important clinical topic for MIPS eligible clinicians.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter opposed removal of measure Q348, citing the removal rationale that there is limited patient population and adoption of the quality measure does not allow for the creation of benchmarks. The commenter indicated that MIPS policies prevent this measure from being used, such as scoring policies that cap the number of performance achievement points that can be earned on measures that lack a benchmark. It also leaves cardiac electrophysiology with only two relevant measures to report and discourages specialty societies from developing new MIPS measures. The commenter discouraged the removal of highly specialized measures that fill an important clinical gap.

Response: We would encourage the commenter to submit comments regarding the MIPS scoring policies. As shown by the continued low adoption rates, measure Q348 is not being implemented by clinicians and a meaningful benchmark cannot be created, meaning this measure is not driving quality care and positive outcomes and is not in alignment with the Meaningful Measure Initiative. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's inability to create a benchmark would limit the score awarded per the 2020 Benchmark File.

After consideration of public comments, we are finalizing the removal of measure Q348 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.8. Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	390
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Collection Type:	MIPS CQMs Specifications
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment.
Measure Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the advancements in hepatitis C treatments. There are now curative treatments over an 8-12-week period with few side effects. Additionally, the measure is at risk of capturing "chronic HCV" patients who are no longer viremic, which would not necessitate HCV shared decision making.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter supported the removal of measure Q390 from the MIPS program.

Response: We thank the commenter for supporting the removal of measure Q390.

After consideration of public comments, we are finalizing the removal of measure Q390 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.9.Opioid Therapy Follow-up Evaluation

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	408
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter opposed removal of measure Q408, stating that opioid treatment agreements ensure that patients have important information regarding potential risks, benefits, and expectations for patient responsibility before using these medications. It is important that clinicians regularly engage patients during opioid treatment, and there are no other measures to achieve this goal. Providers need to continue to educate and follow up with patients regarding their opioid regimens to help combat the opioid crisis. The commenter recommended that this measure be developed further in future rulemaking to include robust evaluation methods.

Several commenters opposed the removal of measure Q408 and stated that following discussion with the measure steward, there are not newer opioid measures to replace the three measures proposed for removal: Q408, Q412, and Q414. The commenters did not agree that these measures do not align with the most recent guidelines and that the measures related to relevant clinical quality activities. Also, without a pain management specialty measure set it is an administrative burden, as there are not an adequate number of quality measures that apply to the specialty of pain management. A commenter cautioned against actions that may limit the current list of quality measures addressing opioid misuse and related issues. Opioid misuse, and substance use disorders more broadly, have become more prevalent during the COVID-19 PHE. CMS must consider additional quality measures that address opioid misuse and related issues to help acknowledge the invaluable work of physicians in addressing such issues among the most vulnerable Medicare beneficiaries.

Response: We thank the commenters for their comments opposing the removal of measure Q408. We agree that this is an important topic and would encourage the commenter to reach out to measure developers to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward believed the measure was no longer aligned with current guidelines and is currently topped out. Given the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS.

After consideration of public comments, we are finalizing the removal of measure Q408 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.10.Documentation of Signed Opioid Treatment Agreement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	412
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	All patients 18 and older prescribed opiates for longer than six weeks duration who signed an opioid treatment agreement at least once during Opioid Therapy documented in the medical record.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter supported the removal of retired measure Q412 from the MIPS program. as indicated in comments on the Neurology and Geriatrics sets..

Response: We thank the commenter for supporting the removal of measure Q412.

Comment: One commenter opposed removal of measure Q412, stating that opioid treatment agreements ensure that patients have important information regarding potential risks, benefits, and expectations for patient responsibility before using these medications. There are no other measures to achieve this goal. The commenter recommended that this measure be further developed in future rulemaking to include robust evaluation methods.

Several commenters opposed the removal of measure Q412 and stated that following discussion with the measure steward, there are not newer opioid measures to replace the three measures proposed for removal: Q408, Q412, and Q414. The commenters did not agree that these measures do not align with the most recent guidelines and that the measures related to relevant clinical quality activities. Also, without a pain management specialty measure set it is an administrative burden, as there are not an adequate number of quality measures that apply to the specialty of pain management. A commenter cautioned against actions that may limit the current list of quality measures addressing opioid misuse and related issues. Opioid misuse, and substance use disorders more broadly, have become more prevalent during the COVID-19 PHE. CMS must consider additional Quality measures that address opioid misuse and related issues to help acknowledge the invaluable work of physicians in addressing such issues among the most vulnerable Medicare beneficiaries.

Response: We thank the commenters for their comments opposing the removal of measure Q412. We agree that this is an important topic and would encourage the commenter to reach out to measure developers to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward believed the measure was no longer aligned with current guidelines and are currently topped out. Given the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS.

After consideration of public comments, we are finalizing the removal of measure Q412 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.11.Evaluation or Interview for Risk of Opioid Misuse

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	414
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	MIPS CQMs Specifications
Measure Description:	All patients 18 and older prescribed opiates for longer than six weeks duration evaluated for risk of opioid misuse using a brief validated instrument (e.g. Opioid Risk Tool, Screener and Opioid Assessment for Patients with Pain, revised (SOAPP-R)) or patient interview documented at least once during Opioid Therapy in the medical record.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the request of the measure steward because this measure does not align with the most recent guidelines. The measure steward will not be further reviewing or updating the measure specifications, citing the measure is topped out and there are newer opioid measures to report that are not topped out.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter supported the removal of retired measure Q414 as indicated in comments on the Neurology and Geriatrics sets. A second commenter was supportive of the proposal to remove 14 quality measures that do not add value to the quality of care, and instead add more meaningful measurements.

Response: We thank the commenters for supporting the removal of measure Q414.

Comment: Several commenters opposed the removal of measure Q414 and stated that following discussion with the measure steward, there are not newer opioid measures to replace the three measures proposed for removal: Q408, Q412, and Q414. The commenters did not agree that these measures do not align with the most recent guidelines and that the measures related to relevant clinical quality activities. Also, without a pain management specialty measure set it is an administrative burden, as there are not an adequate number of quality measures that apply to the specialty of pain management. Another commenter cautioned against actions that may limit the current list of quality measures addressing opioid misuse and related issues. Opioid misuse, and substance use disorders more broadly, have become more prevalent during the COVID-19 PHE. CMS must consider additional Quality measures that address opioid misuse and related issues to help acknowledge the invaluable work of physicians in addressing such issues among the most vulnerable Medicare beneficiaries.

Response: We thank the commenters for their comments opposing the removal of measure Q414. We agree that this is an important topic and would encourage the commenter to reach out to measure developers to collaborate/work towards a more comprehensive measure with robust evaluation methods for future consideration for implementation into MIPS. The measure steward believed the measure was no longer aligned with current guidelines and are currently topped out. Given the measure steward is no longer supporting the measure, we are unable to continue implementation within MIPS.

After consideration of public comments, we are finalizing the removal of measure Q414 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.12. Quality of Life Assessment for Patients With Primary Headache Disorders

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	435
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Collection Type:	Medicare Part B Claims Specifications, MIPS CQMs Specifications
Measure Description:	Percentage of patients with a diagnosis of primary headache disorder whose health related quality of life (HRQoL) was assessed with a tool(s) during at least two visits during the 12-month measurement period AND whose health related quality of life score stayed the same or improved.
Measure Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program at the measure steward's request as it is no longer being maintained for inclusion. As there are various tools that providers may choose to use, it difficult to compare measure performance across MIPS eligible clinicians. Additionally, the scores are difficult to capture within the EHR leading to difficulties in determining whether the QoL is being maintained or improving over time.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.
We received no public comments on the removal of this measure; therefore, we are finalizing the removal of measure Q435 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

C.13. Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality #:	437
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Measure Description:	Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.
Measure Steward:	Society of Interventional Radiology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is considered a standard of care that has limited opportunity to improve clinical outcomes. Performance on this measure is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance for this inverse measure is 1.854 percent for the MIPS CQMs Specifications collection type and 1.031 percent for the Medicare Part B Claims Measure Specifications collection type. For an inverse measure, a lower calculated performance rate indicates better clinical care or control. As such, the MIPS CQMs Specifications collection type and the Medicare Part B Claims Measure Specifications collection type are considered extremely topped out. The average performance rate is based on the current MIPS benchmarking data located at https://qpp-cm-prod-content.s3.amazonaws.com/uploads/824/2020%20MIPS%20Quality%20Benchmarks.zip
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.

Comment: One commenter did not support the removal of measure Q437 since reporting difficulties created by the COVID-19 pandemic may limit relevancy of some measures due to reduced services provided. The use of performance period benchmarks for the 2021 performance year introduces uncertainty in measure selection. The removal of this measure would also limit the pool of measures available for radiologists. A second commenter urged CMS to temporarily halt the removal of topped out measures for the 2021 performance year to provide clinicians with consistency as they recover from the COVID-19 PHE, particularly those that may be aligned with future MVPs. A third commenter said removal of this measure would limit the number of measures for radiologists and wanted this topped out measure to remain.

Response: While we acknowledge the hardships faced due to the COVID-19 PHE and the specializations found within radiology the performance for measure Q437 has an extremely high and unvarying performance rate. This does not allow meaningful benchmarks to be established. Additionally, by removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File.

After consideration of public comments, we are finalizing the removal of measure Q437 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

C.14. All-Cause Hospital Readmission

Category	Description
NQF # / eCQM NQF #:	1789 / N/A
Quality #:	458
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Collection Type:	Administrative Claims
Measure Description:	The 30-day All-Cause Hospital Readmission measure is a risk-standardized readmission rate for beneficiaries age 65 or older who were hospitalized at a short-stay acute care hospital and experienced an unplanned readmission for any cause to an acute care hospital within 30 days of discharge.
Measure Steward:	Yale University
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale for Removal	We proposed the removal of this measure (finalized in 81 FR 77558 through 77675) as a quality measure from the MIPS program because it is duplicative to the new measure being proposed in Table A.1. for the 2021 performance period: Table A.1: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups. This proposed new measure is a re-specification of the hospital-level measure and promotes a systems level approach by clinicians, making it a more applicable measure to MIPS eligible clinicians. In the event we did not finalize the proposed new measure: Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment Program (MIPS) Eligible Clinician Groups, we would have maintained this current measure Q458: All-Cause Hospital Readmission.
In the Circumstance the Measure is Retained	There are no substantive changes or specialty set movement finalized for this measure.
We received no public comments on this measure proposed for removal; therefore, we are finalizing the removal of measure Q458 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years Comments citing measure Q458, due to the replacement of this measure with new measure Q479, Hospital-Wide, 30-Day, All-Cause Unplanned Readmission (HWR) Rate for the Merit-Based Incentive Payment System (MIPS) Groups, are addressed under Table A.1.	

TABLE Group D: Previously Finalized Quality Measures with Substantive Changes Finalized and Not Finalized for the 2023 MIPS Payment Year and Future Years

NOTE: Electronic Clinical Quality Measures (eCQMs) that are National Quality Forum (NQF) endorsed are shown in Table D as follows: NQF # / eCQM NQF #.

The D Tables within this final rule provide the substantive changes finalized for the quality measures in CY 2021. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2021 may not be identified within the NPRM due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2021 CPT and ICD-10 updates and assessment of these codes inclusion by the Measure Steward, these changes may be postponed until CY 2022. The 2021 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program Resource Library at https://qpp.cms.gov/about/resource-library under the measure specifications. For eCQM Release Notes, see the eCQI Resource Center at https://ecqi.healthit.gov/ep-ec?globalyearfilter=2020.

In addition to the finalized substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature but we believe are important to communicate to stakeholders. These changes align with the scope of the current coding, however, this will expand or contract the current eligible population, therefore, review the current year measure specification and the 2021 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes. Language has also been added, to all applicable 2021 quality measure specifications, in the form of an 'Instructions Note', to clarify that telehealth encounters are allowed for determination of denominator eligibility. Only in the instance telehealth encounters have not been previously allowed as denominator eligible, will the D table corresponding to that measure reflect an update to the denominator allowing for telehealth encounters in the 'Substantive Change' cell.

D.1 Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)

Category	Description
NQF # / eCQM NQF #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had hemoglobin A1c > 9.0% during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications. **Updated denominator exclusion: For the eCQM Specification collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types:** Revised: Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the MIPS CQMs Specifications and Medicare Part B Claims Measure Specification collection type:** Added coding to identify patients with advanced illness and frailty **Updated numerator options: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Stratified the Performance Not Met numerator option into three: **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level < 7.0% **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level greater than or equal to 7.0% and less than 8.0% **Performance Not Met:** Most recent hemoglobin A1c (HbA1c) level greater than or equal to 8.0% and less than or equal to 9.0% **Updated numerator instructions: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Added: Do not include HbA1c levels reported by the patient. Added: Only patients with a diagnosis of Type 1 or Type 2 diabetes should be included in the denominator of this measure; patients with a diagnosis of secondary diabetes due to another condition should not be included.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the denominator exclusion language and logic to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. The numerator options for Performance Not Met were stratified to have the ability to better assess hemoglobin A1c levels within the patient population that showed better control. Instructions have been added to ensure the correct patient population as the measure intent is to assess hemoglobin A1c control in Type 1 or Type 2 diabetics and not those patients who have diabetes due to another condition. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

Comment: One commenter opposed the proposed changes to the numerator for measure Q001. The removal of patient-reported HbA1cs could increase unnecessary testing for measure compliance. In addition, further clarification on acceptable sources is necessary.

Two commenters did not agree with the proposal to add a third level of stratification to the "Performance Not Met" numerator option *only for the manual MIPS CQM and Medicare Part B Claims collection types*. The commenters stated that by dividing the latter option into two – Most recent hemoglobin A1c (HbA1c) level greater than or equal to 7.0 percent and less than 8.0 percent; and Most recent hemoglobin A1c (HbA1c) level greater than or equal to 8.0 percent and less than or equal to 9.0 percent, CMS is creating additional burden and additional time required to report for administrative staff, particularly those in small and rural practices without an EHR. The commenter is concerned that CMS is making this measure more difficult to complete and report, but only for manual collection types. This creates burden for small and rural practices. In addition, ophthalmology practices have seen a significant reduction in visits due to COVID-19. The commenter urged CMS not to finalize either of these changes. A second commenter stated that having new stratifications means that CMS may not have sufficient data to establish reliable benchmark for this measure for each stratification. In addition, given the fact that CMS proposed to keep this measure in the APP quality measure list, we believe that CMS should keep the measures as are to reduce any further complication already caused by the transition from the current MIPS APM reporting standard to APP reporting. If CMS finalizes this measure with 3 stratifications, the commenter asked that CMS clarify which stratification will be pay-for performance and which will be pay-for reporting measure, and that CMS identify the benchmark for the pay-for performance stratification early in the performance year.

Response: While we understand the desire to ensure there is not unnecessary testing, the measure only requires the assessment of one hemoglobin A1c

Category	Description
	measurement each performance period and it is important to ensure accurate results are documented. The measure steward believes, and we agree, that it is important to have a more granular picture of hemoglobin A1c levels to ascertain the level of control currently being achieved as diabetes is a leading cause of death in the United States. Additionally, there is ongoing discussions regarding acceptable levels of hemoglobin A1c, it is important to obtain this granular information to continue these discussions and drive quality outcomes. With regard to the benchmark, all 'performance not met' numerator options will be combined and removed from the performance rate calculation. The addition of these stratifications will have no bearing on the ability to create a reliable benchmark for the measure. We encourage the commenter to communicate this request to the measure steward for consideration in future years. After consideration of public comments, we are finalizing the changes to measure Q001 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.

D.2 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Category	Description
NQF # / eCQM NQF #:	0081 / 0081e
Quality#:	005
CMS eCQM ID:	CMS135v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB or ARNI therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated the denominator exception logic**: **For the eCQM Specifications collection type:** Added sacubitril in the Allergy/Intolerance logic. **Updated denominator: For all collection types:** Submission Criteria 1: Added telehealth as eligible for all encounters.
Steward:	
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to include sacubitril in the Allergy/Intolerance logic as this is one of the components of ARNI and an allergy to this ingredient would be a clinically appropriate reason for allowing a denominator exception for this patient population. We proposed to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenters supported the addition of telehealth reporting for measure Q005.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q005 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of additional telehealth encounter eligibility for eCQM Specifications collection type as this is already in the current measure.

D.3 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
NQF # / eCQM NQF #:	0067 / N/A
Quality#:	006
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q006.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q006 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.4 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0070 / 0070e
Quality#:	007
CMS eCQM ID:	CMS145v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF < 40% who were prescribed beta-blocker therapy.
Substantive Change:	**Updated logic: For the eCQM Specifications collection type:** Added constraint to measure logic in instances when the patient has both prior (within the past 3 years) MI and LVEF < 40%. **The guidance is revised to read: For the eCQM Specifications collection type:** Beta-blocker therapy: - For patients with prior MI, beta-blocker therapy includes any agent within the beta-blocker drug class. As of 2015, no recommendations or evidence are cited in current stable ischemic heart disease guidelines for preferential use of specific agents - For patients with prior LVEF <40%, beta-blocker therapy includes the following: bisoprolol, carvedilol, or sustained release metoprolol succinate. The requirement of two or more visits is to establish that the eligible professional or eligible clinician has an existing relationship with the patient. A range value should satisfy the logic requirement for 'Ejection Fraction' as long as the ranged observation value clearly meets the less than 40% threshold noted in the denominator logic. A range that is inclusive of or greater than 40% would not meet the measure requirement. If a patient has had a myocardial infarction (MI) within the past 3 years and a current or prior LVEF < 40% (or moderate or severe LVSD), the patient should only be counted in Population Criteria 1. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. Beta-blocker therapy: **The instructions are revised to read: For the MIPS CQMs Specifications collection type**: This measure is to be submitted a minimum of once per performance period for all patients with a diagnosis of CAD seen during the performance period. Only patients who had at least two denominator-eligible visits during the performance period will be counted for Submission Criteria 1 and Submission Criteria 2 of this measure. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure for the primary management of patients with CAD based on the services provided and the measure-specific denominator coding. The MIPS eligible clinician should submit data on one of the submission criteria, depending on the clinical findings. If the patient has CAD or history of cardiac surgery and a current or prior LVEF < 40% (or moderate or severe LVSD), use Submission Criteria 1. If the patient has CAD or history of cardiac surgery and has a prior (within the past 3 years) MI, use Submission Criteria 2. The 3-year lookback period for the prior MI should be from the time of the encounter that is used to qualify for the denominator and evaluate the numerator. If the patient has had an MI within the past 3 years and has a current or prior LVEF < 40% (or moderate or severe LVSD), the MIPS eligible clinician should submit quality-data codes for Submission Criteria 1 and this will count as appropriate submission for this patient. **Updated denominator criteria: For all collection type:** Added telehealth as eligible for all encounters. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Denominator Criteria One: Revised: Left ventricular ejection fraction (LVEF) < 40% or documentation of moderate or severe LVSD. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication.
Steward:	
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the eCQM Specifications collection type logic to improvement alignment with measure intent as it will add constraints to help prevent double counting of patients who had both a myocardial infarction and LVEF < 40% within the past 3 years. Additionally, the guidance was revised to help clarify which population eligible patients should be included for the purposes of this measure. We also proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. For both the eCQM Specifications and MIPS CQMs Specifications collection types, the guidance and instructions have been updated, respectively, to add moderate or severe LVSD as a proxy for LVEF < 40%. The measure steward's Technical Expert Panel (TEP) determined that moderate or severe LVSD is an appropriate proxy and aligns with the intent of the measure. We agreed with this addition as LVSD can be "defined as a left ventricular ejection fraction less than 40 percent or a narrative description consistent with moderate or severe systolic dysfunction." (Per the Joint Commission Specifications Manual (v2018A)). Additionally, we proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: Several commenters supported the addition of telehealth reporting for measure Q007. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure.	

Category	Description
After consideration of public comments, we are finalizing the changes to measure Q007 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.5 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LSVD)

Category	Description
NQF # / eCQM NQF #:	0083 / 0083e
Quality#:	008
CMS eCQM ID:	CMS144v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12-month period when seen in the outpatient setting OR at each hospital discharge.
Substantive Change:	**Updated denominator: For all collection types:** Submission Criteria 1: Added telehealth as eligible for all encounters. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to revise the 'Medical Reason' value set for the eCQM Specifications collection type based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception.
Comment: Several commenters supported the addition of telehealth reporting for measure Q008. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q008 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of additional telehealth encounter eligibility for eCQM Specifications collection type as this is already in the current measure.	

D.6 Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation

Category	Description
NQF # / eCQM NQF #:	0086 / 0086e
Quality#:	012
CMS eCQM ID:	CMS143v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months.
Substantive Change:	**Modified collection type:** eCQM Specifications **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types as they have reached the end of the topped out lifecycle as finalized in 82 FR 53640. However, the benchmarking data continues to show a gap for the eCQM Specifications collection type, as such, the measure will be retained for this collection type. We also proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We proposed to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

Comment: One commenter opposed CMS's proposal to remove the Medicare Part B Claims Measure Specifications collection type for measure Q012 because it would adversely impact ophthalmologists, particularly those in small and rural practices who must rely on the claims reporting collection type because they cannot afford to adopt CEHRT. The commenter recognized the topped out status under the claims and MIPS CQM collection types, but removing this measure entirely from the claims collection type will result in even fewer measures relevant to ophthalmologists' scope of practice.

Response: We strive to ensure that all measures align with the Meaningful Measures Initiative, including the removal of measures that are at the end of the topped out lifecycle. Additionally, by removing collection types at the end of the topped out lifecycle, we are attempting to reduce reporting burden where there is little room for improvement. Removal allows eligible clinicians to maximize their potential quality performance score as this measure's topped out status would limit the score awarded per the 2020 Benchmark File.

After consideration of public comments, we are finalizing the changes to measure Q012 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.7 Age-Related Macular Degeneration (AMD): Dilated Macular Examination

Category	Description
NQF # / eCQM NQF #:	0087 / N/A
Quality#:	014
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or geographic atrophy or hemorrhage AND the level of macular degeneration severity during one or more office visits within the 12-month performance period.
Substantive Change:	**Updated numerator definition: For all collection types:** Revised: Severity of Macular Degeneration – Early, intermediate and advanced; or active choroidal neovascularization, inactive choroidal neovascularization, or with inactive scar.
Steward:	American Academy of Ophthalmology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the definition referencing the clinical stages for the 'Severity of Macular Degeneration' to clarify and align the concept with ICD-10 terminology. Adding clarity that these codes are clinically relevant and applicable.
Comment: One commenter supported updating the definition referencing the clinical stages for the 'Severity of Macular Degeneration' to clarify and align the concept with ICD-10 terminology. **Response:** We thank the commenter for supporting the change to this measure. After consideration of public comments, we are finalizing the changes to measure Q014 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.8 Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	019
CMS eCQM ID:	CMS142v9
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed with documented communication to the physician who manages the ongoing care of the patient with diabetes mellitus regarding the findings of the macular or fundus exam at least once within 12 months.
Substantive Change:	**Update numerator logic: For the eCQM Specifications collection type**: Removed "sender" and "recipient" attributes. **Updated value set/coding: For the eCQM Specifications collection type**: Removed "sender" and "recipient" attributes. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the "sender" and "recipient" attributes from the numerator logic and the value set/coding of the eCQM Specifications collection type and reverted to the numerator logic from performance year 2019. These attributes increased burden and were difficult to implement. We also proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We proposed to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.
Comment: One commenter supported CMS's proposed removal of "sender" and "recipient" attributes. This will decrease burden and make the measure technically easier to report. The commenter also supported the proposed removal of denominator exception "Medical Reason" codes as they are inappropriate for this measure. **Response:** We thank the commenter for supporting the changes to this measure. After consideration of public comments, we are finalizing the changes to measure Q019 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.9 Advance Care Plan

Category	Description
NQF # / eCQM NQF #:	0326 / N/A
Quality#:	047
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan.
Substantive Change:	**Updated denominator: For all collection types:** Added clinical social worker clinician type.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add the clinical social worker clinician type to the denominator eligible encounters as this clinical concept is applicable to their scope of practice since these clinicians are integral to ensuring patients have up to date advance care plans and/or surrogate decision makers documented within the medical record.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q047 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.10 Chronic Obstructive Pulmonary Disease (COPD): Long-Acting Inhaled Bronchodilator Therapy

Category	Description
NQF # / eCQM NQF #:	0102 / N/A
Quality#:	052
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of COPD (FEV1/FVC < 70%) and who have an FEV1 less than 60% predicted and have symptoms who were prescribed a long-acting inhaled bronchodilator.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications
Steward:	American Thoracic Society
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640. As captured in the 2020 Benchmark File, this collection type also has high performance rate. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q052 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.11 Appropriate Treatment for Children with Upper Respiratory Infection (URI)

Category	Description
NQF # / eCQM NQF #:	0069 / N/A
Quality#:	065
CMS eCQM ID:	CMS154v9
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of children 3 months - 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or 3 days after the episode.
Substantive Change:	**The title is revised from 'Appropriate Treatment for Children with Upper Respiratory Infection (URI)' to:** Appropriate Treatment for Upper Respiratory Infection (URI) **The description is revised to read:** Percentage of episodes for patients 3 months of age and older with a diagnosis of upper respiratory infection (URI) that did not result in an antibiotic dispensing event. **The initial patient population is revised to read: For the eCQM Specifications collection type:** Outpatient visits, telephone visits, online assessments, observation stays or emergency department visits with a diagnosis of URI during the measurement period among patients 3 months of age and older. **Updated stratification: For the eCQM Specifications collection type:** 3 months-17 years, 18-64 years, 65 years and older. **The guidance is revised to read: For the eCQM Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period This eCQM is an episode-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The denominator is revised to read: For the MIPS CQMs Specifications collection type:** Outpatient visits, telephone visits, online assessments, observation stays or emergency department visits with a diagnosis of upper respiratory infection (URI) during the measurement period among patients 3 months of age and older. **Updated denominator criteria: For the MIPS CQMs Specifications collection type:** Revised: Patients aged 3 months of age and older on date of encounter. Revised denominator eligible coding to include telehealth with qualified nonphysician health care professional. **The denominator instruction is revised to read: For the MIPS CQMs Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. If the patient has more than one episode in a 31-day period, include only the first episode. **Updated denominator exclusion:** **For the eCQMs Specifications collection type:** Added: 1. Exclude URI episodes when the patient had a competing comorbid condition during the 12 months prior to or on the episode date. Revised: 1. Exclude URI episodes when the patient had a new or refill prescription of antibiotics in the 30 days prior to or on the episode date. 2. Exclude URI episodes when the patient had competing diagnosis on or 3 days after the episode date. 3. Exclude URI episodes when the patient had hospice care overlapping with the measurement period. **For MIPS CQMs Specifications collection type:** Added: 1. URI episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date (e.g., tuberculosis, neutropenia, cystic fibrosis, chronic bronchitis, pulmonary edema, respiratory failure, rheumatoid lung disease). 2. URI episodes when the patient had a new or refill prescription of antibiotics (Table 1) in the 30 days prior to or on the episode date. Revised: 1. URI episodes when the patient had competing diagnoses on or 3 days after the episode date (e.g., intestinal infection, pertussis, bacterial infection, Lyme disease, otitis media, acute sinusitis, acute pharyngitis, acute tonsillitis, chronic sinusitis, infection of the pharynx/larynx/tonsils/adenoids, prostatitis, cellulitis, mastoiditis, or bone infections, acute lymphadenitis, impetigo, skin staph infections, pneumonia/gonococcal infections, venereal disease (syphilis, chlamydia, inflammatory diseases [female reproductive organs]), infections of the kidney, cystitis or UTI, and acne). Removed: 1. Children who are taking antibiotics in the 30 days prior to the date of the encounter during which the diagnosis was established. **The numerator is revised to read:** **For the eCQMs Specifications collection type:** URI episodes without a prescription for antibiotic medication on or 3 days after the outpatient visit, telephone visit, online assessment, observation stay or emergency department visit for an upper respiratory infection. **For the MIPS CQMs Specifications collection type:** URI episodes without a prescription for antibiotic medication (from Table 1) on or 3 days after the outpatient visit, telephone visit, online assessment, observation stay or emergency department visit for an upper respiratory infection. **The numerator instruction is revised to read: For the MIPS CQMs Specifications collection type:** For performance, the measure will be calculated as the number of patient's encounter(s) where antibiotics from Table 1 were neither prescribed nor

Category	Description
	dispensed on or within 3 days of the episode for URI over the total number of encounters in the denominator. A higher score indicates appropriate treatment of patients with URI (e.g., the proportion for whom antibiotics were not prescribed or dispensed following the episode). Delayed prescriptions (where an antibiotic was prescribed and patient was instructed to delay taking the antibiotic) are considered "Performance Not Met". Table 1 - Antibiotic Medications Note: This list should be used when assessing antibiotic prescriptions for the denominator exclusion and numerator components. Revised: Table 1 – Antibiotic Medication: Added Penicillin G benzathine and removed 'Miscellaneous Antibiotics Category' (Erythromycin-sulfisoxazole) **Updated value set: For the eCQM Specifications collection type:** Added 'Aggressive periodontitis' to the value set for competing diagnosis. Added telehealth services value set to eligible encounters.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding overuse of antibiotics are not limited to the pediatric population. This will allow for clinicians to report on both pediatric and adult patients. The denominator instructions and guidance are revised to clarify that only the first episode should be included if a patient has multiple episodes in a 31-day period. The denominator exclusions have been updated to reflect the change in age range and to align language with the measure submission frequency. Additionally, a denominator exclusion has been added to remove patients with competing comorbid conditions from the denominator population as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. The numerator note for the MIPS CQMs Specifications collection type was updated to clarify use of delayed prescriptions and the antibiotic medication table. Given the intent of the measure is to assess appropriate antibiotic use, delayed prescriptions will be considered numerator non-compliant as this would still constitute prescribing an antibiotic. The antibiotic medication table was also updated to be clinically relevant. The eCQM Specifications collection type value set for competing diagnosis was updated to include aggressive periodontitis as it is clinically relevant to the denominator exclusion intent. Additionally, a telehealth services value set was added to the eligible encounters for a more complete patient population.

We proposed a substantive change to the Numerator for the MIPS CQMs Specifications collection type: however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
URI episodes without a prescription for antibiotic medication (Table 1) on or 3 days after the outpatient visit, telephone visit, online assessment, observation stay or emergency department visit for an upper respiratory infection.

This additional refinement of revising '(from Table 1)' to '(Table 1)' does not affect the intent of the proposed substantive change.

Comment: One commenter stated that placing an acute and transient diagnosis on the patient problem list has the potential to inappropriately identify URI encounters because problem lists do not have expiration dates. The commenter recommended that a URI is an acute diagnosis that should only be captured as a visit diagnosis. The commenter also stated that antibiotics ordered without an end date have the potential to be included in the measure even if the antibiotic order was placed months prior to the URI encounter. The commenter recommended that the logic should not look at any antibiotics outside of the 30 day window.
Response: We thank the commenter for their comment. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q065 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.12 Appropriate Testing for Children with Pharyngitis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	066
CMS eCQM ID:	CMS146v9
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode.
Substantive Change:	**The title is revised from 'Appropriate Testing for Children with Pharyngitis' to:** Appropriate Testing for Pharyngitis **The description is revised to read:** The percentage of episodes for patients 3 years and older with a diagnosis of pharyngitis that resulted in an antibiotic dispensing event and a group A streptococcus (strep) test. **The guidance is revised to read: For the eCQM Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. This eCQM is an episode-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The initial patient population is revised to read: For the eCQM Specifications collection type:** Outpatient, telephone, online assessment, observation, or emergency department (ED) visits with a diagnosis of pharyngitis and an antibiotic dispensing event among patients 3 years or older. **The denominator is revised to read: For the MIPS CQMs Specifications collection type**: Outpatient, telephone, online assessment, observation, or emergency department (ED) visits with a diagnosis of pharyngitis and an antibiotic dispending event among patients 3 years or older. **Updated denominator criteria: For the MIPS CQMs Specifications collection type**: Revised denominator eligible coding to include telehealth with qualified nonphysician health care professional. **The denominator instructions are revised to read: For the MIPS CQMs Specifications collection type:** This is an episode of care measure that examines all eligible episodes for the patient during the measurement period. If a patient has more than one eligible episode in a 31-day period, include only the first eligible episode. **Updated denominator exclusion:** **For the eCQMs Specifications collection type:** Added: 1. Exclude episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date. Revised: 1. Exclude episodes where the patient is taking antibiotics in the 30 days prior to the episode date. 2. Exclude episodes when the patient had hospice care overlapping with the measurement period. 3. Exclude episodes where the patient had a competing diagnosis within 3 days after the episode date. **For MIPS CQMs Specifications collection type:** Added: 1. Episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date (e.g., tuberculosis, neutropenia, cystic fibrosis, chronic bronchitis, pulmonary edema, respiratory failure, rheumatoid lung disease). Revised: 1. Episodes where the patient is taking antibiotics (Table 1) in the 30 days prior to the episode date. 2. Episodes where the patient had a competing diagnosis within 3 days after the episode date (e.g., intestinal infection, pertussis, bacterial infection, Lyme disease, otitis media, acute sinusitis, chronic sinusitis, infection of the pharynx/larynx/tonsils/adenoids, prostatitis, cellulitis, mastoiditis, or bone infections, acute lymphadenitis, impetigo, skin staph infections, pneumonia/gonococcal infections, venereal disease (syphilis, chlamydia, inflammatory diseases [female reproductive organs]), infections of the kidney, cystitis or UTI). **Updated Table 1: For the MIPS CQMs Specifications collection type:** Added: Note: This list should be used when assessing antibiotic prescriptions for the denominator and denominator exclusion components. Revised: Table 1 – Antibiotic Medication: Added Penicillin G benzathine and removed 'Miscellaneous Antibiotics Category' (Erythromycin-sulfisoxazole) **The numerator is revised to read: For all collection types**: A group A streptococcus test in the 7-day period from 3 days prior to the episode date through 3 days after the episode date. **Updated stratification**: **For the eCQM Specifications collection type:** 3-17 years, 18-64 years, 65 years and older. **Updated value set: For the eCQM Specifications collection type:** Added telehealth services value set to eligible encounters.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding appropriate testing are not limited to the pediatric population. This will allow for clinicians to report on both pediatric and adult patients. The denominator instructions and guidance are revised to clarify that only the first episode should be included if a patient has multiple episodes in a 31-day period. The denominator exclusions have been updated to reflect the change in age range and to align language with the measure submission frequency. Additionally,

Category	Description
	a denominator exclusion has been added to remove patients with competing comorbid conditions from the denominator population as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. For the MIPS CQMs Specifications collection type, Table 1 was updated to remain clinically relevant and a note was added to clarify usage of Table 1 for the purposes of this measure. The eCQM Specifications collection type value set for competing diagnosis was updated to include aggressive periodontitis as it is clinically relevant to the denominator exclusion intent. Additionally, a telehealth services value set was added to the eligible encounters for a more complete patient population.
We proposed a substantive change to the denominator exclusion for the MIPS CQMs Specifications collection type: however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Added: 1. Episodes where the patient had a competing comorbid condition during the 12 months prior to or on the episode date (e.g., tuberculosis, neutropenia, cystic fibrosis, chronic bronchitis, pulmonary edema, respiratory failure, rheumatoid lung disease). Revised: 1. Episodes where the patient is taking antibiotics (Table 1) in the 30 days prior to the episode date. 2. Episodes where the patient had a competing diagnosis within three days after the episode date (e.g., intestinal infection, pertussis, bacterial infection, Lyme disease, otitis media, acute sinusitis, chronic sinusitis, infection of the adenoids, prostatitis, cellulitis, mastoiditis, or bone infections, acute lymphadenitis, impetigo, skin staph infections, pneumonia/gonococcal infections, venereal disease (syphilis, chlamydia, inflammatory diseases [female reproductive organs]), infections of the kidney, cystitis or UTI) This additional refinement of language within the competing diagnosis exclusion does not affect the intent of the proposed substantive change, but removes the duplication in denominator eligible clinical encounters that present with a bacterial infection therefore allowing reporting eligible clinicians to report a denominator exclusion for these patients would not influence overall performance of the measure. We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q066 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.13 Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use

Category	Description
NQF # / eCQM NQF #:	654/N/A
Quality#:	093
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy.
Substantive Change:	**Updated denominator: For all collection types**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Two commenters supported the addition of telehealth reporting for measure Q093.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q093 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.14 Adult Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 0104e
Quality#:	107
CMS eCQM ID:	CMS161v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified.
Substantive Change:	**The description is revised to read:** All patient visits during which a new diagnosis of MDD or a new diagnosis of recurrent MDD was identified for patients aged 18 years and older with a suicide risk assessment completed during the visit. **Updated guidance:** Added: In recognition of the growing use of integrated and team-based care, the diagnosis of dementia and the assessment of cognitive function need not be performed by the same provider or clinician. **The initial patient population is revised to read:** Patient visits during which a new diagnosis of MDD, single or recurrent episode, was identified. **The numerator is revised to read:** Patient visits during which a new diagnosis of MDD, single or recurrent episode, was identified and a suicide risk assessment was completed during the visit.
Steward:	Mathematica
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the description, initial patient population, and numerator language to better align with the measure intent and clarify that the measure is episodic in nature. The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agreed that this guidance update is clinically appropriate and aligns better with clinical care workflows.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q107 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.15 Preventive Care and Screening: Influenza Immunization

Category	Description
NQF # / eCQM NQF #:	0041 / 0041e
Quality#:	110
CMS eCQM ID:	CMS147v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications **Updated guidance: For the eCQM Specifications collection type:** Revised: Due to the changing stance of the CDC/ACIP recommendations regarding the live attenuated influenza vaccine (LAIV) for a particular flu season, this measure will not include the administration of this specific formulation of the flu vaccination. Given the variance of the timeframes for the annual update cycles, program implementation, and publication of revised recommendations from the CDC/ACIP, it has been determined that the coding for this measure will specifically exclude this formulation, so as not to inappropriately include this form of the vaccine for flu seasons when CDC/ACIP explicitly advise against it. However, it is recommended that all eligible professionals or eligible clinicians to review the guidelines for each flu season to determine appropriateness of the LAIV and other formulations of the flu vaccine. Should the LAIV be recommended for administration for a particular flu season, eligible professional or clinician may consider one of the following options: 1) satisfy the numerator by reporting either previous receipt or using the CVX 88 for unspecified formulation, 2) report a denominator exception, either as a patient reason (e.g., for patient preference) or a system reason (e.g., the institution only carries LAIV). This is a patient-based measure. **Updated denominator note: For the Medicare Part B Claims Measure Specifications collection type:** Added: For the purposes of the program, to submit on the flu season 2020-2021, the patient must have a qualifying encounter between January 1 and March 31, 2021. to submit on the flu season 2021-2022, the patient must have a qualifying encounter between October 1 and December 31, 2021. A qualifying encounter needs to occur within the flu season that is being submitted; any additional encounter(s) may occur at any time within the measurement period. **Updated denominator exception: For the eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. Updated denominator: For all collection types: Added telehealth as eligible encounter.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the denominator note for the Medicare Part B Claims Measure Specifications collection type to add clarity and align the language with the MIPS CQMs Specifications collection type. We proposed to update the guidance for the eCQM Specifications collection type to better align with the updated CDC/ACIP clinical guidelines and to clarify the intent of the measure. We also proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts, which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

We proposed a substantive change to the Denominator Note for the Medicare Part B Claims Measure Specifications collection type; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: For the purposes of the program, in order to submit on the flu season 2020-2021, the patient must have a qualifying encounter between January 1 and March 31, 2021. In order to submit on the flu season 2021-2022, the patient must have a qualifying encounter between October 1 and December 31, 2021. A qualifying encounter needs to occur within the flu season that is being submitted; any additional encounter(s) may occur at any time within the measurement period.

This additional refinement of including the language 'in order' preceding the instance of 'to submit' within the proposed language does not affect the intent of the proposed substantive change.

Comment: One commenter supported the addition of telehealth reporting for measure Q110.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

Comment: One commenter did not support the addition of telehealth reporting for measure Q110.

Response: We believe that it is important to ensure all patients have received an influenza vaccine as this is critical to the community and population health. It is important to have a complete denominator patient population to assess numerator compliance, which should include those encounters that occur via telehealth.

Category	Description
After consideration of public comments, we are finalizing the changes to measure Q110 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications. In addition, we are not finalizing the proposed additional telehealth encounter eligibility substantive change for the eCQM Specifications collection type because this is already specified in the current measure.	

D.16 Breast Cancer Screening

Category	Description
NQF # / eCQM NQF #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of women 50 - 74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed logic and value set related to unilateral mastectomy. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised**:** Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications collection type and the MIPS CQMs Specifications collection type:** Added coding to identify patients with advanced illness and frailty
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection, we proposed removing the logic and value set related to unilateral mastectomy to ensure that all patients with existing breast tissue are included in the initial patient population as it is important they receive screening for breast cancer on remaining breast tissue. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

Comment: One commenter had concerns about removing unilateral mastectomy from the mammogram quality measure. Current specifications clarify that both a right and left unilateral must be completed to count as an exclusion. The commenter saw no reason to remove that logic, as it still accomplishes what CMS is asking for by ensuring that, "all patients with existing breast tissue are included in the initial patient population as it is important they receive screening for breast cancer on remaining breast tissue." A second commenter requested that CMS provide clarification on the statement "Removed logic and value set related to unilateral mastectomy," as the commenter believed the intent of this statement is unclear.

Response: This revision was made to ensure that the logic is in alignment with the measure intent. As the logic is currently, a patient would be excluded if they had two unilateral mastectomy codes. However, it is possible for a patient to have two partial mastectomies on the same breast. Therefore, instances of mastectomies without indication of right or left side are being removed to increase specificity and ensure only those patients with total mastectomies are excluded. This will capture a more complete patient population for the assessment of the quality action and ensure patients with existing breast tissue are screened for breast cancer.

After consideration of public comments, we are finalizing the changes to measure Q112 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.

D.17 Colorectal Cancer Screening

Category	Description
NQF # / eCQM NQF #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 50-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: 1. Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. 2. Exclude patients with a diagnosis or past history of total colectomy or colorectal cancer. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator criteria: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types**: Removed coding not applicable to preventive value sets. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added coding to identify patients with advanced illness and frailty.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection type We also proposed to revise the language for the exclusion for diagnosis or past history of total colectomy or colorectal cancer for clarity and to align with the other denominator exclusions. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We proposed to remove denominator eligible coding that is not applicable to a preventive value set and may not be appropriate for inclusion in the measure's denominator eligible patient population. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q113 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.	

D.18 Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis

Category	Description
NQF # / eCQM NQF #:	0058 / N/A
Quality#:	116
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adults 18–64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription.
Substantive Change:	**The title is revised from 'Avoidance of Antibiotic Treatment in Adults With Acute Bronchitis' to:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis. **The description is revised to read:** The percentage of episodes for patients ages 3 months and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event. **The instructions are revised to read:** This measure is to be submitted at each occurrence of acute bronchitis/bronchiolitis during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The denominator is revised to read:** All patients aged 3 months or older with an outpatient, telephone visit, online assessment, observation visit or emergency department (ED) visit with a diagnosis of acute bronchitis/bronchiolitis during the measurement period. **Updated denominator criteria:** Revised: Patients 3 months of age and older on date of encounter. Added: Diagnosis for bronchiolitis. **Updated denominator exclusion:** Revised: 1. Outpatient, ED or Observation visits that result in an inpatient admission. Added: 2. Acute bronchitis/bronchiolitis episodes when the patient had a new or refill prescription of antibiotics (Table 1) in the 30 days prior to or on the episode date. **The denominator note is revised to read:** Do not include outpatient, ED or observation visits that result in an inpatient admission. When an outpatient, ED or observation visit and an inpatient stay are billed on separate claims, the visit results in an inpatient stay when the outpatient/ED/observation date of service occurs on the day prior to the admission date or any time during the admission (admission date through discharge date). An outpatient, ED or observation visit billed on the same claim as an inpatient stay is considered a visit that resulted in an inpatient stay. **The numerator instructions are revised to read:** For performance, the measure will be calculated as the number of patient encounters where antibiotics were neither prescribed nor dispensed on or within 3 days of the episode for acute bronchitis/bronchiolitis over the total number of encounters in the denominator (patients aged 3 months and older with an outpatient, telephone, online assessment, observation or ED visit for acute bronchitis/bronchiolitis). A higher score indicates appropriate treatment of patients with acute bronchitis/bronchiolitis (e.g., the proportion for whom antibiotics were not prescribed or dispensed on or 3 days after the encounter). Delayed prescriptions (where an antibiotic was prescribed and patient was instructed to delay taking the antibiotic) are considered "Performance Not Met". **Updated numerator instructions:** Added: Note: This list should be used when assessing antibiotic prescriptions for the denominator exclusion and numerator components. Removed "Norfloxacin" from Table 1 – Antibiotic Medications.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed the measure language be updated to reflect a broader denominator eligible population by revising the age to include all patients over 3 months of age as concerns regarding appropriate use of antibiotics are not limited to the adult population. This will allow for clinicians to report on both pediatric and adult patients. The title, description, instructions, and denominator are also being revised to include the diagnosis of bronchiolitis as denominator eligible to better align with the broadened age range as bronchiolitis is more commonly seen in babies and children. The diagnosis is clinically relevant to the intent of this measure. The denominator exclusion and denominator note are revised to better clarify that all visits resulting in an inpatient admission should be excluded as it may be clinically appropriate and warranted to treat them with antibiotics in accordance with appropriate care. The numerator instructions have been updated to align language with the denominator patient population updates, as well as to clarify that delayed prescriptions are still considered to be a "Performance Not Met" as the clinician is still prescribing or dispensing a prescription, which does not align with the measure's intent.
We proposed a substantive change to the denominator; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: All patients aged 3 months or older with an outpatient visit, telephone visit, online assessment, observation visit or emergency department (ED) visit with a diagnosis of acute bronchitis/bronchiolitis during the measurement period. This additional refinement of 'outpatient' to 'outpatient visit' does not affect the intent of the proposed substantive change. We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q116 as indicated for	

Category	Description
the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.19 Diabetes: Eye Exam

Category	Description
NQF # / eCQM NQF #:	0055 / N/A
Quality#:	117
CMS eCQM ID:	CMS131v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes and an active diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or diabetics with no diagnosis of retinopathy overlapping the measurement period who had a retinal or dilated eye exam by an eye care professional during the measurement period or in the 12 months prior to the measurement period.
Substantive Change:	**Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications:** Revised: Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added coding to identify patients with advanced illness and frailty. **The numerator options are revised to read: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** **Performance Met:** • Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed. • Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy. • 7 standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist documented and reviewed. • 7 standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist documented and reviewed; without evidence of retinopathy. • Eye imaging validated to match diagnosis from 7 standard field stereoscopic photos results documented and reviewed. • Eye imaging validated to match diagnosis from 7 standard field stereoscopic photos results documented and reviewed, without evidence of retinopathy. • Low risk for retinopathy (no evidence of retinopathy in the prior year)*. **Performance Not Met:** • Dilated eye exam was not performed, reason not otherwise specified. **Updated numerator options note: For the MIPS CQM Specifications and Medicare Part B Claims Measure Specifications collection type:** Removed: ****Note:** For Performance Year 2020 reporting, the Centers for Medicare & Medicaid Services and the American Medical Association have approved the use of the 8P modifier with HCPCS codes to report the Performance Not Met numerator option for Quality ID #117.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. The numerator options are being updated to stratify numerator compliant patients into those who are complaint and those who are compliant with evidence of retinopathy. This granularity will give a better picture of the patient population and the percentage of those patients who did not have evidence of retinopathy, and may fall into low risk for retinopathy, for the purposes of this measure. The numerator option note associated with the "Performance Not Met" option is being removed as it will not be applicable as the numerator options are being updated.

Comment: One commenter supported the inclusion of this measure for 2021 MIPS participants, but urged CMS to ensure that application of the measure is consistent with NCQA's update to this measure in its 2021 measure set, namely, NCQA's clarification that "eye exam results read by a system that provides an artificial intelligence (AI) interpretation meet criteria," as stated in NCQA's changes to HEDIS MY 2020 and MY 2021. The commenter is concerned that, absent this clarification, there will be confusion for practitioners who participate in MIPS and read the measure to require an eye exam by an "eye care professional," as indicated in CMS' table of Previously Finalized Measures in the Family Medicine Set for MIPS measure Q117. Such a clarification would also be consistent with the American Diabetes Association (ADA) 2020 standards for diabetes care, which provide, "Artificial intelligence systems that detect more than mild diabetic retinopathy and diabetic macular edema authorized for use by the FDA represent an alternative to traditional screening approaches."

Response: We support technology that enhances a clinician's ability to diagnosis and treat patients safely and efficiently. Annually, we collaborate with measure stewards to gather revisions and incorporate them into the MIPS quality measures to ensure the program reflects the most recent version of the specification. We are not responsible to ensure the revisions provided by the measure steward align with specifications outside of MIPS. Additionally, there may be timing considerations for revisions to be updated within MIPS that did not allow the measure steward to align the MIPS version of the specification to the HEDIS specification. We believe that we captured the measure steward's intent for this measure for this performance period. We believe by stratifying the numerator options, more granular data can be captured to discern between patients with and without evidence of retinopathy. This information may give insight into those patients with controlled blood sugar and those with uncontrolled blood sugar. We encourage the commenters to collaborate with the measure steward regarding the request of further stratification of the numerator for this measure to be considered for future years.

Category	Description
	Comment: One commenter opposed the changes to the numerator for measure Q117. CMS proposed to add stratification to the "Performance Met" numerator option *only for the manual MIPS CQM and Medicare Part B Claims collection types.* The commenter stated that currently, "Performance Met" includes the following four options: G2102 Dilated retinal eye exam with interpretation by an ophthalmologist or optometrist documented and reviewed Or; G2103 Seven standard field stereoscopic photos with interpretation by an ophthalmologist or optometrist documented and reviewed Or; G2104 Eye imaging validated to match diagnosis from seven standard field stereoscopic photos results documented and reviewed; Or 3072F Low risk for retinopathy (no evidence of retinopathy in the prior year). CMS is proposing to add further stratification by dividing the first three of these current options into two each – one as currently written and a second with "; without evidence of retinopathy" addended to the end of the option description. The commenter stated that not only is this information irrelevant to the measure, but CMS is also creating significant additional burden by nearly doubling the number of classifications that manual reporters must organize patients into in order to report the measure. This created burden on small and rural practices without an EHR, which also concerning due to COVID-19. The commenter urged CMS not to finalize this additional stratification of the numerator options for measure Q117. **Response:** We support technology that enhances a clinician's ability to diagnosis and treat patients safely and efficiently. Annually, we collaborate with measure stewards to gather revisions and incorporate them into the MIPS quality measures to ensure the program reflects the most recent version of the specification. We believe that we captured the measure steward's intent for this measure for this performance period. We believe by stratifying the numerator options, more granular data can be captured to discern between patients with and without evidence of retinopathy. This information may give insight into those patients with controlled blood sugar and those with uncontrolled blood sugar. We encourage the commenters to collaborate with the measure steward regarding the request of further stratification of the numerator for this measure to be considered for future years. After consideration of public comments, we are finalizing the changes to measure Q117 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.20 Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%)

Category	Description
NQF # / eCQM NQF #:	0066 / N/A
Quality#:	118
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy.
Substantive Change:	**Updated denominator criteria**: Added: Eligible coding for the additional patient encounter is identical to 'Patient encounter during the performance period' criteria. **Updated denominator:** Added telehealth as eligible for all encounters.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. Additionally, we proposed to clarify the denominator eligible coding for the two visits necessary for denominator eligibility.

Comment: One commenter supported the addition of telehealth reporting for measure Q118.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q118 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.21 Diabetes: Medical Attention for Nephropathy

Category	Description
NQF # / eCQM NQF #:	0062 / N/A
Quality#:	119
CMS eCQM ID:	CMS134v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period.
Substantive Change:	**Updated denominator: For the eCQM Specifications collection type:** Revised**:** Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic**: **For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the MIPS CQMs Specifications collection type:** Revised**:** Patients age 66 and older in Institutional Special Needs Plans (SNP) or residing in long-term care with a POS code 32, 33, 34, 54 or 56 for more than 90 consecutive days during the measurement period **Updated denominator exclusion: For the MIPS CQMs Specifications collection type**: Added coding to identify patients with advanced illness and frailty.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed that the denominator exclusion language and logic be updated to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q119 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.22 Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation

Category	Description
NQF # / eCQM NQF #:	0417 / N/A
Quality#:	126
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.
Substantive Change:	**Updated denominator exception:** Added: Clinician documented that patient had medical reason for not performing lower extremity neurological exam.
Steward:	American Podiatric Medical Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a denominator exception for patients with medical reasons for not performing a lower extremity neurological exam. As there may be instances where a patient is denominator eligible, however, a lower extremity neurological exam would not be reasonably performed due the presence of a burn, ulceration, or infection, for example. Adding this denominator exception allows the MIPS eligible clinician to exercise their clinical judgement as to when it is not feasible to perform a lower extremity neurological exam.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q126 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.23 Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear

Category	Description
NQF # / eCQM NQF #:	0416 / N/A
Quality#:	127
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.
Substantive Change:	**Updated denominator exclusion:** Added: Clinician documented that patient was not an eligible candidate for evaluation of footwear as patient is bilateral lower extremity amputee.
Steward:	American Podiatric Medical Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a denominator exclusion for bilateral lower extremity amputee as this patient population is not applicable to this measure and should not be included in the denominator eligible patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q127 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.24 Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	128
CMS eCQM ID:	CMS69v9
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 12 months AND with a BMI outside of normal parameters, a follow-up plan is documented during the encounter or during the previous 12 months of the current encounter. Normal Parameters: Age 18 years and older BMI ≥ 18.5 and < 25 kg/m2.
Substantive Change:	**The description is revised to read:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous 12 months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters. **Updated guidance: For the eCQM Specifications collection type:** Removed: Review the following to apply the Medical Reason exception criteria: The Medical Reason exception could include, but is not limited to, the following patients as deemed appropriate by the health care provider: * Elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as the following examples: * Illness or physical disability * Mental illness, dementia, confusion * Nutritional deficiency such as Vitamin/mineral deficiency * Patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status Revised: See denominator exception section for examples. **Updated definition: For all collection types:** Added**:** Normal BMI Parameters – Age 18 years and older BMI >= 18.5 and < 25 kg/m2 **For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Not Eligible for BMI Calculation or Follow-Up Plan (Denominator Exclusion) – A patient is not eligible if one or more of the following reasons are documented: • Patients receiving palliative or hospice care on the date of the current encounter or any time prior to the current encounter • Patients who are pregnant on the date of the current encounter or any time during the measurement period prior to the current encounter Patients with no documented BMI or a documented BMI outside normal parameters and a documented reason for not completing BMI follow-up plan during the current encounter or within the previous 12 months of the current encounter (Denominator Exception) – • Patients with a documented medical reason for not documenting BMI or for not documenting a follow-up plan for a BMI outside normal parameters (e.g., elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as illness or physical disability, mental illness, dementia, confusion, or nutritional deficiency such as vitamin/mineral deficiency; patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status) • Patients who refuse measurement of height and/or weight on the date of the current encounter or any time during the measurement period prior to the current encounter **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed: Patients who refuse measurement of height and/or weight. Added: Hospice care value sets **Updated denominator exception:** **For the eCQM Specifications collection type:** Added: Patients who refuse measurement of height and/or weight. Revised: Patients with a documented medical reason for not documenting BMI or for not documenting a follow-up plan for a BMI outside normal parameters (e.g., elderly patients (65 or older) for whom weight reduction/weight gain would complicate other underlying health conditions such as illness or physical disability, mental illness, dementia, confusion, or nutritional deficiency such as vitamin/mineral deficiency; patients in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). **For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection type:** Added: BMI not documented due to medical reason OR patient refusal of height or weight measurement. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process

Category	Description
Rationale:	We proposed to update the measure description language to reduce redundancy throughout the specification and clarify the intent. The guidance for the eCQM Specifications collection type was updated to move the medical reason exception language to the denominator exceptions header as this language is more suitable for this field. The definition for "Normal BMI Parameters" was moved to the definition section as it is more applicable here and helps readability. During the change review process, the patient refusal denominator exclusion was moved to the denominator exception. We agreed that patient refusal is more appropriately classified as a denominator exception as the patient would still be denominator eligible. For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type, the definitions for the denominator exclusion and denominator exception were updated to reflect the changes and to align language across collection types. Additionally, a denominator exception was added to reflect the definition revisions and capture patients for whom BMI was not documented due to medical reasons or patient refusal. We proposed to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center.

We proposed a substantive change to the description; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
Percentage of patients aged 18 years and older with a BMI documented during the current encounter or within the previous twelve months AND who had a follow-up plan documented if most recent BMI was outside of normal parameters.

This additional refinement of spelling out of the number 12 does not affect the intent of the proposed substantive change.

Comment: One commenter indicated that the BMI range is too narrow (60 percent US adults is above 25) and is not practical as many practitioners do not begin to discuss weight management with patients until the BMI is around 29. Widening the BMI range will begin to capture the a more targeted population. The commenter asked stated that higher BMI ranges get consumed with other conditions so weight is not addressed for the BMI alone but for co-existing conditions (diabetes, GI etc.). The commenter recommended that an exclusion be provided for other conditions involving weight management.

Response: We thank the commenter for their comment. As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years. Part of the Meaningful Measures Initiative is to align with current medical guidelines and implementing measures the drive quality care, reduce risk factors, and promote positive patient outcomes.

Comment: One commenter stated that measure Q128 requires clinicians to measure patients' height and weight and establish a goal. However, significant weight loss is unreasonable during the relatively short length of stay for patients requiring rehabilitation services. The collection of this information therefore serves no role for the patient during their course of care and in the calculation of Medicare's payment for therapy services.

Response: We thank the commenter for their comment. We agree that a patient may not have enough time to experience significant weight loss while receiving rehabilitation services. Although, the intent of the measure is provide a follow-up plan for patients that have a body mass index (BMI) outside normal parameters. The follow-up may include a referral to, for example, a Registered Dietitian Nutritionist (RDN), occupational therapist, physical therapist, primary care provider, exercise physiologist, mental health professional, or surgeon), for lifestyle/behavioral therapy and/or exercise counseling which could support the patient after discharge from rehabilitation services.

After consideration of public comments, we are finalizing the changes to measure Q128 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.25 Documentation of Current Medications in the Medical Record

Category	Description
NQF # / eCQM NQF #:	0419 / 0419e
Quality#:	130
CMS eCQM ID:	CMS68v10
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older for which the MIPS eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list **must** include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND **must** contain the medications' name, dosage, frequency and route of administration.
Substantive Change:	**The description is revised to read: For all collection types:** Percentage of visits for patients aged 18 years and older for which the eligible professional or eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter. **The guidance is revised to read: For the eCQM Specifications collection type**: This eCQM is an episode-based measure. This measure is to be reported for every encounter during the measurement period. Eligible professionals or eligible clinicians reporting this measure may document medication information received from the patient, authorized representative(s), caregiver(s) or other available healthcare resources. This list must include all known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration. This measure should also be reported if the eligible professional or eligible clinician documented the patient is not currently taking any medications. By reporting the action described in this measure, the provider attests to having documented a list of current medications utilizing all immediate resources available at the time of the encounter. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The denominator exception is revised to read: For the eCQM Specifications collection type:** Documentation of a medical reason(s) for not documenting, updating, or reviewing the patient's current medications list (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). **The numerator is revised to read: For all collection types:** Eligible professional or eligible clinician attests to documenting, updating or reviewing the patient's current medications using all immediate resources available on the date of the encounter. **Updated numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: This list must include ALL known prescriptions, over-the-counter (OTC) products, herbals, vitamins, minerals, dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration. **Updated denominator exception: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection type:** Revised**:** Documentation of a medical reason(s) for not documenting, updating, or reviewing the patient's current medications list (e.g., patient is in an urgent or emergent medical situation).
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description to remove language that is more appropriate for the guidance/notes sections of the measure specification. This will help with measure intent, clarity, and readability. The guidance for the eCQM Specifications collection type has been updated to clarify the intent of the measure. The intent is to document all known prescriptions, since the measure steward believes that MIPS eligible clinician should not be held accountable for information that is not available utilizing all immediate resources. The denominator exception was updated in all collection types to add clarity regarding use of the denominator exception and to align the language throughout the specification. The numerator notes for the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types was updated with information removed from the description. This information outlines what is necessary for numerator compliance and is better suited for the numerator notes section for ease of use.

Comment: One commenter supported CMS's proposal to update the measure description to clarify that clinicians must only document all known medications and that clinicians should not be held accountable for information that is not available utilizing all immediate resources. This clarification will decrease burden on MIPS eligible clinicians reporting this measure.

Response: We thank the commenter for supporting the change to this measure.

Comment: One commenter stated that inclusion of the Dialysis SNOMED code creates a burden for Nephrology providers who report this measure. The commenter urged CMS to consider creating a denominator exclusion for measure Q130 (CMS 68v10) for patients who are undergoing dialysis, OR remove the current dialysis SNOMED code from the measure's value set.

The 2020 eCQM Specification for this measure states that the initial population for this measure includes "All visits occurring during the 12-month measurement period for patients aged 18 years and older" *(a)*. Additionally, the "Encounter to Document Medications" Value Set currently included in the measure includes SNOMED code 385973000 - Dialysis care management (procedure). The consequence of using this SNOMED code is that any patients who are undergoing dialysis are eligible for the measure each time they have a Dialysis visit. Clinically, dialysis patients have eligible encounters multiple times a week and it is unnecessary to reconcile a dialysis patient's medication mere days after their previous encounter, as no significant changes are likely to have occurred. The frequency that providers are required to reconcile medications discourages Nephrology TIN's from using this measure.

Category	Description
Response: As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years. Part of the Meaningful Measures Initiative is to align with current medical guidelines and implementing measures the drive quality care, reduce risk factors, and promote positive patient outcomes. After consideration of public comments, we are finalizing the changes to measure Q130 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.26 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	0418 / 0418e
Quality#:	134
CMS eCQM ID:	CMS2v10
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or 14 days prior to the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications. **The description is revised to read: For all collection types:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the eligible encounter. **The definition is revised to read: For all collection types:** Screening: Completion of a clinical or diagnostic tool used to identify people at risk of developing or having a certain disease or condition, even in the absence of symptoms. Standardized Depression Screening Tool: A normalized and validated depression screening tool developed for the patient population in which it is being utilized Examples of standardized depression screening tools include but are not limited to: * Adolescent Screening Tools (12-17 years) * Patient Health Questionnaire for Adolescents (PHQ-A) * Beck Depression Inventory-Primary Care Version (BDI-PC) * Mood Feeling Questionnaire (MFQ) * Center for Epidemiologic Studies Depression Scale (CES-D) * Patient Health Questionnaire (PHQ-9) * Pediatric Symptom Checklist (PSC-17) * PRIME MD-PHQ2 * Adult Screening Tools (18 years and older) * Patient Health Questionnaire (PHQ9) * Beck Depression Inventory (BDI or BDI-II) * Center for Epidemiologic Studies Depression Scale (CES-D) * Depression Scale (DEPS) * Duke Anxiety-Depression Scale (DADS) * Geriatric Depression Scale (GDS) * Cornell Scale for Depression in Dementia (CSDD) * PRIME MD-PHQ2 * Hamilton Rating Scale for Depression (HAM-D) * Quick Inventory of Depressive Symptomatology Self-Report (QID-SR) * Computerized Adaptive Testing Depression Inventory (CAT-DI) * Computerized Adaptive Diagnostic Screener (CAD-MDD) * Perinatal Screening Tools * Edinburgh Postnatal Depression Scale * Postpartum Depression Screening Scale * Patient Health Questionnaire 9 (PHQ-9) * Beck Depression Inventory * Beck Depression Inventory-II * Center for Epidemiologic Studies Depression Scale * Zung Self-rating Depression Scale Follow-Up Plan: Documented follow-up for a positive depression screening must include one or more of the following: * Referral to a practitioner who is qualified to diagnose and treat depression * Pharmacological interventions * Other interventions or follow-up for the diagnosis or treatment of depression **The numerator definition is revised to read: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Examples of a follow-up plan include but are not limited to: • Referral to a practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression • Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Patients with a Documented Reason for not Screening for Depression (Denominator Exception) Patient Reason(s) Patient refuses to participate OR Medical Reason(s)

Category	Description
	Documentation of medical reason for not screening patient for depression (e.g., cognitive, functional, or motivational limitations that may impact accuracy of results; patient is in an urgent or emergent situation where time is of the essence and to delay treatment would jeopardize the patient's health status) **Updated denominator exclusion definition: For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Revised: Not Eligible for Depression Screening or Follow-Up Plan (Denominator Exclusion) Patients who have been diagnosed with bipolar disorder- F31.10, F31.11, F31.12, F31.13, F31.2, F31.30, F31.31, F31.32, F31.4, F31.5, F31.60, F31.61, F31.62, F31.63, F31.64, F31.70, F31.71, F31.72, F31.73, F31.74, F31.75, F31.76, F31.77, F31.78, F31.81, F31.89, F31.9 Patients who have been diagnosed with depression-- F01.51, F32.0, F32.1, F32.2, F32.3, F32.4, F32.5, F32.89, F32.9, F33.0, F33.1, F33.2, F33.3, F33.40, F33.41, F33.42, F33.8, F33.9, F34.1, F34.81, F34.89, F43.21, F43.23, F53.0, F53.1, O90.6, O99.340, O99.341, O99.342, O99.343, O99.345 **The guidance is revised to read: For the eCQM Specifications collection type:** A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a practitioner who is qualified to treat depression, pharmacological interventions or other interventions for the treatment of depression. This eCQM is a patient-based measure. Depression screening is required once per measurement period, not at all encounters. The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. Screening Tools: * An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. * The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record * The depression screening must be reviewed and addressed in the office of the provider, filing the code, on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice * The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter * The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool Follow-Up Plan: The follow-up plan must be related to a positive depression screening, for example: "Patient referred for psychiatric evaluation due to positive depression screening." Examples of a follow-up plan include but are not limited to: * Referral to a practitioner or program for further evaluation for depression, for example, referral to a psychiatrist, psychologist, social worker, mental health counselor, or other mental health service such as family or group therapy, support group, depression management program, or other service for treatment of depression * Other interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options Should a patient screen positive for depression, a clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool will not qualify as a follow-up plan. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated denominator criteria: For the Medicare Part B Claims Measures Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients aged ≥ 12 years. **For the eCQM Specifications collection type:** Added physical therapy MIPS eligible clinician. **Updated denominator note: For the Medicare Part B Claims Measures Specifications and the MIPS CQMs Specifications collection types:** Added: The intent of the measure is to screen for depression in patients who have never had a diagnosis of depression or bipolar disorder prior to the eligible encounter used to evaluate the numerator. Patients who have ever been diagnosed with depression or bipolar disorder will be excluded from the measure. **Updated denominator exclusion:** **For the eCQM Specifications collection type:** Revised: Patients who have been diagnosed with depression or with bipolar disorder. **For the MIPS CQMs Specifications and the Medicare Part B Claims Measure Specifications collection type:** Revised: Documentation stating the patient has had a diagnosis of depression or has had a diagnosis of bipolar disorder. **Updated numerator: For the eCQM Specifications collection type:** Removed additional evaluation or assessment for depression and suicide risk assessment as follow-up from the measure in header and from technical specifications and add guidance statement regarding suicide risk assessment. **The numerator instruction is revised to read: For the Medicare Part B Claims Measures Specifications collection type and the MIPS CQM Specifications collection type:** A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a practitioner who is qualified to treat depression, pharmacological interventions or other interventions for the treatment of depression. Depression screening is required once per measurement period, not at all encounters. An age-appropriate, standardized, and validated depression screening tool must be

Category	Description
	used for numerator compliance. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. The depression screening must be reviewed and addressed in the office of the provider on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter. The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Should a patient screen positive for depression, a clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool, will not qualify as a follow-up plan.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the description to provide clarity and better align with the measure intent. We proposed to update the measure language in the definitions, guidance, and numerator note sections to provide clarity as to what constitutes a follow-up plan. The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, since that would serve as the most recent screening. To satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool. Additionally, suicide risk assessments have been removed as a numerator compliant follow-up plan option as this should be completed when appropriate and based on the assessment by the clinician regarding the severity of the patient's symptoms of depression at the time of depression screening. We also proposed to update the measure language and denominator exclusions to reflect that this measure is screening of depression for patients who have not been previously diagnosed or have an active diagnosis of depression or bipolar disorder. This preventive measure assesses screening and follow up plan for patients that are screened positive for depression. We also proposed to update the denominator criteria for the Medicare Part B Claims Measure Specifications and the MIPS CQM Specifications collection types to align with the measure denominator language which states patients age 12 or older at the beginning of the measurement period. Additionally, we proposed to add the physical therapy MIPS eligible clinician type based on stakeholder feedback regarding the applicability of this measure to this clinician type. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

We proposed a substantive change to the numerator instruction for the Medicare Part B Claims Measures Specifications collection type and the MIPS CQM Specifications collection type; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:

A depression screen is completed on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan must be documented on the date of the encounter, such as referral to a practitioner who is qualified to treat depression, pharmacological interventions or other interventions for the treatment of depression. Depression screening is required once per measurement period, not at all encounters. An age-appropriate, standardized, and validated depression screening tool must be used for numerator compliance. The name of the age-appropriate standardized depression screening tool utilized must be documented in the medical record. The depression screening must be reviewed and addressed in the office of the provider on the date of the encounter. Positive pre-screening results indicating a patient is at high risk for self-harm should receive more urgent intervention as determined by the provider practice. The screening should occur during a qualifying encounter or up to 14 days prior to the date of the qualifying encounter.

The measure assesses the most recent depression screening completed either during the eligible encounter or within the 14 days prior to that encounter. Therefore, a clinician would not be able to complete another screening at the time of the encounter to count towards a follow-up, because that would serve as the most recent screening. In order to satisfy the follow-up requirement for a patient screening positively, the eligible clinician would need to provide one of the aforementioned follow-up actions, which does not include use of a standardized depression screening tool.

Should a patient screen positive for depression, a clinician should opt to complete a suicide risk assessment when appropriate and based on individual patient characteristics. However, for the purposes of this measure, a suicide risk assessment or additional screening using a standardized tool, will not qualify as a follow-up plan.

This additional refinement of adding 'In order' prior to 'to satisfy' does not affect the intent of the proposed substantive change.

Comment: One commenter cited follow-up plan may not follow provider workflow. For example, an EHR software may capture the date the order was signed which may be signed by the provider the next day (not the day of the order). The commenter recommended that grace period be allowed for providers to get caught up with paper work (1 to 3 days after the encounter).

Response: We thank the commenter for their comment. As the measure steward, we will take this feedback into consideration during the annual revisions for possible implementation in future years.

Comment: One commenter agreed with the proposal to remove suicide risk assessment from a numerator option. A suicide risk assessment is a screening tool, and if needed, should be done at the initial screening point, rather than a follow up.

Response: We thank the commenter for supporting the change to this measure.

After consideration of public comments, we are finalizing the changes to measure Q134 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR

Category	Description
50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Measure Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Measure Specifications. For this measure, we note that 2020 CMS Web Interface Measure Specifications included the following change, Numerator/Numerator Codes/Numerator Drug Codes: Follow-up Plan (For Positive Screen) REMOVED ADDITIONAL_EVAL_CODE SNM. Such change is applicable for the 2021 MIPS performance period/2023 MIPS payment year given that the 2021 CMS Web Interface Measure Specifications reflect the 2020 CMS Web Interface Measure Specifications. Also, it should be noted that the CMS Web Interface Specifications collection type is not able to establish a benchmark for this measure. Thus, this measure will be excluded from the Merit-based Incentive Payment System (MIPS) scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the measure meets the data completeness requirement and the data applicable to the measure is reported via the CMS Web Interface Measure Specifications.	

D.27 Melanoma: Continuity of Care – Recall System

Category	Description
NQF # / eCQM NQF #:	N/A/N/A
Quality#:	137
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12-month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Structure
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q137. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q137 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.28 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care

Category	Description
NQF # / eCQM NQF #:	0563 / N/A
Quality#:	141
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre-intervention level, a plan of care was documented within the 12-month performance period.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications as it shows very high performance year after year leaving little opportunity to drive improvement in quality outcomes. However, the benchmarking data continues to show a gap for the MIPS CQMs Specifications collection type, as such, the measure will be retained for this collection type.

Comment: One commenter opposed CMS's proposal to remove the claims collection type from measure Q141. Removal of the measure from claims would adversely impact ophthalmologists, particularly those in small and rural practices who must rely on the claims reporting collection type because they cannot afford to adopt CEHRT. The commenter recognized that this measure is topped out under the claims collection type, but clinicians reporting these measures are already limited in the number of points they can receive for this measure.

Response: We understand that ensuring there are measures available for small and rural practices is important; however, we strive to ensure that all measures align with the Meaningful Measures Initiative. After careful considerations, we will maintain the Medicare Part B Claims Measure Specifications collection type for consistency and stability as it is not extremely topped out and still in alignment with guidelines, but may consider removal in the future.

After consideration of public comments, we are not finalizing the changes to measure Q141 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.29 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
NQF # / eCQM NQF #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v9
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Substantive Change:	**Updated logic**: **For the eCQM Specifications collection type:** Revised logic to limit the date range for chemotherapy administered within 31 days before and after the measurement period. Added definition: Chemotherapy within 30 days Prior and After the Measurement Period. **The guidance is revised to read: For the eCQM Specifications collection type:** This eCQM is an episode-of-care measure; the level of analysis for this measure is every visit for patients with a diagnosis of cancer who are also currently receiving chemotherapy or radiation therapy during the measurement period. For patients receiving radiation therapy, pain intensity should be quantified at each radiation treatment management encounter where the patient and physician have a face-to-face interaction. Due to the nature of some applicable coding related to radiation therapy (e.g., delivered in multiple fractions), the billing date for certain codes may or may not be the same as the face-to-face encounter date. In this instance, for the reporting purposes of this measure, the billing date should be used to pull the appropriate patients into the initial population. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face encounter occurring on the actual billing date or within the 6 days prior to the billing date. For patients receiving chemotherapy, pain intensity should be quantified at each face-to-face encounter with the physician while the patient is currently receiving chemotherapy. For purposes of identifying eligible encounters, patients "currently receiving chemotherapy" refers to patients administered chemotherapy within 30 days prior to the encounter AND administered chemotherapy within 30 days after the date of the encounter. Pain intensity should be quantified using a standard instrument, such as a 0-10 numerical rating scale, visual analog scale, a categorical scale, or pictorial scale. Examples include the Faces Pain Rating Scale and the Brief Pain Inventory (BPI). This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated Instructions: For the MIPS CQM Specifications collection type:** Revised note to reflect both face-to-face and telehealth encounters are allowed. **The denominator note is revised to read: For the MIPS CQMs Specifications collection type:** For the reporting purposes for this measure, in instances where CPT code 77427 is reported, the billing date, which may or may not be the same date as the face-to-face or telehealth encounter with the physician, should be used to pull the appropriate patient population into the denominator. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments. A lookback (retrospective) period of 7 days, including the billing date, may be used to identify the actual face-to-face or telehealth encounter, which is required to assess the numerator. Therefore, pain intensity should be quantified during the face-to-face or telehealth encounter occurring on the actual billing date or within the 6 days prior to the billing date. **Updated denominator: For all collection types:** Added telehealth as eligible encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the logic within the eCQM Specifications collection type to limit the range of time for chemotherapy procedures to only capture the chemotherapy procedures that satisfy the measure requirements. This will decrease implementation burden for some MIPS eligible clinicians while improving reporting capabilities for some practices. Additionally, the eCQM Specifications and MIPS CQMs Specifications collection types the guidance/denominator note was proposed to be revised to allow for a lookback period when utilizing CPT codes that may not have the same billing and encounter date. This will align more closely with actual clinical workflow and encounter billing practices. We proposed to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter indicated that the rationale included in the 2021 PFS proposed rule for Table D.29 should be corrected to read: "We propose to add telehealth encounters as denominator eligible for submission criteria 1 and 2 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured." Another commenter supported the addition of telehealth reporting for this measure.

Response: We thank the commenter for their comment regarding telehealth for measure Q143. As currently specified for PY 2020, the measure allows for telehealth visits for denominator submission criteria two, but contains a telehealth exclusion for denominator submission criteria one. For PY2021, we proposed to allow for telehealth as an eligible encounter for submission criteria one so both submission criteria will allow for telehealth encounters to ensure a complete patient population is captured for assessment of the quality action.

Comment: One commenter supported the proposed changes to measure Q143, which ensure pain assessment and subsequent management is incorporated into virtual health care and align with current cancer care guidelines. It is critical to account for the growing need and utilization of virtual care, and the variety providers qualified to conduct these visits, including advanced practice providers.

Category	Description
Response: We thank the commenter for supporting the changes to this measure. After consideration of public comments, we are finalizing the changes to measure Q143 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.30 Oncology: Medical and Radiation - Plan of Care for Pain

Category	Description
NQF # / eCQM NQF #:	0383 / N/A
Quality#:	144
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Substantive Change:	**Updated instructions:** Added: THERE ARE TWO SUBMISSION CRITERIA FOR THIS MEASURE: 1) All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain OR 2) All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **The denominator is revised to read:** Submission Criteria 1: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who reporting having pain Denominator (Submission Criteria 1): All visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy who report having pain Submission Criteria 2: All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain Denominator (Submission Criteria 2): All visits for patients, regardless of age, with a diagnosis of cancer currently receiving radiation therapy who report having pain **Updated denominator: For all collection types:** Added telehealth as eligible encounter. **Updated denominator criteria:** Revised: Submission Criteria One • Removed coding for radiation therapy Submission Criteria Two • Added coding for cancer diagnosis • Added coding for patient procedure **Updated denominator note: For Submission Criteria Two:** Added: For the reporting purposes of this measure, in instances where CPT code77427 is reported, the billing date, which may or may not be the same date as the face-to-face or telehealth encounter with the physician, should be used to pull the appropriate patient population into the denominator. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face encounter during the series of treatments. **The numerator is revised to read:** NUMERATOR (SUBMISSION CRITERIA 1): Patient visits that included a documented plan of care to address pain. NUMERATOR (SUBMISSION CRITERIA 2): Patient visits that included a documented plan of care to address pain. **Updated numerator instructions: For Submission Criteria Two:** Added: A documented plan of care may include: use of opioids, nonopioid analgesics, psychological support, patient and/or family education, referral to a pain clinic, or reassessment of pain at an appropriate time interval. **Updated numerator options: For Submission Criteria Two:** Added: **Performance Met:** Plan of care to address pain documented **Performance Not Met:** Plan of care for pain not documented, reason not otherwise specified
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to separate the measure into two submission criteria based upon treatment to add clarity based on stakeholder feedback. This also aligns the measure with the format of measure Q143: Oncology: Medical and Radiation – Pain Intensity Quantified. The patient procedure coding was updated to ensure only coding applicable to the updated submission criteria is included within the denominator criteria. We proposed to add telehealth encounters as denominator eligible for submission criteria 1 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

We proposed a substantive change to the denominator note for submission criteria two; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
For the reporting purposes of this measure, in instances where CPT code77427 is reported, the billing date, which may or may not be the same date as the face-to-face or telehealth encounter with the physician, should be used to pull the appropriate patient population into the denominator. It is expected, though, that the numerator criteria would be performed at the time of the actual face-to-face or telehealth encounter during the series of treatments.

This additional refinement of the addition of 'or telehealth' in the final sentence does not affect the intent of the proposed substantive change, but clarifies and aligns with the other revisions.

Comment: One commenter indicated that the rationale included in the 2021 PFS proposed rule for Table D.30 should be corrected to read: "We propose to add

Category	Description
	telehealth encounters as denominator eligible for submission criteria 1 and 2 as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured." Another commenter supported telehealth reporting for this measure. **Response:** We thank the commenter for their comment regarding telehealth for measure Q144. As currently specified for PY 2020, the measure allows for telehealth visits for all procedural codes, but contains a telehealth exclusion for patient encounters associated with the chemotherapy patient population. For PY2021, we proposed to allow for telehealth as an eligible encounter for submission criteria one, which is those patients who are receiving chemotherapy and the only criteria for a patient encounter, so both submission criteria will allow for any available telehealth encounters and procedures, to ensure a complete patient population is captured for assessment of the quality action. **Comment**: One commenter supported the proposed changes to measure Q144, which ensures pain assessment and subsequent management is incorporated into virtual health care and align with current cancer care guidelines. It is critical to account for the growing need and utilization of virtual care, and the variety of providers qualified to conduct these visits, including advanced practice providers. **Response:** We thank the commenter for supporting the changes to this measure. After consideration of public comments, we are finalizing the changes to measure Q144 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.31 Radiology: Exposure Dose Indices or Exposure Time and Number of Images Reported for Procedures Using Fluoroscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	145
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available).
Substantive Change:	**Updated numerator instructions: For all collection types:** Added: Documentation: Information populating the final report may reside in a dedicated field in the electronic health record (EHR) or picture archiving and communication system (PACS), however fluoroscopy exposure dose or time should be included in the final report to be readily accessible in all circumstances.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator criteria encounter coding to ensure that all of the codes are associated with fluoroscopy and to create a more complete patient population. Additionally, we proposed to add numerator instructions to further clarify how the fluoroscopy information should be recorded in the final report to be numerator compliant and meet the intent of the measure.

We proposed a substantive change to the numerator instructions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Documentation: Information populating the final report may reside in a dedicated field in the electronic health record (EHR) or picture archiving and communication system (PACS), however fluoroscopy exposure dose or time should be included in the final report in order to be readily accessible in all circumstances. This additional refinement does not affect the intent of the proposed substantive change.

Comment: One commenter recognized the changes to measure Q145 without issue. A second commenter supported the changes as they better fit the intent of the measure and will lessen clinical burden to some extent.

Response: We thank the commenters for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q145 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.32 Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	147
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, Magnetic Resonance Imaging (MRI), Computed Tomography (CT), etc.) that were performed.
Substantive Change:	**The denominator is revised to read: For all collection types:** All final reports for patients, regardless of age, undergoing bone planar and whole body scintigraphy.
Steward:	Society of Nuclear Medicine and Molecular Imaging
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the denominator to account for encounter codes that can be utilized for imaging other than bone scintigraphy. This will narrow the eligible patient population to those using bone imaging agents and only assess MIPS eligible clinicians that are relevant to this measure's intent.

Comment: One commenter supported the changes to measure Q147 as they better fit the intent of this measure and will lessen clinical burden to some extent.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q147 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.33 Rheumatoid Arthritis (RA): Tuberculosis Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 12 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD).
Substantive Change:	**The title is revised from 'Rheumatoid Arthritis (RA): Tuberculosis Screening' to:** Tuberculosis Screening Prior to First Course Biologic Therapy **The description is revised to read:** If a patient has been newly prescribed a biologic disease-modifying anti-rheumatic drug (DMARD) therapy, then the medical record should indicate TB testing in the preceding 12-month period. **The instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for patients who are being considered or prescribed a first course of biologic disease-modifying anti-rheumatic drug therapy seen during the performance period. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding. **The denominator is revised to read:** All patients aged 18 years and older who are receiving a first course of therapy using a biologic DMARD. **The denominator instructions are updated to read:** Patients are considered to be receiving a first course of therapy using a biologic DMARD only if they have been prescribed DMARD biologic therapy during the measurement period and were not prescribed DMARD biologic therapy in the 12 months preceding the encounter where DMARD biologic therapy was newly started. Biologic DMARD therapy includes:-Abatacept (Orencia) -Adalimumab (HUMIRA) -Anakinra (Kineret) -Baricitinib (Olumiant) -Canakinumab (ILARIS) -Certolizumab pegol and lyophilized certolizumab pegol (CIMZIA) -Denosumab (Prolia) -Etanercept (Enbrel) -Golimumab (Simponi) -Infliximab (REMICADE) -Infliximab-dyyb (Inflectra) -Infliximab-abda (Renflexis) -Sarilumab (KEVZARA) -Secukinumab (Cosentyx) -Tocilizumab (ACTEMRA) -Tofacitinib (XELJANZ) -Ustekinumab (STELARA) The list of biologic DMARD therapies is subject to change as new therapies are approved by the FDA. **Updated denominator criteria:** Removed: 'Diagnosis for RA' criteria Revised**:** Patient receiving first-time biologic disease modifying anti-rheumatic drug therapy **Updated denominator:** Added telehealth as eligible encounter. **The numerator is revised to read:** Patients for whom any record of TB testing is documented or performed (PPD, IFN-gamma release assays, or other appropriate method) in the medical record in the 12 months preceding the biologic prescription. **Updated numerator definition:** Removed 'Biologic DMARD Therapy' definition. **Updated numerator options:** Revised: **Performance Met:** TB screening performed and results interpreted within 12 months prior to initiation of first-time biologic disease modifying anti-rheumatic drug therapy.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to expand the measure to remove disease specificity from the measure to assess all patients prescribed a first course biologic DMARD therapy. This will expand monitoring of patient safety guidance compliance to all patients initiating DMARD therapy. The language throughout the measure has been updated to align with the change in patient population. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

We proposed a substantive change to the denominator instructions; however, during review of this proposed substantive change, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
Patients are considered to be receiving a first course of therapy using a biologic DMARD only if they have been prescribed DMARD biologic therapy during the measurement period and were not prescribed DMARD biologic therapy in the 12 months preceding the encounter where DMARD biologic therapy was newly started. Biologic DMARD therapy includes:-Abatacept (Orencia) -Adalimumab (HUMIRA) -Anakinra (Kineret) -Baricitinib (Olumiant) -Canakinumab (ILARIS) -Certolizumab pegol and lyophilized certolizumab pegol (CIMZIA) -Etanercept (Enbrel) -Golimumab (Simponi) -Infliximab (REMICADE) -Infliximab-dyyb (Inflectra) -Infliximab-abda (Renflexis) -Sarilumab (KEVZARA) -Secukinumab (Cosentyx) -Tocilizumab (ACTEMRA) -Tofacitinib (XELJANZ) -Ustekinumab (STELARA) The list of biologic DMARD therapies is subject to change as new therapies are approved by the FDA.
This refinement removes the medication Denosumab (Prolia) from the list of biological DMARD therapies as it is not necessary to complete a TB test prior to use of this medication. Inclusion of this medication would be in contradiction of current medical guidelines and would subject patients to unnecessary testing, with potential of deleterious effects, while creating additional and unnecessary costs. It is for these reasons that we feel Denosumab (Prolia) must be removed as patient safety and making care affordable are healthcare priorities.

Comment: One commenter supported the addition of telehealth reporting for measure Q176.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

Category	Description
Comment: Several commenters opposed the removal of measure Q337: Psoriasis: Tuberculosis (TB) Prevention for Patients with Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis on a Biological Immune Response Modifier as stated under Table C.6. The proposed update to measure Q176 would mean the denominator population would overlap with measure Q337. Instead of the measure being specific to rheumatoid arthritis (measure Q176) or psoriasis patients (measure Q337), it looks to assess all patients prescribed a first course biologic DMARD therapy. The commenters stated that the revision to measure Q176 does not sufficiently cover the patients that dermatologist treat or the medications that are used, as are currently reported under measure Q337. **Response:** After consideration of public comments, we are no longer finalizing the removal of measure Q337. See Table C.6 of the final rule for further information. We encourage the commenters to reach out to the measure steward to work towards possible revisions in an effort to develop a unified measure reflecting a broader patient population and more inclusive medication therapy for possible future implementation. After consideration of public comments, we are finalizing the changes to measure Q176 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.34 Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	178
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenter supported the addition of telehealth reporting for measure Q178.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q178 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.35 Rheumatoid Arthritis (RA): Glucocorticoid Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	180
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone > 5 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American College of Rheumatology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q180. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q180 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.36 Elder Maltreatment Screen and Follow-Up Plan

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	181
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening tool on the date of encounter AND a documented follow-up plan on the date of the positive screen.
Substantive Change:	**Updated denominator: For all collection types:** Added care management services.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add coding applicable to chronic care management services as these capture encounters where screening may occur and is an appropriate patient population for this measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q181 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.37 Functional Outcome Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	182
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of the encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies.
Substantive Change:	**Updated denominator: For all collection types:** Added home health and domiciliary/rest home settings. **The numerator note is revised to read: For all collection types**: The intent of this measure is for a functional outcome assessment tool to be utilized at a minimum of every 30 days but submission is only required at each qualifying encounter due to coding limitations. Therefore, for visits occurring within 30 days of a previously documented functional outcome assessment, the numerator quality-data code G8942 should be used for submission purposes. **Updated numerator definition: For all collection types**: Revised: Current (Functional Outcome Assessment) – A patient having a documented functional outcome assessment utilizing a standardized tool and a care plan if indicated at a qualifying encounter within the previous 30 days.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add the home health and domiciliary/rest home settings as denominator eligible settings as functional assessments may occur at these visits and would lead to a more complete denominator eligible patient population. Additionally, we proposed to update the definition for 'Current (Functional Outcome Assessment)' and the numerator note to clarify the measure intent, which is to only report for qualifying encounters and not each visit.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q182 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.38 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
NQF # / eCQM NQF #:	0565 / 0565e
Quality#:	191
CMS eCQM ID:	CMS133v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated numerator: For the eCQM Specifications collection type:** Added data element: "Best Corrected Visual Acuity Exam Using Snellen Chart" (2.16.840.1.113883.3.526.3.1560)
Steward:	American Academy of Ophthalmology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	For the eCQM Specifications collection type, we proposed to add a data element for "Best Corrected Visual Acuity Exam Using Snellin Chart" allowing an alternative method to capture an exam commonly used in clinical practice that may not have been accurately captured prior. This added numerator compliant option is clinically in line with the measure intent and appropriate for inclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q191 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.39 Radiology: Stenosis Measurement in Carotid Imaging Reports

Category	Description
NQF # / eCQM NQF #:	0507 / N/A
Quality#:	195
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement.
Substantive Change:	**The instructions are revised to read: For all collection types:** This measure is to be submitted each time a carotid imaging study is performed during the performance period for patients aged 18 years and older during the submission period. There is no diagnosis associated with this measure. Merit-based Incentive Payment System (MIPS) eligible clinicians who provide the professional component of diagnostic imaging studies of the carotids will submit this measure. **The denominator is revised to read: For all collection types**: All final reports for carotid imaging studies (neck MR angiography [MRA], neck CT angiography [CTA], neck duplex ultrasound, carotid angiogram) performed on patients aged 18 years and older during the submission period. **Updated denominator criteria: For all collection types:** Added: Patients aged ≥ 18 years on date of encounter.
Steward:	American College of Radiology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure's eligible patient population to include only patients aged 18 years and older. This will allow for closer monitoring regarding who is eligible and more appropriate for inclusion in the eligible patient population, which will decrease overall burden for the clinicians reporting this measure.

Comment: One commenter recognized the changes to measure Q195 without issue. A second commenter supported the changes to this measure as they better fit the intent of this measure and will lessen clinical burden to some extent.

Response: We thank the commenters for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q195 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.40 Functional Status Change for Patients with Knee Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	217
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the Knee FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with knee impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the knee impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near Discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Knee FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We proposed to update the denominator exception language to add clarity and better align with measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q217 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.41 Functional Status Change for Patients with Hip Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	218
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the Hip FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with hip impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the hip impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Hip FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We proposed to update the denominator exception language to add clarity and better align with measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q218 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.42 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	219
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the Foot/Ankle FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with foot, ankle and lower leg impairments. The change in functional status (FS) is assessed using the FOTO Lower Extremity Physical Function (LEPF) patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator criteria:** Revised ICD-10 coding for 'With a lower leg, foot, or ankle impairment and/or diagnosis pertaining to a functional deficit affecting lower leg, foot, or ankle'. **Updated denominator exclusion:** Revised: Patient unable to complete the LEPF PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the LEPF PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown). **Updated numerator options:** Revised: **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the lower leg, foot or ankle impairment not measured because the patient did not complete the LEPF PROM at Initial Evaluation and/or near discharge, reason not given.
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the description, denominator exclusion, numerator statement, and numerator options to reflect the change in functional assessment tool, Hip FS PROM to the LEPF PROM. The assessment is being revised to address scientific updates and maintenance necessary for item-response theory based outcome measures. We proposed to update the denominator exception language to add clarity and better align with measure's intent. Additionally, we proposed to update the ICD-10 coding related to the denominator criteria statement, 'With a lower leg, foot, or ankle impairment and/or diagnosis pertaining to a functional deficit affecting lower leg, foot, or ankle,' to align with current coding.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q219 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.43 Functional Status Change for Patients with Low Back Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	220
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the Low Back FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with low back impairments. The change in functional status (FS) is assessed using the FOTO Low Back FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to refine the description for easier readability. We proposed to update the denominator exception language to add clarity and better align and communicate the measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q220 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.44 Functional Status Change for Patients with Shoulder Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	221
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the Shoulder FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.).The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with shoulder impairments. The change in functional status (FS) is assessed using the FOTO Shoulder FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to refine the description for easier readability. We proposed to update the denominator exception language to add clarity and better align and communicate the measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q221 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.45 Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	222
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	A patient-reported outcome measure of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist or hand impairments. The change in FS is assessed using the Elbow/Wrist/Hand FS patient-reported outcome measure (PROM) (©2009-2019 Focus on Therapeutic Outcomes, Inc.) The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure).
Substantive Change:	**The description is revised to read:** A patient-reported outcome measure of risk-adjusted change in functional status for patients 14 years+ with elbow, wrist, or hand impairments. The change in functional status (FS) is assessed using the FOTO Elbow/Wrist/Hand FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static measure). **Updated definition:** Revised: Encounter – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. **Updated denominator exception:** Revised: 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to refine the description for easier readability. We proposed to update the denominator exception language to add clarity and better align and communicate the measure's intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q222 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.46 Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention

Category	Description
NQF # / eCQM NQF #:	0028 / 0028e
Quality#:	226
CMS eCQM ID:	CMS138v9
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months **AND** who received tobacco cessation intervention if identified as a tobacco user a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months. b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention. c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 24 months AND who received tobacco cessation intervention if identified as a tobacco user.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specifications, and MIPS CQMs Specifications. **The description is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. T**he description is revised to read: For the eCQM Specifications collection type**: Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user. Three rates are reported: a. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months b. Percentage of patients aged 18 years and older who were identified as a tobacco user who received tobacco cessation intervention c. Percentage of patients aged 18 years and older who were screened for tobacco use one or more times within 12 months AND who received tobacco cessation intervention if identified as a tobacco user **Updated instructions: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised the language to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated guidance: For the eCQM Specifications collection type:** Revised**:** To satisfy the intent of this measure, a patient must have at least one tobacco use screening during the 12-month period. If a patient has multiple tobacco use screenings during the 12-month period, only the most recent screening, which has a documented status of tobacco user or tobacco non-user, will be used to satisfy the measure requirements. Added: To promote a team-based approach to patient care, the tobacco cessation intervention can be performed by another healthcare provider; therefore, the tobacco use screening and tobacco cessation intervention do not need to be performed by the same provider or clinician. **Updated denominator: For all collection types:** Added Physical Therapy MIPS eligible clinician and telehealth as eligible encounters for all submission criteria. **Updated denominator exception: For eCQM Specifications collection type:** Removed coding from the 'Medical Reason' value set for concepts not indicating medical contraindication. **Updated logic: For the eCQM Specifications collection type:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated numerator: For the eCQM Specifications collection type:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. Additionally, revised the logic to unlink the intervention from having to occur after the tobacco user status. **Updated numerator: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action. **Updated numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised to reflect a 12-month timeframe for the look back period and assessment of clinical quality action.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure to shorten the look back period to 12 months and require that tobacco screening and cessation, if patient screened positive, occur every 12 months. The revision is based upon stakeholder feedback, input from the eCQM clinical review process, and the measure steward's technical expert panel (TEP). We agreed that it is important to do this annually as tobacco use is an important population health concern and smoking is the leading cause of preventable death (https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm). The language throughout the measure specification is being

Category	Description
	revised to reflect this update. Additionally, we proposed to add physical therapy MIPS eligible clinicians to the denominator eligible encounters as this is applicable to their scope of practice. For the eCQM Specifications collection type we proposed to unlink the intervention from having to occur after the tobacco status within the measure logic. This revision is better aligned with the clinical reality that for patients actively trying to quit a plan will be in place and further tobacco cessation intervention is redundant, as well as lessening the burden of clinicians, especially for those patients who are not planning on quitting. The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agreed that this guidance update is clinically appropriate and aligns better with clinical care workflows. Additionally, we proposed to revise the 'Medical Reason' value set based upon expert and stakeholder feedback to remove codes based upon intent of concepts which do not indicate a medical contraindication, but rather a provider decision to discontinue or adjust a course of treatment. These codes do not meet the intent of the denominator exception. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

Comment: One commenter supported the update of the denominator to add physical therapy MIPS-eligible clinicians and telehealth as eligible encounters for measure Q226. Multiple commenters supported the addition of telehealth reporting for this measure.

Response: We thank the commenters for supporting adding physical therapists to this measure and for supporting the adding telehealth as eligible encounters.

Comment: One commenter greatly appreciated the numerator change to tobacco cessation for eCQMs, specifically the language "Additionally, revised the logic to unlink the intervention from having to occur after the tobacco user status."

Response: We thank the commenter for supporting this change to the numerator language for eCQMs.

Comment: One commenter agreed, and one commenter disagreed with the proposal to shorten the lookback period for evidence of tobacco use screening from 24 to 12 months. The vast majority of smokers pick up the habit before age 18. Consequently, while tobacco screening and intervention should – of necessity – be more frequent in the years of patient adolescence and young adulthood, there is little evidence to indicate more frequent screening is warranted in older adults. The commenter preferred that the lookback period stay at 24 months. An alternative – though admittedly a burdensome one – is for the lookback period to vary by age to account for clinical realities.

Response: We thank the commenters for their comments. The U.S. Preventive Services Task Force indicated that "Tobacco use is the leading preventable cause of disease, disability, and death in the United States. Cigarette smoking results in more than 480,000 premature deaths each year and accounts for approximately 1 in every 5 deaths". Due to the harmful effect tobacco use can have on patients' health, we believe that clinicians should engage with their patients to screen for tobacco use and, if positive, provide tobacco cessation counseling annually.

After consideration of public comments, we are finalizing the changes to measure Q226 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications. In addition, we are not finalizing the proposed additional telehealth encounter eligibility substantive change for the eCQM Specifications collection type because this is already specified in the current measure.

D.47 Controlling High Blood Pressure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	236
CMS eCQM ID:	CMS165v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure Specifications, eCQM Specification and MIPS CQMs Specifications **Updated denominator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: The diagnosis of essential hypertension must be present sometime between 1 year prior to the measurement period and before the end of the measurement period (January 1, 2020 through December 31, 2021). **Updated denominator exclusion: For the eCQM Specification collection type:** Revised: Exclude patients 66 and older who are living long term in an institution for more than 90 consecutive days during the measurement period. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Updated encounters so they are "on or" before the end of the measurement period. Updated the LTI exclusion to be 90 consecutive days. Changed the name of the under 81 exclusion definition to "FrailtyLTI.Advanced Illness and Frailty Exclusion Not Including Over Age 80". **Updated denominator exclusion: For the MIPS CQMs Specifications and Medicare Part B Claims Measure Specification collection type:** Added coding to identify patients with advanced illness and frailty **Updated logic: For the eCQM Specifications collection type:** Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to and during the measurement period. **Updated denominator exclusion: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: 1. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the measurement period. 2. Patients 66-80 years of age with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period 3. Patients 66-80 years of age with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period Added: 1. Patients 81 years of age and older with at least one claim/encounter for frailty during the measurement period. **Updated instructions note/numerator note: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Added: • Reported by or taken by the patient (with the exception of BP values taken by a remote monitoring device, which are then reported to the provider).
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed that the denominator exclusion language and logic be updated in all collection types to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. For the eCQM Specifications collection type we proposed to update the logic to allow for new hypertension diagnoses within the first 6 months of the performance period to better align with the intent of the measure. We proposed to add a denominator note to clarify the patient population eligible for the measure and to reflect the revision in timing for the essential hypertension diagnosis; ensuring patients that should be assessed are included within the denominator eligible patient population. Additionally, for the MIPS CQMs Specifications and Medicare Part B Claims Measure Specifications collection types, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We also proposed to update the instructions note and the numerator note to add clarity regarding the use of remote monitoring devices for the purposes of this measure in response to stakeholder feedback. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.
Comment: One commenter stated that although telehealth is available for this measure, it is restricted to using only remote devices (via Bluetooth technology). The concern is that this may be restrictive to some patients who might benefit from telehealth (virtual visits) but do not have and/or cannot afford a new device and/or technology. The commenter recommended that the measure follow HEDIS specifications that allows visual confirmation on the blood pressure measuring device by the provider during the virtual visit and then to record the blood pressure in the EHR.	

Category	Description

Response: We thank the commenter for their comment. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q236 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.

We have identified a technical error in the language for the update to the eCQM Specifications collection type for the denominator logic. For the eCQM Specifications collection type, we inadvertently indicated that the timeframe for the hypertension diagnosis must be present prior to "and" during the measurement period. To resolve this technical error, the "and" was replaced with "or". We have updated the language for the logic from the proposed change for the eCQM Specifications collection type as follows:
Technical error: Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to and during the measurement period.
To resolve technical error: Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to OR during the measurement period.

This reflects the change to the denominator logic proposed for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. The 2021 performance period eCQM measure specifications have been published since May 7, 2020 on the CMS Electronic Clinical Quality Improvement (eCQI) Resource Center website at https://ecqi.healthit.gov/ecqm/ep/2021/cms165v9 and we have not received feedback or public comments regarding this change in denominator logic.

Further refinements were made to the measure specifications in order to align with the proposed update to the denominator note for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. We are finalizing a modification of the Measure Description for the Medicare Part B Claims Measure Specifications, eCQM Specification, and MIPS CQMs Specifications collection types as follows:
Current: Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Revised to read: Percentage of patients 18-85 years of age who had a diagnosis of hypertension overlapping the measurement period or the year prior to the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.

Additionally, we are finalizing a modification to the Denominator Statement for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types, and the Initial Patient Population for the eCQM Specifications collection type. The following finalized modification pertains to the Denominator Statement for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types.
Current: Patients 18-85 years of age who had a visit and a diagnosis of hypertension overlapping the measurement period.
Revised to read: Patients 18-85 years of age who had a visit and diagnosis of essential hypertension overlapping the measurement period or the year prior to the measurement period.

The following finalized modification pertains to the Initial Patient Population for the eCQM Specifications collection type.
Current: Patients 18-85 years of age who had a visit and diagnosis of essential hypertension overlapping the measurement period.
Revised to read: Patients 18-85 years of age who had a visit and diagnosis of essential hypertension overlapping the measurement period or the year prior to the measurement period.

We are finalizing the denominator note for the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types as proposed. For the reasons noted above, we are finalizing a modification of the logic for the eCQM Specifications collection type: Change to the Essential Hypertension Diagnosis definition logic used to define the initial patient population requires hypertension overlap the measurement period indicating hypertension must be present prior to or during the measurement period.

The additional changes to the description, denominator statement, and initial patient population do not affect the intent of the proposed substantive change, but adds alignment and clarity between the collection types in order to ensure proper implementation within and across collection types.

D.48 Use of High-Risk Medications in the Elderly

Category	Description
NQF # / eCQM NQF #:	0022 / N/A
Quality#:	238
CMS eCQM ID:	CMS156v9
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were ordered high-risk medications. Two rates are submitted. 1) Percentage of patients who were ordered at least one high-risk medication. 2) Percentage of patients who were ordered at least two of the same high-risk medications.
Substantive Change:	**The title is revised from 'Use of High-Risk Medications in the Elderly' to:** Use of High-Risk Medications in Older Adults. **The description is revised to read:** Percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications. **Updated measure analytics: For all collection types**: One performance rate. **The guidance is revised to read: For the eCQM Specifications collection type**: The intent of the measure is to assess if the patient has been prescribed at least two of the same high-risk medications on different days. The intent of the measure is to assess if the reporting provider ordered the high-risk medication(s). If the patient had a high-risk medication previously prescribed by another provider, they would not be counted towards the numerator unless the reporting provider also ordered a high-risk medication for them. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated instructions: For the MIPS CQMs Specifications collection type:** Removed language related to the submission of two performance rates and two submission criteria. **Updated denominator: For all collection types:** Removed submission criteria one. **For MIPS CQMs Specifications collection type:** Added ophthalmology, skilled nursing facility, and domiciliary/rest home settings and preventive care services. **The numerator is revised to read: For all collection type**: Patients with at least two orders for the same high-risk medication on different days during the measurement period. **Updated numerator: For the MIPS CQMs Specifications collection type:** Removed submission criteria one numerator. Revised High-Risk Medications at any dose or duration Table 1: Added: Pyrilamine, Orphenadrine, Chlordiazepoxide-clidinium, Methscopolamine, Glimepiride Removed: Clidinium Chloradiazepoxide, Ticlopidine, Pentazocine **For the eCQM Specifications collection type:** Added medication value sets: Scopolamine, Secobarbital, Propantheline, Doxylamine, Ergoloid Mesylates, Butalbital, Amobarbital, Pentobarbital
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove submission criteria one from this measure and continue to assess the percentage of patients 65 years of age and older who were ordered at least two of the same high-risk medications. This change will lessen clinician burden while still assessing an important aspect of patient safety. This patient population is a better assessment of the riskier, longer-term use and allows MIPS eligible clinicians/groups to address potentially inappropriate medication dispensing to improve quality outcomes. The eCQM Specifications collection type added medication value sets to the numerator to align with the Beers Criteria for Potentially Inappropriate Medication list, as well as to reflect expert review and stakeholder feedback. These updates ensure all high-risk medications are being assessed for numerator compliance. The MIPS CQMs Specifications collection type was revised to align medications across collection types. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q238 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.49 Cardiac Rehabilitation Patient Referral from an Outpatient Setting

Category	Description
NQF # / eCQM NQF #:	0643 / N/A
Quality#:	243
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients evaluated in an outpatient setting who within the previous 12 months have experienced an acute myocardial infarction (MI), coronary artery bypass graft (CABG) surgery, a percutaneous coronary intervention (PCI), cardiac valve surgery, or cardiac transplantation, or who have chronic stable angina (CSA) and have not already participated in an early outpatient cardiac rehabilitation/secondary prevention (CR) program for the qualifying event/diagnosis who were referred to a CR program.
Substantive Change:	**Updated denominator:** Added Skilled Nursing Facility, Domiciliary/Rest Home, Home Visit, and Outpatient Consultation settings. Added telehealth as eligible encounter.
Steward:	American Heart Association
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add settings, Skilled Nursing Facility, Domiciliary/Rest Home, Home Visit, and Outpatient Consultation, as denominator eligible as they are clinically relevant settings that can ensure that patients receive or continue outpatient cardiac rehabilitation to support positive outcomes in their clinical care. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: Several commenters supported the addition of telehealth reporting for measure Q243. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q243 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.50 Biopsy Follow-Up

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	265
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q265. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q265 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.51 Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	268
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients of childbearing potential (12 years and older) diagnosed with epilepsy who were counseled at least once a year about how epilepsy and its treatment may affect contraception and pregnancy.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **The denominator is revised to read:** All females, including all individuals of childbearing potential (12 years and older) with a diagnosis of epilepsy. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type. The limited patient population and adoption of the quality measure for this collection type does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. We proposed the denominator statement be revised to be more inclusive of the eligible patient population. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter requested the removal of Medicare Part B Claims Measure Specifications for measure Q268 through the measure review process. The commenter noted that these changes were not reflected in the 2021 PFS proposed rule and the measure specifications should be removed, as the measure steward is no longer maintaining these specifications.

Response: We did propose to modify the collection type to only include the MIPS CQMs Specifications collection type. We thank the commenter for their support in the removal of the Medicare Part B Claims Measure Specifications collection type.

Comment: One commenter supported the addition of telehealth reporting for measure Q268.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q268 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.52 Sleep Apnea: Severity Assessment at Initial Diagnosis

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	277
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q277.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q277 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.53 Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	279
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Sleep Medicine
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q279.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

After consideration of public comments, we are finalizing the changes to measure Q279 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.54 Dementia: Cognitive Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 2872e
Quality#:	281
CMS eCQM ID:	CMS149v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12-month period.
Substantive Change:	**The guidance is revised to read:** Use of a standardized tool or instrument to assess cognition other than those listed will meet numerator performance. Standardized tools can be mapped to the concept "Intervention, Performed": "Cognitive Assessment" included in the numerator logic below. The requirement of two or more visits is to establish that the eligible professional or eligible clinician has an existing relationship with the patient. In recognition of the growing use of integrated and team-based care, the diagnosis of dementia and the assessment of cognitive function need not be performed by the same provider or clinician. The DSM-5 has replaced the term dementia with major neurocognitive disorder and mild neurocognitive disorder. For the purposes of this measure, the terms are equivalent. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	The measure steward's technical expert panel suggested adding language within the guidance statement to reflect that team-based care is appropriate for this measure. We agreed that this is an important concept and applicable to this measure, adding the language helps to clarify the measure intent.

Comment: One commenter supported the changes for measure Q281 related to dementia and associated screening assessments.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q281 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.55 Dementia: Functional Status Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	282
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia for whom an assessment of functional status was performed at least once in the last 12 months.
Substantive Change:	**The definition is revised to read:** Assessment of functional status - Functional status is assessed by use of a validated tool, direct assessment of the patient, or by querying a knowledgeable informant. A direct assessment of functional status includes an evaluation of the patient's ability to perform instrumental activities of daily living (IADL) and basic activities of daily living (ADL). **Updated denominator:** Added telehealth as eligible encounter. **The numerator instructions are revised to read:** To meet this measure, providers must assess BOTH IADL and ADL performance. 1. IADL Assessment (users must meet one of the two below bullets to meet IADL assessment component) • To meet the measure's IADL component using a validated tool, providers must use one of the following tools: o Lawton Instrumental Activities of Daily Living Scale o Bristol Activities of Daily Living Scale o Katz Index of Independence in Activities of Daily Living o Functional Activities Questionnaire o Functional Independence Measure Instrument • To meet the measure's IADL component using a direct assessment, providers must document 3 out of the following 5 domains. o Cleaning or hobbies o Money management, o Medication management, o Transportation, and o Cooking or communication 2. ADL Assessment (users must meet one of the two below bullets to meet ADL assessment component) • To meet the measure's ADL component using a validated tool, providers must use either: o Barthel ADL Index o Bristol Activities of Daily Living Scale • To meet the measure's ADL component using a direct assessment, providers must document 3 out of the following 7 domains. o Grooming, o Bathing, o Dressing, o Eating, o Toileting, o Gait, and o Transferring **The numerator notes is revised to read:** The 12-month look back period is defined as 12 months from the date of the denominator eligible encounter. Denominator Exception(s) are determined on the date of the denominator eligible encounter. Documentation of advanced stage dementia and caregiver knowledge is limited would meet the measure exception criteria. **The denominator exception is revised to read**: Documentation of advanced stage dementia and caregiver knowledge is limited.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed the measure definition and numerator instructions to provide clarity regarding expectations for numerator compliance. This updated language should address any stakeholder confusion for implementing the measure. The numerator note was updated to align with revised denominator exception. We proposed to update the denominator exception to reduce ambiguity regarding patient scenarios where an exception is clinically appropriate. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the changes for measure Q282 related to dementia and associated screening assessments. Another commenter supported adding telehealth reporting to this measure. Another commenter support adopting language in its guidance recognizing the growing use of integrated and team-based care in the diagnosis of dementia and the assessment of cognitive impairment and concur with CMS's continued recognition that functional status includes an evaluation of a patient's ability to perform instrumental activities of daily living (IADLs) and activities of daily living (ADLs). The commenter also applauded CMS's ongoing monitoring and measurement of the percentage of patients with dementia for whom there is documented screening because it reflects CMS's recognition of the critical importance of regular screening, assessment, and management of patients with dementia for other behavioral and psychiatric symptoms.

Response: We thank the commenters for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q282 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.56 Dementia Associated Behavioral and Psychiatric Symptoms Screening and Management

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	283
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia for whom there was a documented screening for behavioral and psychiatric symptoms, including depression, and for whom, if symptoms screening was positive, there was also documentation of recommendations for management in the last 12 months.
Substantive Change:	**Updated denominator:** Added telehealth as eligible encounter. **The definition is revised to read:** Behavioral and Psychiatric Symptoms Screening - Screening is defined as using a validated instrument or directly examining the patient or knowledgeable informant to determine the presence or absence of symptoms from three domains: Activity disturbances, mood disturbances (including depression), and thought and perceptional disturbances. The following validated instruments can be used to meet the measure: • Dementia Signs and Symptoms (DSS) Scale • Neuropsychiatric Inventory (NPI) • Minimum Data Set (MDS) (suggested for nursing home only). **Updated numerator instructions:** Added: Thought and perceptual disturbances under 'Thought and perceptual disturbances'. Revised: Examples of reliable and valid instruments that can be used to assess behavioral and psychiatric symptoms are: Dementia Signs and Symptoms (DSS) Scale or Neuropsychiatric Inventory (NPI). For patients residing in nursing homes, it may be the Minimum Data Set (MDS). Other reliable and valid instruments may be used to assess individual measure components for activity disturbances, mood disturbances including depression, and thought and perceptual disturbances.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the definition to remove 'positive', as this was not appropriate or aligned with the definition for the purposes of this measure. Additionally, information regarding approved screening instruments was moved to this section as it is more appropriately in this section of the measure specification. We proposed to update the numerator instructions to add 'thought and perceptual disturbance' and provide greater clarity regarding the requirements of numerator compliance for this measure. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the changes for measure Q283 related to dementia and associated screening assessments. Another commenter supported adding telehealth reporting to this measure.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q283 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.57 Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	286
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia or their caregiver(s) for whom there was a documented safety concerns screening in two domains of risk: 1) dangerousness to self or others and 2) environmental risks; and if safety concerns screening was positive in the last 12 months, there was documentation of mitigation recommendations, including but not limited to referral to other resources.
Substantive Change:	**The denominator exception is revised to read**: Documentation patient unable to communicate and informant not available. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exception to better align with real-world clinical scenarios where safety screening could not be completed and therefore no mitigation recommendations could be provided. This change aids clinicians reporting the measure with an exception to excuse them from performance in a clinical situation they are unable to control. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the changes for measure Q286 related to dementia and associated screening assessments. Another commenter supported adding telehealth reporting to this measure. **Response:** We thank the commenter for supporting the changes to this measure. After consideration of public comments, we are finalizing the changes to measure Q286 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.58 Dementia: Education and Support of Caregivers for Patients with Dementia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	288
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Substantive Change:	**Updated denominator:** Added telehealth as eligible encounter. **Updated denominator exceptions:** Revised: Patient does not have a caregiver. Added: 1. Documentation caregiver is trained and certified in dementia care. 2. Patient/caregiver dyad has been referred to appropriate resources and connection to those resources is confirmed.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to revise the denominator exception to reduce ambiguity regarding patient scenarios where an exception is clinically appropriate. Additionally, we proposed to add two denominator exceptions to further clarity clinical scenarios where it may not be appropriate to attribute the quality action to that MIPS eligible clinician. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the changes for measure Q288 related to dementia and associated screening assessments. Another commenter supported adding telehealth reporting to this measure.

Response: We thank the commenter for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q288 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.59 Parkinson's Disease: Psychiatric Symptoms Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	290
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for psychiatric symptoms once in the past 12 months. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description to include the word 'once' to provide added clarity regarding measure intent. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q290. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q290 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.60 Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment for Patients with Parkinson's Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	291
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease [PD] who were assessed for cognitive impairment or dysfunction once in the past 12 months. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure description to include the word 'once' to provide added clarity regarding measure intent. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q291. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q291 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.61 Parkinson's Disease: Rehabilitative Therapy Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months. **Updated denominator exception**: Removed: Documentation of medical reason(s) for not discussing rehabilitative therapy options with patient (or caregiver). **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description to include the word 'once' to provide added clarity regarding measure intent. Additionally, we proposed to remove the denominator exception, which allowed for medical reason(s) for not discussing rehabilitative therapy options. We agreed that MIPS eligible clinicians should discuss rehabilitative therapy options with all patients/caregivers as these therapies play an important role in not only improving function in the patient, but also their quality of life. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q293. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q293 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.61 Parkinson's Disease: Rehabilitative Therapy Options

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	293
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed in the past 12 months.
Substantive Change:	**The description is revised to read:** Percentage of all patients with a diagnosis of Parkinson's Disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (i.e., physical, occupational, and speech therapy) discussed once in the past 12 months. **Updated denominator exception**: Removed: Documentation of medical reason(s) for not discussing rehabilitative therapy options with patient (or caregiver). **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description to include the word 'once' to provide added clarity regarding measure intent. Additionally, we proposed to remove the denominator exception, which allowed for medical reason(s) for not discussing rehabilitative therapy options. We agreed that MIPS eligible clinicians should discuss rehabilitative therapy options with all patients/caregivers as these therapies play an important role in not only improving function in the patient, but also their quality of life. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q293. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q293 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.63 Cervical Cancer Screening

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	309
CMS eCQM ID:	CMS124v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: • Women age 21-64 who had cervical cytology performed every 3 years • Women age 30-64 who had cervical cytology/human papillomavirus (HPV) co-testing performed every 5 years.
Substantive Change:	**The description is revised to read:** Percentage of women 21-64 years of age who were screened for cervical cancer using either of the following criteria: * Women age 21-64 who had cervical cytology performed within the last 3 years * Women age 30-64 who had cervical human papillomavirus (HPV) testing performed within the last 5 years **The guidance is revised to read:** To ensure the measure is only looking for a cervical cytology test only after a woman turns 21 years of age, the youngest age in the initial population is 23. Patient self-report for procedures, as well as diagnostic studies should be recorded in 'Procedure, Performed' template or 'Diagnostic Study, Performed' template in QRDA-1. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. This eCQM is a patient-based measure. **The numerator is revised to read:** Women with one or more screenings for cervical cancer. Appropriate screenings are defined by any one of the following criteria: * Cervical cytology performed during the measurement period or the two years prior to the measurement period for women who are at least 21 years old at the time of the test * Cervical human papillomavirus (HPV) testing performed during the measurement period or the four years prior to the measurement period for women who are 30 years or older at the time of the test. **Updated logic**: Updated logic definition to use HPV only every 5 years and remove Pap test.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure to align with current clinical guidelines, which removes the Pap test requirement and allow HPV only testing every 5 years. This update is reflected in revisions to the description, guidance, numerator, and logic.

Comment: One commenter opposed the proposed changes to measure Q309, citing that the proposal was to update the measure to align with the current clinical guidelines, which removes the Pap/HPV test (co-testing) requirement and allow only HPV testing every 5 years. While this proposed change would align to the recently updated American Cancer Society (ACS) cervical cancer screening guidelines, the commenter stated the change is not consistent with the current recommendations from the American College of Obstetricians and Gynecologists (ACOG), the United States Preventive Services Task Force (USPSTF), the National Committee for Quality Assurance (NCQA), and numerous other guideline bodies or current clinical practice in the United States.

In response to the ACS guidelines, ACOG issued a statement affirming their current guidelines, which encompasses all three screening regimens (high-risk human papillomavirus testing alone, cervical cytology alone, and co-testing). In August 2018, the USPSTF recommended screening women aged 30 to 65 years, screening every 3 years with cervical cytology alone, every 5 years with high-risk human papillomavirus (hrHPV) testing alone, or every 5 years with hrHPV testing in combination with cytology (contesting)3 with an "A" rating.

In addition, the NCQA HEDIS measure is also in conflict with the proposed revisions to the MIPS measure. The NCQA HEDIS measure for cervical cancer screening includes all three screening regimens (high-risk human papillomavirus testing alone, cervical cytology alone, and co-testing). Lastly, the proposed change to the MIPS quality measure eliminated the recommended option of co-testing for cervical cancer, a change that is inconsistent with current guidelines recommended by ACOG, the USPSTF and NCQA. Accordingly, the leading authorities in cervical cancer screening are on record that co-testing is a valuable cervical cancer screening test. The commenter asked for measure Q309 to be retained without any revisions. A second commenter sought clarification on whether the measure is specifically looking at HPV only testing every 5 years. The description and logic have conflicting definitions between the usage of cervical cytology and HPV testing, and solely HPV testing. A third commenter cited the proposal to change the measure description to remove "co-testing" from the criteria for HPV testing. The commenter indicated that it had affirmed its 2018 Practice Advisory, which includes all three cervical cancer screening strategies (high-risk human papillomavirus testing alone, cervical cytology alone, and co-testing). The commenter's current screening guidelines reflect a balance of benefit and potential harms and support shared decision-making between patients and their clinicians and recommended that changes to this measure not be finalized.

Response: We thank the commenters for their comments. The revisions to this measure are in alignment with the updated clinical guidelines. The guidelines for patients 30 to 65 years of age recommend that either; cervical cytology only be completed every 3 years or hrHPV testing alone every 5 years or co-testing (hrHPV + cervical cytology) every 5 years. The guidelines now allow hrHPV testing alone every 5 years as opposed to requiring that co-testing be completed every 5 years. However, if co-testing was completed every 5 years this would be numerator compliant as co-testing contains the hrHPV testing component. Conversely, if co-testing was completed every 3 years, this would also suffice for numerator compliance as the co-testing has the cervical cytology component. Therefore, the components of screening are all still included for the purposes of achieving the quality action for this measure, but the requirements have been revised to align with the updated guidelines. We encourage the commenters to reach out to the measure steward to discuss revisions in language to help clarify the numerator component for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q309 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.64 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	317
CMS eCQM ID:	CMS22v9
National Quality Strategy	Community/Population Health

Category	Description
Domain:	
Current Collection Type:	Medicare Part B Claims Specifications, eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older seen during the submitting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated.
Substantive Change:	**The description is revised to read: For all collection types:** Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is pre-hypertensive or hypertensive. **The guidance is revised to read: For the eCQM Specifications collection type**: This eCQM is an episode-based measure and should be reported at every visit for patients aged 18 years and older. This measure will be calculated based upon the clinical actions performed at every visit during the measurement period for each patient. The measure requires that blood pressure measurements (i.e., diastolic and systolic) be obtained during each visit to determine the blood pressure reading used to evaluate if an intervention is needed. Both the systolic and diastolic blood pressure measurements are required for inclusion. If there are multiple blood pressures obtained during a patient visit, only the last, or most recent, pressure measurement will be used to evaluate the measure requirements. The intent of this measure is to screen patients for high blood pressure and provide recommended follow-up as indicated. The documented follow-up plan must be related to the current blood pressure reading as indicated, example: "Patient referred to primary care provider for BP management." This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **The instructions are revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs collections type:** This measure is to be submitted at each visit for patients seen during the measurement period. Merit-based Incentive Payment System (MIPS) eligible clinicians who submit the measure must perform the blood pressure screening at each patient visit by a MIPS eligible clinician and may not obtain measurements from external sources. **The initial patient population is revised to read: For the eCQM Specifications collection type:** All patient visits for patients aged 18 years and older at the beginning of the measurement period. **The denominator is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs collections type:** All patient visits for patients aged 18 years and older at the beginning of the measurement period. **The denominator exception is revised to read: For the eCQM Specifications collection type**: 1. Documentation of medical reason(s) for not screening for high blood pressure (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). 2. Documentation of patient reason(s) for not screening for blood pressure measurements or for not ordering an appropriate follow-up intervention if patient is pre-hypertensive or hypertensive (e.g., patient refuses). **Updated denominator exception logic: For the eCQM Specifications collection type:** Added: 1. Follow-up within 1 year 2. Follow-up within 4 weeks **The numerator is revised to read: For all collection types:** Patient visits where patients were screened for high blood pressure AND have a recommended follow-up plan documented, as indicated, if the blood pressure is pre-hypertensive or hypertensive. **Updated numerator definition: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Revised: Patients with a Documented Reason for not Screening or no Follow-Up Plan for High Blood Pressure (Denominator Exception) – • Documentation of medical reason(s) for not screening for high blood pressure (e.g., patient is in an urgent or emergent medical situation where time is of the essence and to delay treatment would jeopardize the patient's health status). • Documentation of patient reason(s) for not screening for blood pressure measurements or for not ordering an appropriate follow-up intervention if patient is pre-hypertensive or hypertensive (e.g., patient refuses). **The numerator notes is revised to read: For the Medicare Part B Claims Measure Specifications and the MIPS CQMs Specifications collection types:** Although the recommended screening interval for a normal BP reading is every 2 years, to meet the intent of this measure, BP screening and follow-up must be performed at every patient visit. For patients with Normal blood pressure, a follow-up plan is not required (G8783). Denominator Exception(s) are determined on the date of the denominator eligible encounter. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure frequency so that the clinical quality action is occurring at all denominator eligible visits. Hypertension is a prevalent condition, and the United States Preventive Services Task Force (USPSTF) found good evidence that screening for and treatment of high blood pressure in adults substantially reduces the incidence of cardiovascular events. In alignment with this update, the measure language has been revised to reflect the change in frequency to all visits. Additionally, the eCQM Specifications collection type revised the logic to align with the measure's reporting frequency update, as well as updating the denominator exception logic to add two elements that were missing from the existing logic to ensure that all valid denominator exception options are accounted for within the logic. The denominator exception language was revised in the eCQM Specifications collection type to follow best practices and add clarity to implementing the measure. To align with this

Category	Description
	update, the definition for denominator exception was revised in the Medicare Part B Claims Measure Specifications and MIPS CQMs Specifications collection types. We proposed to remove telehealth encounters from the denominator of the eCQM Specifications collection type as telehealth is not an appropriate setting for this measure, as well as to align with the other collection types. This guidance can be found in a separate document that will be published on the eCQI Resource Center. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
Comment: One commenter opposed the proposed change in the frequency of blood pressure screening required for this measure from annual to every patient encounter. CMS states that this is in response to the update on screening recommendations from the United States Preventive Services Task Force (USPSTF). The USPSTF is updating their guidance, but their most recent draft guidance states the following on recommended screening frequency: The USPSTF suggests annual screening for hypertension in adults age 40 years or older and for adults at increased risk for hypertension (such as persons with high-normal blood pressure, who are overweight or obese, or who are African American). Screening less frequently (i.e., every 3 to 5 years) is appropriate for adults ages 18 to 39 years not at increased risk for hypertension and with a prior normal blood pressure reading. CMS's proposed change is in opposition to recommended best practices and unnecessarily creates additional burden for clinicians. Meaningful measures should be based on best evidence. **Response:** While the USPSTF does give these suggestions, they also note that available evidence regarding optimal screening intervals for hypertension are limited. However, given the prevalence of the condition, as hypertension affects approximately 45% of the adult U.S. population (https://www.cdc.gov/nchs/products/databriefs/db364.htm), and is a major contributing factor to chronic conditions such as heart failure, heart attack, stroke, and chronic kidney disease, we believe it is important to screen blood pressure often to ensure the opportunity to offer a timely diagnoses. After consideration of public comments, we are finalizing the changes to measure Q317 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.65 Falls: Screening for Future Fall Risk

Category	Description
NQF # / eCQM NQF #:	0101 / N/A
Quality#:	318
CMS eCQM ID:	CMS139v9
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications
Current Measure Description:	Percentage of patients 65 years of age and older who were screened for future fall risk during the measurement period.
Substantive Change:	**Modified collection type:** eCQM Specifications **Updated denominator exclusion: For the eCQM Specifications collection type:** Removed: Exclude patients who were non-ambulatory at some point in the measurement period.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the denominator exclusion for non-ambulatory patients to address implementation challenges as there is a lack of available documentation for a non-ambulatory status. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

Comment: One commenter supported the proposal to remove the denominator exclusion for non-ambulatory patients.

Response: We thank the commenter for supporting the change to this measure.

After consideration of public comments, we are finalizing the changes to measure Q318 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Specifications.

D.66 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
NQF # / eCQM NQF #:	1525 / N/A
Quality#:	326
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with nonvalvular atrial fibrillation (AF) or atrial flutter who were prescribed warfarin OR another FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Substantive Change:	**The denominator is revised to read: For all collection types:** All patients aged 18 years and older with a diagnosis of nonvalvular AF or atrial flutter who do not have a documented CHA_2DS_2-VASc risk score of 0 or 1 for men or 0, 1, or 2 for women. **The denominator/numerator note is revised to read: For all collection types:** The intent of the denominator exclusion G9931 is to allow patients with a low risk for a thromboembolic event (i.e. a CHA_2DS_2-VASc score of 0 or 1 for men or 0, 1, or 2 for women) to be excluded from the sample. This denominator exclusion serves as documentation that a patient's risk for a thromboembolic event was appropriately assessed using the CHA_2DS_2-VASc scoring tool and that the risk was low enough to not warrant anticoagulation treatment. To exclude low risk patients, eligible clinicians must use the CHA_2DS_2-VASc assessment tool to determine a patient's risk score and must document either the numeric score (i.e. 0 or 1 for men or 0, 1, or 2 for women) or all the individual risk factors assessed to support an assessment of the CHA_2DS_2-VASc score. **Updated denominator exclusion: For all collection types:** Revised: Documentation of CHA_2DS_2-VASc risk score of 0 or 1 for men; 0, 1, or 2 for women. **Updated denominator: For all collection types:** Added telehealth as eligible encounter.
Steward:	American Heart Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the measure to reflect the updated guidelines regarding when it is clinically appropriate to prescribe an oral anticoagulant for patients that are diagnosed with atrial fibrillation or atrial flutter. This update is reflected in the denominator statement, denominator note, and denominator exclusion. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q326. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q326 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.67 Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	331
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, aged 18 years and older, with a diagnosis of acute viral sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: Several commenters supported the addition of telehealth as an eligible encounter to measure Q331. The commenter appreciated CMS recognizing telehealth as an appropriate modality for effective, high quality patient care.

Response: We thank the commenters for supporting the substantive change to measure Q331.

After consideration of public comments, we are finalizing the changes to measure Q331 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.68 Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	332
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: Several commenters supported the addition of telehealth as an eligible encounter to measure Q332. The commenter appreciated CMS recognizing telehealth as an appropriate modality for effective, high quality patient care. **Response:** We thank the commenters for supporting the change to measure Q332. After consideration of public comments, we are finalizing the changes to measure Q332 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.69 Maternity Care: Elective Delivery or Early Induction Without Medical Indication at < 39 Weeks (Overuse)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	335
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication.
Substantive Change:	**The description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at < 39 weeks of gestation completed who had elective deliveries by cesarean section (C-section), or early inductions of labor, without medical indication. **Updated instructions:** Revised: This measure is to be submitted each time a procedure is performed for patients undergoing delivery by C-section, or induction of labor, at less than 39 weeks gestation during the performance period. **The denominator is revised to read:** All patients, regardless of age, who gave birth during a 12-month period delivering a live singleton at < 39 weeks of gestation completed. **The numerator is revised to read:** Patients who had elective deliveries by C-section, or early inductions of labor, without medical indication. **Updated numerator options:** Revised: **Performance Met:** Early elective delivery by C-section, or early elective induction, not performed (< 39 weeks gestation). **Performance Not Met:** Early elective delivery by C-section, or early elective induction, performed (< 39 weeks gestation).
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the description and instructions to provide further clarity regarding what suffices for elective deliveries. Additionally, we proposed to move the "without medical indication" from the denominator to the numerator as the denominator should capture all patients with a single live birth at less than 39 weeks gestation. The numerator assesses whether or not there was medical indication for an early elective delivery by C-section, or early elective induction. This update will better align the language with the measure intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q335 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.70 Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	336
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care within 8 weeks of giving birth and who received a breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Substantive Change:	**The description is revised to read:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at the postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure description for clarity and readability so that it is easy to understand the measure intent.
We proposed a substantive change to the description; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 8 weeks of giving birth and received the following at a postpartum visit: breast-feeding evaluation and education, postpartum depression screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update. This additional refinement does not affect the intent of the proposed substantive change. We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q336 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.71 Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	364
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for CT imaging studies with a finding of an incidental pulmonary nodule for patients aged 35 years and older that contain an impression or conclusion that includes a recommended interval and modality for follow-up (e.g., type of imaging or biopsy) or for no follow-up, and source of recommendations (e.g., guidelines such as Fleischner Society, American Lung Association, American College of Chest Physicians).
Substantive Change:	**Updated denominator note:** Added: Granulomas, hamartomas or lesions with internal fat, or other characteristically benign findings are not considered incidental findings in the context or intent of this measure. Therefore, they are not included in the measure denominator. However, generally accepted radiology practices should be followed for communication and management of these characteristically benign findings.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add language to the denominator note to add clarity as to which incidental findings are not appropriate for the purposes of this measure. Some incidental findings are widely known to be benign and would therefore not necessitate a specific documentation of a recommendation of no follow-up. This will reduce clinician burden and ensure only the appropriate patients are included in the denominator eligible population.

We proposed a substantive change to the denominator note; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state: Granulomas, hamartomas or lesions with internal fat, or other characteristically benign findings are not considered incidental findings in the context or intent of this measure. Therefore, they are not included in the measure denominator. However, generally accepted radiology practices should be followed with respect to communication and management of these characteristically benign findings.

Comment: One commenter recognized the changes to measure Q364 without issue. A second commenter supported the changes as they better fit the intent of these measures and will lessen clinical burden to some extent.

Response: We thank the commenters for supporting the changes to this measure.

After consideration of public comments, we are finalizing the changes to measure Q364 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.72 Depression Remission at Twelve Months

Category	Description
NQF # / eCQM NQF #:	0710 / 0710e
Quality#:	370
CMS eCQM ID:	CMS159v9
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescent patients 12 to 17 years of age and adult patients 18 years of age or older with major depression or dysthymia who reached remission 12 months (+/- 60 days) after an index event date.
Substantive Change:	**Modified collection type:** eCQM Specifications and MIPS CQMs Specifications **Updated guidance: For the eCQM Specifications collection type:** Added: When a baseline assessment is conducted with PHQ 9M, the follow-up assessment can use either a PHQ 9M or PHQ 9. This eCQM is a patient-based measure. This version of the eCQM uses QDM version 5.5. Please refer to the eCQI resource center (https://ecqi.healthit.gov/qdm) for more information on the QDM. **Updated denominator: For the MIPS CQMs Specifications collection type:** Added telehealth with qualified non-physician healthcare professional. **Updated denominator exclusion: For the eCQM Specifications collection type:** Revised: Patients with a diagnosis of personality disorder emotionally labile.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to update the guidance for eCQM Specifications collection type to add clarity regarding the assessment that may be used for the follow-up assessment for the purposes of meeting performance for this measure. Additionally, we proposed to revise the denominator exclusion language for a diagnosis of personality disorder to further clarify ensuring the correct patient population is being excluded from quality action assessment. We proposed to update the denominator of the MIPS CQMs Specifications collection type to include telehealth encounters with qualified non-physician healthcare professionals as it would be appropriate to assess this patient population for numerator compliance. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q370 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Measure Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Measure Specifications. Also, it should be noted that the CMS Web Interface Specifications collection type is not able to establish a benchmark for this measure. Thus, this measure will be excluded from the Merit-based Incentive Payment System (MIPS) scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the measure meets the data completeness requirement and the data applicable to the measure is reported via the CMS Web Interface Measure Specifications.	

D.73 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	374
CMS eCQM ID:	CMS50v9
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	eCQM Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred.
Substantive Change:	**Updated logic: For the eCQM Specifications collection type:** Updated logic for 'First Referral During Measurement Period' to allow an additional, optional way to capture the first referral. **Updated denominator: For all collection types:** Added telehealth as eligible encounter. **Updated numerator: For the eCQM Specifications collection type:** Removed pathology consult note from 'Consultant Report' value set.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the logic for 'First Referral During Measurement Period' to allow for a referral order, in addition to a referral being performed. This revision is consistent with the measure intent and provides options to capture the first referral within the electronic medical record. Additionally, we proposed to remove the pathology consult note from the 'Consultant Report' value set based upon terminology updates as the availability of the general consult note is available as an option. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.

Comment: One commenter supported the addition of telehealth reporting for measure Q374.

Response: We thank the commenter for supporting the addition of telehealth reporting for this measure.

Comment: One commenter requested additional clarification on the proposed updated eCQM logic to capture a referral order without a referral actually being made or conducted. It is unclear how a clinician can close the referral loop if a referral does not occur.

Response: This revision is in alignment with the intent of the measure, which is to ensure patient's referred for an outside consultation complete the encounter with a consult report being returned to the referring physician. As the measure steward, we will review and consider revision of the coding within the measure for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q374 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.74 Functional Status Assessments for Congestive Heart Failure

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	377
CMS eCQM ID:	CMS90v9
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients 18 years of age and older with congestive heart failure who completed initial and follow-up patient-reported functional status assessments.
Substantive Change:	**Updated logic**: **Initial Patient Population**: Revised timing of congestive heart failure (CHF) diagnosis in the initial population logic so it overlaps before the measurement period. **Qualifying Encounter:** Revised timing of the encounter from the start of the measurement period to the end of the measure period. **Numerator:** • Revised to ensure assessments completed during the encounter count toward the numerator. • Revised KCCQ logic to address the 6 domain subcategories used to account for the KCCQ assessment total score. • Added the KCCQ Total Assessment Score logic to include the summary score as an option to meet the KCCQ assessment requirement. • Revised timing and logic of the follow-up functional status assessment (FSA) to relate to the initial FSA performed and not the encounter. • Revised measurement period for the Veterans RAND 12 Item Health Survey (VR-12) to allow for the initial FSA to occur prior to the measurement period if the encounter occurs within the first few days of the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the initial patient population logic to ensure the CHF diagnosis occurs before the denominator eligible encounter, which aligns more closely with the measure intent. We proposed to update the qualifying encounter logic to account for leap year. This refinement will eliminate the need to adjust the number of days for leap years. Additionally, we proposed to update the numerator logic for the Kansas City Cardiomyopathy Questionnaire (KCCQ) FSA so that it can be reported by either utilizing the six domain subcategories or the total score. This added flexibility better aligns with different clinical workflows, and is consistent with measure intent. The logic and timing were revised to relate to the initial functional status (FSA) and not the encounter to better align with the measure intent. We proposed, to all the VR-12, to allow for the initial FSA to occur prior to the measurement in the instance the encounter occurs within the first few days of the measurement period to improve harmonization with the measure intent.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q377 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.75 Children Who Have Dental Decay or Cavities

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v9
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who have had tooth decay or cavities during the measurement period.
Substantive Change:	**The description is revised to read**: Percentage of children, 6 months - 20 years of age, who have had tooth decay or cavities during the measurement period. **The stratification is revised to read:** None **The initial patient population is revised to read:** Children, 6 months - 20 years of age, with a visit during the measurement period. **Updated denominator:** Removed: "Office Visit" (2.16.840.1.113883.3.464.1003.101.12.1001) "Preventive Care - Established Office Visit, 0 to 17" (2.16.840.1.113883.3.464.1003.101.12.1024) "Preventive Care Services - Established Office Visit, 18 and Up" (2.16.840.1.113883.3.464.1003.101.12.1025) "Preventive Care Services-Initial Office Visit, 18 and Up" (2.16.840.1.113883.3.464.1003.101.12.1023) "Preventive Care- Initial Office Visit, 0 to 17" (2.16.840.1.113883.3.464.1003.101.12.1022)
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to raise the minimum age for this measure to 6 months to better align with average tooth eruption. Children under 6 months of age are less likely to have teeth and would therefore not meet numerator criteria, which is why they are being removed from the initial patient population. Additionally, we proposed to update the denominator to limit the denominator eligible encounters to the "Clinical Oral Evaluation" value set as the clinical quality action is more appropriate for the dentistry MIPS eligible clinician.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q378 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.76 Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	379
CMS eCQM ID:	CMS74v10
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period.
Substantive Change:	**The description is revised to read**: Percentage of children, 6 months - 20 years of age, who received a fluoride varnish application during the measurement period. **The stratification is revised to read:** Population 1: age 6 months-5 years Population 2: age 6-12 Population 3: age 13-20 **The initial patient population is revised to read:** Children, 6 months - 20 years of age, with a visit during the measurement period.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to raise the minimum age for this measure to 6 months to better align with average tooth eruption. Children under 6 months of age are less likely to have teeth and would therefore not meet numerator criteria, which is why they are being removed from the initial patient population.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q379 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.77 Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment

Category	Description
NQF # / eCQM NQF #:	N/A / 1365e
Quality#:	382
CMS eCQM ID:	CMS177v9
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk.
Substantive Change:	**Updated guidance:** Added: In recognition of the growing use of integrated and team-based care, the diagnosis of depression and the assessment for suicide risk need not be performed by the same provider or clinician.
Steward:	Mathematica
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	The measure steward updated the guidance statement based upon technical expert feedback to reflect that team-based care would be appropriate for this measure. We agreed that this guidance update is clinically appropriate and aligns better with clinical care workflows.

Comment: One commenter stated that guidance reads "A suicide risk assessment should be performed at every visit for major depressive disorder during the measurement period." Feedback from specialists in this field voice the following: "Our concern is that therapists provide group visits and some of those teens have MDD on their problem list. Currently, suicide risk assessments are not conducted at group visits. Most patients who attend group visits also have a cadence of seeing their therapists separately." The commenter recommended that this requirement make exceptions of the required suicide assessment during group visits.

Response: We thank the commenter for their comment. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q382 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.78 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
NQF # / eCQM NQF #:	1879 / N/A
Quality#:	383
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months).
Substantive Change:	**The description is revised to read:** Percentage of individuals at least 18 years of age with schizophrenia or schizoaffective disorder as of the beginning of the performance period who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period. **Updated instructions:** Revised: This measure is to be submitted a minimum of once per performance period for all patients with a preexisting (before the performance period) diagnosis of schizophrenia or schizoaffective disorder who are seen during the performance period. **The denominator statement is revised to read:** Individuals at least 18 years of age with schizophrenia or schizoaffective disorder as of the beginning of the performance period and at least two prescriptions filled for antipsychotic medications during the performance period. **Updated denominator criteria:** Revised the timing for the diagnosis for schizophrenia or schizoaffective disorder to be prior to the performance period. **Updated denominator exclusion:** Added opioid abuse with intoxication with perceptual disturbance to diagnosis for dementia. **Updated numerator note:** Revised: PDC NUMERATOR: The PDC numerator is the sum of the days covered by the days' supply of all antipsychotic prescriptions. The period covered by the PDC starts on the day within the performance period when the first prescription is filled (i.e., the index date) and lasts through the end of the performance period, or death, whichever comes first. For prescriptions with a days' supply that extends beyond the end of the performance period, count only the days for which the drug was available to the individual during the performance period. If there are prescriptions for the same drug (generic name) on the same date of service, keep the prescription with the largest days' supply. If prescriptions for the same drug (generic name) overlap, then adjust the prescription start date to be the day after the previous fill has ended.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We proposed to update the measure language to reflect that the diagnosis of schizophrenia or schizoaffective disorder should be prior to the performance period as this aligns more closely to the intent of the measure and allows for assessment of medication adherence over a longer timeframe. We proposed to remove the "12 consecutive months" from the description as this was causing confusion amongst MIPS eligible clinicians. The denominator exclusion coding was expanded to include opioid abuse with intoxication with perceptual disturbance as this is appropriate for identifying patients with a dementia diagnosis and therefore, applicable to the denominator exclusion. Additionally, we proposed to update the numerator note to clarify that the index date is the date the prescription was first filled during the performance period.

We, as the measure steward, have decided not to finalize the substantive change to revise the timing of the diagnosis for schizophrenia or schizoaffective disorder to be prior to the performance period, to ensure patient safety and drive positive clinical outcomes. Research has shown that adherence to antipsychotic medications in individuals with first-episode psychosis (FEP) improves patient outcomes while preventing downstream harm. Treatment FEP has shown favorable outcomes, including positive effects on likelihood of remission and risk/rate of relapse, and improvement in cognitive deficits (Karson, C., et al. *Neuropsychiatric Disease and Treatment*, 12, 57-67). Given the potential long-term benefits for treatment of FEP, we believe that it is important to assess all patients with a diagnosis for schizophrenia or schizoaffective disorder for medication adherence, regardless of when diagnosed. This aligns with our healthcare priority of promoting effective treatment of chronic diseases and current clinical best practices.

We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q383 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years, with the exception of the revisions in the timing of diagnosis for schizophrenia or schizoaffective disorder. This revision is located within the description, instructions, denominator statement, and denominator criteria and will be updated as needed for clarity of the concept as needed within the specification.

D.79 Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	386
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g., advance directives, invasive ventilation, hospice) at least once annually.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q386. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q386 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.80 Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	387
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients, regardless of age, who are active injection drug users who received screening for HCV infection within the 12-month reporting period.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: Several commenters supported the addition of telehealth reporting for measure Q387. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q387 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.81 Follow-Up After Hospitalization for Mental Illness (FUH)

Category	Description
NQF # / eCQM NQF #:	0576 / N/A
Quality#:	391
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness or intentional self-harm diagnoses and who had a follow-up visit with a mental health practitioner. Two rates are submitted: • The percentage of discharges for which the patient received follow-up within 30 days after discharge. • The percentage of discharges for which the patient received follow-up within 7 days after discharge.
Substantive Change:	**Updated numerator options:** Revised: Submission Criteria 1: **Performance Met:** Patient received follow-up within 30 days after discharge.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the performance met numerator option to align with the numerator statement, which prohibits the use of visits that occur on the date of discharge, as this would not meet the intent of the measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q391 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.82 Immunizations for Adolescents

Category	Description
NQF # / eCQM NQF #:	1407 / N/A
Quality#:	394
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday.
Substantive Change:	**The description is revised to read**: The percentage of adolescents 13 years of age who had one dose of meningococcal vaccine (serogroups A, C, W, Y), one tetanus, diphtheria toxoids and acellular pertussis (Tdap) vaccine, and have completed the human papillomavirus (HPV) vaccine series by their 13th birthday.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to revise the description to detail the components within the measure. This allows for a more clear understanding of the intent of the measure.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q394 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.83 Lung Cancer Reporting (Biopsy/Cytology Specimens)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	395
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Communication and Care Coordination
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.
Substantive Change:	**The numerator is revised to read: For all collection types**: Biopsy and cytology specimen reports with a diagnosis of primary non-small cell lung cancer classified into specific histologic type (including but not limited to squamous cell carcinoma, adenocarcinoma, large cell carcinoma) OR classified as NSCLC-NOS with an explanation included in the pathology report.
Steward:	College of American Pathologists
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the numerator statement to more clearly detail the acceptable histologic types. This revision, provided based on stakeholder feedback, includes keywords that are can be used in clinical practice.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q395 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.84 One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	400
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis, OR birthdate in the years 1945-1965 who received one-time screening for hepatitis C virus (HCV) infection.
Substantive Change:	**Updated denominator**: Added telehealth as eligible encounter.
Steward:	American Gastroenterological Association
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: Several commenter supported the addition of telehealth reporting for measure Q400. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q400 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.85 Appropriate Follow-up Imaging for Incidental Abdominal Lesions

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	405
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols
Substantive Change:	**The description is revised to read:** Percentage of final reports for imaging studies for patients aged 18 years and older with one or more of the following noted incidentally with a specific recommendation for no follow-up imaging recommended based on radiological findings: • Cystic renal lesion that is simple appearing* (Bosniak I or II) • Adrenal lesion less than or equal to 1.0 cm • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **The denominator is revised to read: For all collection types**: All final reports for imaging studies for patients aged 18 years and older with one or more of the following incidentally noted: • Cystic renal lesion that is simple appearing (Bosniak I or II) or • Adrenal lesion less than or equal to 1.0 cm or • Adrenal lesion greater than 1.0 cm but less than or equal to 4.0 cm classified as likely benign or diagnostic benign by unenhanced CT or washout protocol CT, or MRI with in- and opposed-phase sequences or other equivalent institutional imaging protocols **Updated denominator criteria: For all collection types:** Removed diagnostic ultrasound procedures. **The denominator note is revised to read: For all collection types:** The intent of this measure is to ensure patients with incidental findings that are highly likely to be benign do not receive follow up imaging routinely. * "Simple-appearing criteria": • § Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017) • § Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017) When reporting this measure, masses and lesions that do not meet all the criteria for "no further work-up" as provided in Management of the Incidental Renal Mass on CT: A White Paper of the ACR Incidental Findings Committee or the Management of the Incidental Adrenal Mass on CT: A White Paper of the ACR Incidental Findings Committee should not be considered in the context or intent of this measure. However, generally accepted radiology practices should be followed for communication and management of any characteristically benign findings. A measure performance goal of 100% should not substitute for clinical judgment in individual cases. **Updated numerator note: For the Medicare Part B Claims Measure Specifications collection type:** Removed numerator note. **Updated numerator options: For all collection types:** Revised: **Performance Not Met:** Final reports for imaging studies with follow-up imaging recommended, or final reports that do not include a specific recommendation of no follow-up.
Steward:	American College of Radiology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the numerator options to add clarifying language that accounts for those instances where no follow-up recommendation is given within the final reports for imaging studies. The intent of the measure includes the documentation of follow-up recommendations within the final report. Additionally, we proposed to remove diagnostic ultrasound procedures from the denominator eligible criteria as it does not align with the intent of the measure.

We proposed a substantive change to the denominator note; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
The intent of this measure is to ensure patients with incidental findings that are highly likely to be benign do not receive follow up imaging routinely. * "Simple-appearing criteria":
- § Incidental renal mass on non-contrast enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU or ≥70 HU. (ACR, 2017)
- § Incidental renal mass on contrast-enhanced abdominal CT that does not contain fat, is homogenous in appearance, -10-20 HU. (ACR, 2017)

When reporting this measure, masses and lesions that do not meet all the criteria for "no further work-up" as provided in Management of the Incidental Renal Mass on CT: A White Paper of the ACR Incidental Findings Committee or the Management of the Incidental Adrenal Mass on CT: A White Paper of the ACR Incidental Findings Committee should not be considered in the context or intent of this measure. However, generally accepted radiology practices should be followed with respect to communication and management of any characteristically benign findings. A measure performance goal of 100% should not substitute for clinical judgment in individual cases.

This additional refinement of changing 'for communication' to 'with respect to communication' does not affect the intent of the proposed substantive change.

Category	Description
Comment: One commenter supported the changes to measure Q405 as they better fit the intent of these measures and will lessen clinical burden to some extent. **Response:** We thank the commenter for supporting the changes to this measure. **Comment:** One commenter believed that the changes to measure Q405 should be more comprehensive. The measure focuses exclusively on reporting "no-follow up recommended" for incidental and likely benign renal and adrenal lesions. While the commenter understood the intention to address inappropriate use of imaging, the measure neglects appropriate usage. It should also support evidence-based recommendations for follow-up of worrisome lesions. A more balanced approach would indicate performance met when specific evidence-based guidance is used for necessary follow-up and when no follow-up is necessary, as included in the measure steward's two white papers referenced in the measure. **Response:** We encourage the commenter to reach out the measure steward to discuss possible revisions for consideration for future implementation. After consideration of public comments, we are finalizing the changes to measure Q405 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.86 Psoriasis: Clinical Response to Systemic Medications

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	410
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of psoriasis vulgaris patients receiving systemic medication who meet minimal physician-or patient- reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician-and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment.
Substantive Change:	**The instructions are revised to read:** This measure is to be submitted a minimum of once per performance period for all patients during the performance period. The most recent denominator eligible encounter in which the numerator action was performed, should be used. **Updated denominator:** Added telehealth as eligible encounter.
Steward:	American Academy of Dermatology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to revise the instructions language to clarify what denominator eligible encounter should be used when assessing the quality action. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured.
Comment: One commenter supported the addition of telehealth reporting for measure Q410. **Response:** We thank the commenter for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q410 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.87 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	415
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.
Substantive Change:	**Updated denominator criteria:** Diagnosis for minor blunt head trauma - removed coding for fracture of skull and facial bones and superficial injury of neck. **The definition is revised to read:** Indications for a head CT in patients presenting to the emergency department for minor blunt head trauma: Patients with no loss of consciousness (LOC) AND no post-traumatic amnesia AND any one of the following: • GCS score less than 15 • Severe headache • Vomiting • Age 65 years and older • Physical signs of a basilar skull fracture (signs include haemotympanum, "raccoon" eyes, cerebrospinal fluid leakage from the ear or nose, Battle's sign) • Focal neurological deficit • Coagulopathy • Thrombocytopenia • Currently taking any of the following anticoagulant medications**: apixaban, argatroban, betrixaban, bivalirudin, dabigatran, dalteparin, desirudin, edoxaban, enoxaparin, fondaparinux, heparin, rivaroxaban, warfarin • Dangerous mechanism of injury (i.e., ejection from a motor vehicle, a pedestrian struck, and a fall from a height of more than 3 feet or 5 stairs) OR Patients with either LOC OR Posttraumatic amnesia AND any one of the following: • GCS score less than 15 • Headache • Age 60 years and older, and less than 65 years • Drug/alcohol intoxication • Short-term memory deficits • Evidence of trauma above the clavicles (physical location, any trauma to the head or neck [i.e., laceration, abrasion, bruising, ecchymosis, hematoma, swelling, fracture]) • Posttraumatic seizure.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to update the coding for 'Diagnosis of minor blunt head trauma' base on the measure steward's clinical expert input as closed fractures of the skull and facial bones, as well as concepts that relate to neck of below the head anatomical locations. The measures intent is to capture those patients with minor blunt head trauma and the fractures captured above are not clinically appropriate for the denominator criteria and should not be assessed for the purposes of this measure. We proposed revisions to the definition language to improve clarity regarding indications for a head CT for the purposes of this measure. We agreed that these revisions better define how to determine appropriate indication(s) for a head CT.

Comment: One commenter supported the substantive changes to measure Q415, which will improve clarity regarding indications for a head CT for the purposes of this measure.

Response: We thank the commenter for supporting the changes to measure Q415.

After consideration of publication comments, we are finalizing the changes to measure Q415 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.88 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	416
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of emergency department visits for patients aged 2 through 17 years who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network (PECARN) prediction rules for traumatic brain injury.
Substantive Change:	**Updated denominator criteria:** Diagnosis for minor blunt head trauma - removed coding for fracture of skull and facial bones and superficial injury of neck. **The numerator definition is revised to read: For all collection types:** Low Risk for Traumatic Brain Injury according to PECARN prediction rules – Patients can be classified as low risk if ALL of the following are met: • No signs of altered mental status (e.g., agitation, somnolence, repetitive questioning, slow response to verbal communication) OR no GCS < 15 • No signs of basilar skull fracture (signs include haemotympanum, "raccoon" eyes, cerebrospinal fluid leakage from the ear or nose, Battle's sign) • No loss of consciousness • No vomiting • No severe mechanism of injury (i.e., motor vehicle crash with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorized vehicle; falls of more than 5 feet; or head struck by a high-impact object) • No severe headache.
Steward:	American College of Emergency Physicians
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to update the coding for 'Diagnosis of minor blunt head trauma' base on the measure steward's clinical expert input as closed fractures of the skull and facial bones, as well as concepts that relate to neck of below the head anatomical locations. The measures intent is to capture those patients with minor blunt head trauma and the fractures captured above are not clinically appropriate for the denominator criteria and should not be assessed for the purposes of this measure. We proposed revisions to the definition language to improve clarity regarding low risk for traumatic brain injury (TBI) for the purposes of this measure. We agreed that these revisions better define how to appropriately determine whether the patient is low risk for traumatic brain injury or not.
Comment: One commenter supported the substantive changes to measure Q416, which will improve clarity regarding indications for a head CT for the purposes of this measure. **Response:** We thank the commenter for supporting the changes to measure Q416. After consideration of public comments, we are finalizing the changes to measure Q416 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.89 Osteoporosis Management in Women Who Had a Fracture

Category	Description
NQF # / eCQM NQF #:	0053 / N/A
Quality#:	418
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	The percentage of women age 50-85 who suffered a fracture in the six months prior to the performance period through June 30 of the performance period and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis in the six months after the fracture.
Substantive Change:	**Updated denominator criteria: For all collection types**: Option 1: Added denominator eligible patient encounters including discharge, outpatient observation, outpatient consultation, emergency department, home services, preventive medicine and counseling, work related/medical disability, care planning, and annual well check. **Updated denominator exclusions: For all collection type**: Option 1 and Option 2: Revised: 1. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during 6 months prior to the measurement period through December 31 of the measurement period. 2. Patient 66 - 80 years of age and had at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period. 3. Patients 66 - 80 years of age and had at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period. Added: 1. Patients 81 years of age and older with at least one claim/encounter for frailty during 6 months prior to the measurement period through December 31 of the measurement period. **Updated denominator exclusion: For all collection types:** For Option 1 and Option 2: Added coding to identify patients with advanced illness and frailty **Updated definition: For all collection types:** Revised: Pharmacologic Therapy – U.S. Food and Drug Administration approved pharmacologic options for osteoporosis prevention and/or treatment of postmenopausal osteoporosis include: bisphosphonates, alendronate, alendronate-cholecalciferol, ibandronate, risedronate, zoledronic acid, teriparatide, denosumab, abaloparatide, romosozumab, and raloxifine.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to expand the eligible encounter coding for Option 1 to include all relevant encounters and create a more complete eligible patient population. We proposed that the denominator exclusion language and logic be updated in all collection types to clarify that, for the measure, long-term care will be defined as patients staying 90 consecutive days at the long-term care facility versus any 90 days within the performance period. A denominator exclusion was added to remove patient 81 years of age and older with a frailty encounter during the measurement period as patients within this age stratification are more appropriately assessed less stringently when determine if they should be excluded from the eligible patient population. Additionally, we proposed adding applicable coding to better define the advanced illness and frailty patient population for the purposes of this measure. We proposed to update the definition for pharmacologic therapy to align with the current U.S. Food and Drug Administration approved pharmacologic options for osteoporosis prevention and/or treatment of postmenopausal osteoporosis.

We proposed a substantive change to the denominator exclusions; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:

Updated denominator exclusions: For all collection type: Option 1 and Option 2: Revised:

1. Patients age 66 or older in Institutional Special Needs Plans (SNP) or residing in long-term care with POS code, 32, 33, 34, 54, or 56 for more than 90 consecutive days during the six months prior to the measurement period through December 31 of the measurement period
2. Patients 66 - 80 years of age with at least one claim/encounter for frailty during the measurement period AND a dispensed medication for dementia during the measurement period or the year prior to the measurement period
3. Patients 66 - 80 years of age with at least one claim/encounter for frailty during the measurement period AND either one acute inpatient encounter with a diagnosis of advanced illness or two outpatient, observation, ED or nonacute inpatient encounters on different dates of service with an advanced illness diagnosis during the measurement period or the year prior to the measurement period

Added:

1. Patients 81 years of age and older with at least one claim/encounter for frailty during the six months prior to the measurement period through December 31 of the measurement period

This additional refinement does not affect the intent of the proposed substantive change.

We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q418 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.90 Overuse of Imaging for the Evaluation of Primary Headache

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	419
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of patients for whom imaging of the head (CT or MRI) is obtained for the evaluation of primary headache when clinical indications are not present.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications **Updated denominator criteria:** Removed inpatient setting. Removed "Patients with no clinical indications for imaging of the head". Added telehealth as eligible encounter. **Updated denominator instructions:** Removed denominator instructions. **Updated denominator exclusion:** Added: Patients with clinical indications for imaging of the head • Head trauma • New or change in headache above 50 years of age • Abnormal neurologic exam • Headache radiating to the neck • Positional headaches • Temporal headaches in patients over 55 years of age • New onset headache in pre-school children or younger (<6 years of age) • New onset headache in pediatric patients with disabilities for which headache is a concern as inferred from behavior • Occipital headache in children • Thunderclap headache • Trigeminal pain • Persistent headaches **Updated denominator exception:** Revised: Imaging needed as part of a clinical trial; or other clinician ordered the study.
Steward:	American Academy of Neurology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type. The limited adoption of the quality measure for this collection type does not allow for the creation of benchmarks to provide a meaningful impact to quality improvement. We proposed to update the denominator criteria to remove the inpatient setting as this measure is appropriate for the outpatient setting only. We proposed to remove the denominator criteria for patients with no clinical indications for head imaging and replace it with a denominator exclusion that clarifies patients with clinical indications for whom imaging of the head would be clinically relevant and warranted. The denominator instructions were removed as they were duplicative of the added denominator exclusion. Additionally, we proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. The denominator exception is being updated to delete outdated language and no longer allows for system reason(s).

Comment: One commenter requested the removal of Medicare Part B Claims Measure Specifications for measure Q419 through the measure review process. The commenter noted that these changes were not reflected in the 2021 PFS proposed rule and the measure specifications should be removed, as the measures steward is no longer maintaining these specifications. A second commenter opposed the removal of the Claims collection type because it would adversely impact ophthalmologists, particularly those in small and rural practices who must rely on the claims reporting collection type because they cannot afford to adopt CEHRT.

Response: We refer the commenter to the substantive change proposed to include a modification to the collection type resulting in the removal of the Medicare Part B Claims Measure Specification. We thank the commenter for their support in the removal of the Medicare Part B Claims Measure Specification collection type.

Comment: One commenter supported and one commenter did not support the addition of telehealth reporting for measure Q419.

Response: We believe that including telehealth encounters as denominator eligible as this will lead to a more complete patient population to ensure appropriate use of imaging for a diagnosis of primary headache. We encourage the commenter who did not support adding telehealth to this measure to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q419 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.91 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling

Category	Description
NQF # / eCQM NQF #:	2152 / N/A
Quality#:	431
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Community/Population Health
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 24 months AND who received brief counseling if identified as an unhealthy alcohol user.
Substantive Change:	**The description is revised to read:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as an unhealthy alcohol user. **Updated instructions:** Revised: For the purposes of the measure, the most recent denominator eligible encounter should be used to determine if the numerator action for the submission criteria was performed within the 12-month look back period. Added: This measure will be calculated with 3 performance rates: 1) Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months 2) Percentage of patients aged 18 years and older who were identified as unhealthy alcohol users who received brief counseling 3) Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months AND who received brief counseling if identified as unhealthy alcohol users The denominator of submission criteria 2 is a subset of the resulting numerator for submission criteria 1, as submission criteria 2 is limited to assessing if patients identified as unhealthy alcohol users received brief counseling. For all patients, submission criteria 1 and 3 are applicable, but submission criteria 2 will only be applicable for those patients who are identified as unhealthy alcohol users. Therefore, data for every patient that meets the age and encounter requirements will only be submitted for submission criteria 1 and 3, whereas data submitted for submission criteria 2 will be for a subset of patients who meet the age and encounter requirements, as the denominator has been further limited to those who were identified as unhealthy alcohol users. THERE ARE THREE SUBMISSION CRITERIA FOR THIS MEASURE: 1) All patients who were screened for unhealthy alcohol use using a systematic screening method AND 2) All patients who were identified as unhealthy alcohol users who received brief counseling AND 3) All patients who were screened for unhealthy alcohol use using a systematic screening method and, if identified as unhealthy alcohol users received brief counseling, or were not identified as unhealthy alcohol users This measure contains three submission criteria which aim to identify patients who were screened for unhealthy alcohol use using a systematic screening method (submission criteria 1), patients who were identified as unhealthy alcohol users and who received brief counseling (submission criteria 2), and a comprehensive look at the overall performance on unhealthy alcohol use screening and brief counseling (submission criteria 3). By separating this measure into various submission criteria, the MIPS eligible professional or MIPS eligible clinician will be able to better ascertain where gaps in performance exist, and identify opportunities for improvement. The overall rate (submission criteria 3) should be utilized to compare performance to published versions of this measure prior to the 2021 performance year, when the measure had a single performance rate. For accountability reporting in the CMS MIPS program, the rate for submission criteria 2 is used for performance. **The denominator is revised to read:** Submission Criteria 1: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period. Submission Criteria 2: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period who were screened for unhealthy alcohol use and identified as an unhealthy alcohol user. Submission Criteria 3: All patients aged 18 years and older seen for at least two visits or at least one preventive visit during the measurement period. **Updated denominator:** Added telehealth as eligible encounter. **The numerator is revised to read:** Submission Criteria 1: Patients who were screened for unhealthy alcohol use using a systematic screening method at least once within the last 12 months. Submission Criteria 2: Patients who received brief counseling. Submission Criteria 3: Patients who were screened for unhealthy alcohol use using a systematic screening method at least once within 12 months AND who received brief counseling if identified as an unhealthy alcohol user. **The numerator definition is revised to read**: Submission Criteria 1: Systematic screening method – For purposes of this measure, one of the following systematic methods to assess unhealthy alcohol use must be utilized. Systematic screening methods and thresholds for defining unhealthy alcohol use include: • AUDIT Screening Instrument (score ≥ 4) • AUDIT-C Screening Instrument (score ≥ 4 for men; score ≥ 3 for women) • Single Question Screening - How many times in the past year have you had 5 (for men) or 4 (for women and all adults older than 65 years) or more drinks in a day? (response ≥ 1). Submission Criteria 2 and 3: Brief counseling – Brief counseling for unhealthy alcohol use refers to one or more counseling sessions, a minimum of 5-15 minutes, which may include: feedback on alcohol use and harms; identification of high risk situations for drinking and coping strategies; increased motivation and the development of a personal plan to reduce drinking.

Category	Description
	Updated numerator note: Submission Criteria 1: Added: To satisfy the intent of this measure, a patient must have at least one screening for unhealthy alcohol use during the 12-month period. If a patient has multiple screenings for unhealthy alcohol use during the 12-month period, only the most recent screening, which has a documented status of unhealthy alcohol user or unhealthy alcohol non-user, will be used to satisfy the measure requirements. Submission Criteria 2: Added: In the event that a patient is screened for unhealthy alcohol use and identified as an unhealthy user but did not receive brief alcohol cessation counseling submit GXXXX. Denominator Exception(s) are determined on the date of the most recent denominator eligible encounter for all submission criteria. Submission Criteria 3: Added: To satisfy the intent of this measure, a patient must have at least one unhealthy alcohol use screening during the 12-month period. If a patient has multiple unhealthy alcohol use screenings during the 12-month period, only the most recent screening, which has a documented status of unhealthy alcohol user or unhealthy alcohol non-user, will be used to satisfy the measure requirements. In the event that a patient is screened for unhealthy alcohol use and identified as an unhealthy user but did not receive brief alcohol cessation counseling submit G9624. Denominator Exception(s) are determined on the date of the most recent denominator eligible encounter for all submission criteria. **Updated numerator options:** **Submission Criteria 1:** Revised: **Performance Met:** Patient identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method. **Performance Not Met:** Patient not screened for unhealthy alcohol use using a systematic screening method, reason not given. **Submission Criteria 2:** Added: **Performance Met:** Patient identified as an unhealthy alcohol user received brief counseling. **Denominator Exception:** Documentation of medical reason(s) for not providing brief counseling (e.g., limited life expectancy, other medical reasons). **Performance Not Met:** Patient did not receive brief counseling if identified as an unhealthy alcohol user, reason not given. **Submission Criteria 3:** **Performance Met:** Patient identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method and received brief counseling. **Performance Met:** Patient not identified as an unhealthy alcohol user when screened for unhealthy alcohol use using a systematic screening method. **Denominator Exception:** Documentation of medical reason(s) for not screening for unhealthy alcohol use (e.g., limited life expectancy, other medical reasons). **Denominator Exception:** Documentation of medical reason(s) for not providing brief counseling if identified as an unhealthy alcohol user (e.g., limited life expectancy, other medical reasons). **Performance Not Met:** Patient not screened for unhealthy alcohol use using a systematic screening method OR patient did not receive brief counseling if identified as an unhealthy alcohol user, reason not given. **Updated performance rate calculation:** Revised into three submission criteria. Submission Criteria 2 will be used for benchmarking purposes.
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to update the measure overall by splitting the measure into separate populations for three submission criteria. This will allow MIPS eligible clinicians to more readily find where the gaps in performance lie, allowing them to be better informed and able to adjust to improve quality care and patient outcomes. We proposed to revise the measure to shorten the look back period to 12 months and require that unhealthy alcohol screening who received brief counseling, if patient screened positive, occur every 12 months. The revision is based upon stakeholder feedback and input from the eCQM Clinical Review Process (CRP) and the measure steward's technical expert panel (TEP) and we agreed that it is important to do this annually excessive alcohol use is one of the most common causes of premature mortality in the United States (https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/unhealthy-alcohol-use-in-adolescents-and-adults-screening-and-behavioral-counseling-interventions). The numerator definition for Systematic screening method has been revised to align with current recommendations for the AUDIT C and the Single Questions Screening threshold. We proposed to add telehealth encounters as denominator eligible as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
Comment: Several commenters supported the addition of telehealth reporting for measure Q431. **Response:** We thank the commenters for supporting the addition of telehealth reporting for this measure. After consideration of public comments, we are finalizing the changes to measure Q431 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.92 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v4
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications, CMS Web Interface Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥ 21 years who have ever had a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial or pure hypercholesterolemia; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL.
Substantive Change:	**Modified collection type:** eCQM Specifications, MIPS CQMs Specifications **Updated denominator logic: For the eCQM Specifications collection type:** Added "CABG, PCI Procedure" 2.16.840.1.113762.1.4.1138.566 value set. **Updated denominator exclusion logic: For the eCQM Specifications collection type:** Added Hospice Care value sets. **The numerator definition is revised to read: For the MIPS CQMs Specifications collection type**: Statin therapy - Administration of one or more of a group of medications that are used to lower plasma lipoprotein levels in the treatment of hyperlipoproteinemia. Table 1 - Statin Medication Therapy List (NOTE: List does NOT include dosage): Atorvastatin, Fluvastatin, Lovastatin (Mevinolin), Pitavastatin, Pravastatin Sodium, Rosuvastatin Calcium, Simvastatin, Amlodipine Besylate/Atorvastatin, Ezetimibe/Simvastatin **Updated denominator note: For the MIPS CQMs Specifications collection type**: Revised: Denominator Exclusions should be active at any time during the measurement period. **Updated denominator: For the MIPS CQMs Specifications collection type:** Added telehealth as eligible encounters for all submission criteria.
Steward:	Centers for Medicare & Medicaid Services
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a value set to the eCQM Specifications collection type denominator to allow for the use of CPT and HCPCS codes for reporting patients who have had a CABG or PCI for inclusion within the denominator. This will improve data capture to ensure a more complete patient population. Additionally, a Hospice Care value set was added to align with the measure intent to exclude both palliative care and hospice patients. We proposed to add telehealth encounters as denominator eligible for the MIPS CQMs Specifications collection type as the telehealth setting is directly applicable to this measure and these patients should be included in the denominator to allow for numerator compliance to be measured. We proposed to add the numerator definition for the MIPS CQMs Specifications collection type to include a table of medications within this section and not in the clinical recommendations statement to ensure MIPS eligible clinicians are following these recommendations based on the clinical guidelines. Additionally, we proposed to update the denominator note to add clarity regarding when the denominator exclusion would be assessed within the medical record for the purposes of reporting this measure. We proposed to remove the CMS Web Interface Measure Specifications collection type. This collection type was proposed to be sunset for the purposes of MIPS starting with the 2021 performance year. We have determined it is not fiscally viable, feasible, or sustainable for MIPS to continue this collection type/submission type due to an 80 percent reduction and a continued decrease in interest of groups and virtual groups seeking to report quality data on CMS Web Interface measures. For further rationale, please see section IV.A.3.c.(1)(c) of this final rule.

Comment: Several commenters supported the addition of telehealth reporting for measure Q438.

Response: We thank the commenters for supporting the addition of telehealth reporting for this measure.
Comment: One commenter was not opposed to CMS being more prescriptive with the qualifying medications as long as frequent updates are made to the acceptable medications list.

Response: We thank the commenter for supporting the substantive change to the medication list for measure Q438.

After consideration of public comments, we are finalizing the changes to measure Q438 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years with the exception of the CMS Web Interface Specifications collection type. At § 414.1305, we proposed to modify the definition of the terms collection type and submission type by removing the CMS Web Interface Specifications as an available option starting with the 2023 payment year (85 FR 50290); however, the CMS Web Interface Measure Specifications collection type will be an available option for an extension of one additional year (2021 MIPS performance period/2023 MIPS payment year) and will be removed as a collection and submission type starting with the 2022 MIPS performance period/2024 MIPS payment year. None of the substantive changes above will be applied to the CMS Web Interface Measure Specifications for the 2021 MIPS performance period. The CMS Web Interface Measure Specifications for the 2021 MIPS performance period will reflect the 2020 CMS Web Interface Measure Specifications. Also, it should be noted that the CMS Web Interface Specifications collection type is not able to establish a benchmark for this measure. Thus, this measure will be excluded from the Merit-based Incentive Payment System (MIPS) scoring in accordance with § 414.1380(b)(1)(i)(A)(2)(i) provided that the measure meets the data completeness requirement and the data applicable to the measure is reported via the CMS Web Interface Measure Specifications.

D.93 Age Appropriate Screening Colonoscopy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	439
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.
Substantive Change:	**The description is revised to read:** The percentage of screening colonoscopies performed in patients greater than or equal to 86 years of age from January 1 to December 31. **The denominator is revised to read:** All screening colonoscopy examinations performed on patients greater than or equal to 50 years of age during the encounter period. **Updated denominator criteria:** Revised: All patients greater than or equal to 50 years of age on date of encounter receiving a colonoscopy for screening purposes only. **The numerator is revised to read:** Screening colonoscopies performed in patients greater than or equal to 86 years of age. **The numerator options are revised to read:** **Performance Met:** Patients greater than or equal to 86 years of age who underwent a screening colonoscopy and did not have a history of colorectal cancer or other valid medical reason for the colonoscopy, including: iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits. **Denominator Exception:** Documentation of medical reason(s) for a colonoscopy performed on a patient greater than or equal to 86 years of age (e.g., iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial history of adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits). **Performance Not Met:** Patients greater than or equal to 86 years of age who received a colonoscopy for an assessment of signs/symptoms of GI tract illness, and/or because the patient meets high risk criteria, and/or to follow-up on previously diagnosed advanced lesions. **Performance Not Met:** Patients between 50 and 85 years of age who received a screening colonoscopy during the performance period.
Steward:	American Gastroenterological Association
High Priority Measure:	Yes
Measure Type:	Efficiency
Rationale:	We proposed to update the denominator population to include all patients aged 50 and older to ensure a more complete patient population as the intent of the measure is to assess age appropriate screening colonoscopies, which include patients under the age of 86 years. The description, denominator, and denominator criteria have been updated to reflect these revisions. The numerator and numerator options have been revised to more clearly reflect the patient population and a performance not met numerator option was added to reflect the expanded denominator eligible patient population. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.

We proposed a substantive change to the numerator options; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
The numerator options are revised to read:
Performance Met: Patients greater than or equal to 86 years of age who underwent a screening colonoscopy and did not have a history of colorectal cancer or other valid medical reason for the colonoscopy, including: iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits.
Performance Not Met: Documentation of medical reason(s) for a colonoscopy performed on a patient greater than or equal to 86 years of age (e.g., iron deficiency anemia, lower gastrointestinal bleeding, Crohn's Disease (i.e., regional enteritis), familial history of adenomatous polyposis, Lynch Syndrome (i.e., hereditary non-polyposis colorectal cancer), inflammatory bowel disease, ulcerative colitis, abnormal finding of gastrointestinal tract, or changes in bowel habits).
Performance Not Met: Patients greater than or equal to 86 years of age who received a colonoscopy for an assessment of signs/symptoms of GI tract illness, and/or because the patient meets high risk criteria, and/or to follow-up on previously diagnosed advanced lesions.
Performance Not Met: Patients between 50 and 85 years of age who received a screening colonoscopy during the performance period.

This additional refinement of changing the Denominator Exception to a Performance Not Met does not affect the intent of the proposed substantive change. This revision aligns with the current measure specification and will not affect the final performance as this is an inverse measure. It is just a reclassification of the numerator option.

Comment: One commenter supported the changes to measure Q439.

Response: We thank the commenter for supporting the changes to this measure.
After consideration of public comments, we are finalizing the changes to measure Q439 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.94 Medication Management for People with Asthma

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	444
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Efficiency and Cost Reduction
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	The percentage of patients 5-64 years of age during the performance period who were identified as having persistent asthma and were dispensed appropriate medications that they remained on for at least 75% of their treatment period.
Substantive Change:	**Updated numerator:** Updated medication table to split medications by controller versus reliever and adding 'Medication List' and 'Route' column. Asthma Controller Medications: Dyphylline-guaifenesin, Omalizumab, Benralizumab, Mepolizumab, Reslizumab, Budesonide-formoterol, Fluticasone-salmeterol, Fluticasone-vilanterol, Formoterol-mometasone, Beclomethasone, Budesonide, Ciclesonide, Flunisolide, Fluticasone, Mometasone, Montelukast, Zafirlukast, Zileuton, Theophylline. Asthma Reliever Medications: Albuterol, Levalbuterol.
Steward:	National Committee for Quality Assurance
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the medications table to ensure the list includes current and appropriate medications for the purposes of meeting performance of this measure. The measure specification medication tables were reformatted for clarity and readability.

Comment: One commenter encouraged CMS to double check the list of medications for completeness for this measure.

Response: We thank the commenter for their comment. This list has been reviewed for accuracy; however, we encourage the commenter to reach out to the measure steward regarding the medication list for potential revisions for possible inclusion in future years.

After consideration of public comments, we are finalizing the changes to measure Q444 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.95 Trastuzumab Received By Patients With AJCC Stage I (T1c) – III And HER2 Positive Breast Cancer Receiving Adjuvant Chemotherapy

Category	Description
NQF # / eCQM NQF #:	1858 / N/A
Quality#:	450
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients (aged 18 years and older) with AJCC stage I (T1c) – III, human epidermal growth factor receptor 2 (HER2) positive breast cancer receiving adjuvant chemotherapy who are also receiving Trastuzumab.
Substantive Change:	**The title is revised from 'Trastuzumab received by patients with AJCC stage I (T1c) - III and HER2 positive breast cancer receiving adjuvant chemotherapy' to:** Appropriate Treatment for Patients with Stage I (T1c) - III HER2 Positive Breast Cancer. **The description is revised to read**: Percentage of female patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer for whom appropriate treatment is initiated. **The denominator is revised to read**: All female breast cancer patients aged 18 to 70 with stage I (T1c) - III HER2 positive breast cancer. **Updated denominator criteria**: Revised: Female patients age 18-70 years on date of encounter. Removed: Breast Adjuvant Chemotherapy administered. **Updated denominator exclusions:** Removed: • Patient transferred to practice after initiation of chemotherapy. • Patient has metastatic disease at diagnosis. Added: • Patients with pregnancy during adjuvant treatment course. **The numerator is revised to read:** Patients whose adjuvant treatment course includes both chemotherapy and HER2-targeted therapy. **The numerator note is revised to read**: The quality action of this measure is the appropriateness of treatment rather than timeliness of treatment. The timing of administration of HER2-targeted therapies is expected to vary depending on the cytotoxic agents used. The numerator statement is intended to capture an adjuvant treatment course that includes both chemotherapy and HER2-targeted therapy, independent of possible administration sequences. Adjuvant chemotherapy is defined as a chemotherapy regimen initiated within 6 months of cancer diagnosis. An FDA-approved trastuzumab biosimilar is an appropriate substitute for trastuzumab. **The numerator options are revised to read:** **Performance Met:** Patient received adjuvant treatment course including both chemotherapy and HER2-targeted therapy. **Denominator Exception:** Reason for not administering adjuvant treatment course including both chemotherapy and HER2-targeted therapy (e.g. poor performance status (ECOG 3-4; Karnofsky ≤50), cardiac contraindications, insufficient renal function, insufficient hepatic function, other active or secondary cancer diagnoses, other medical contraindications, patients who died during initial treatment course or transferred during or after initial treatment course). **Performance Not Met:** Patient did not receive adjuvant treatment course including both chemotherapy and HER2-targeted therapy.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to expand the scope and clinical focus of the measure to include all female patients age 18 – 70 years with stage I (T1c) - III HEr2 positive breast cancer, allowing for assessment of chemotherapy within the numerator, necessitating the removal of the denominator criteria for chemotherapy. NCCN recommendations support the administration of chemotherapy and trastuzumab for this patient population. We proposed to remove the current denominator exclusions and add new denominator exclusions based upon feasibility testing which determined these histologies are rare enough and are unlikely to have HER2 positivity such that it is not necessary to specifically target for removal from the denominator population. We agreed that these exclusions are not appropriate for inclusion. The added denominator exclusions reflect the measure's change in clinical scope and allows for removal of patients for whom treatment with chemotherapy and HER2-targeted therapy would not be appropriate. The measure steward's technical expert panel acknowledged that patients who fail to receive timely treatment may also fail to receive appropriate treatment. Because the quality action of this measure is appropriateness rather than timeliness of treatment, a broader timeframe is utilized to capture patients who may be less likely to receive appropriate treatment, therefore, 6 months was chosen to define adjuvant chemotherapy. The inclusion of an FDA-approved trastuzumab biosimilar as substitute for trastuzumab is in accordance with updated NCCN breast cancer guidelines. We agreed with this revision to the numerator note as it clarifies the updated measure scope and aligns with current clinical guidelines. Additionally, we proposed to update the numerator options to reflect the updated scope and clinical focus of the measure. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
We received no public comments on the substantive changes propose for this measure; therefore, we are finalizing the changes to measure Q450 as proposed for	

Category	Description
the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.96 RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy

Category	Description
NQF # / eCQM NQF #:	1859 / N/A
Quality#:	451
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer who receive anti-epidermal growth factor receptor monoclonal antibody therapy for whom RAS (KRAS and NRAS) gene mutation testing was performed.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q451 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.97 Patients with Metastatic Colorectal Cancer and RAS (KRAS or NRAS) Gene Mutation Spared Treatment with Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibodies

Category	Description
NQF # / eCQM NQF #:	1860 / N/A
Quality#:	452
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Patient Safety
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of adult patients (aged 18 or over) with metastatic colorectal cancer and RAS (KRAS or NRAS) gene mutation spared treatment with anti-EGFR monoclonal antibodies.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q452 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.98 Percentage of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0210 / N/A
Quality#:	453
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer receiving chemotherapy in the last 14 days of life.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q453 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.99 Percentage of Patients Who Died from Cancer Admitted to the Intensive Care Unit (ICU) in the Last 30 Days of Life (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0213 / N/A
Quality#:	455
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer admitted to the ICU in the last 30 days of life.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q455 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.100 Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)

Category	Description
NQF # / eCQM NQF #:	0216 / N/A
Quality#:	457
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients who died from cancer and admitted to hospice and spent less than 3 days there.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Society of Clinical Oncology
High Priority Measure:	Yes
Measure Type:	Outcome
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

Comment: One commenter was concerned about adding a telehealth exclusion to measure Q457 because CMS claimed that telehealth encounters were not applicable to this measure. The commenter disagreed with this statement and believed it would be appropriate to include telehealth encounters in this measure. This measure aims to identify patients who either did not have a hospice referral prior to death or received hospice care too late. Including telehealth encounters would help CMS to more comprehensively and accurately identify patients who were unable to benefit from hospice services.

Response: We thank the commenter for their comment. This measure currently requires two or more encounters at the reporting site and that the patient be enrolled in hospice as part of the denominator eligibility criteria. The inclusion of a telehealth modifier exclusion for the patient encounters aligns with the intent of the measure. To be eligible for this measure, the patient must already be enrolled in hospice. This measure assesses whether or not patients were enrolled in hospice in a timely manner in order to maximize benefits that may be attained from this service. We encourage the commenter to reach out to the measure steward to discuss revisions for possible implementation in future years.

After consideration of public comments, we are finalizing the changes to measure Q457 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.101 Back Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	459
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, back pain is rated by the patients as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q459 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.102 Back Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	460
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, back pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q460 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.103 Leg Pain After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	461
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar discectomy/laminectomy procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the VAS Pain scale at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q461 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.104 Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	462
CMS eCQM ID:	CMS645v4
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	eCQM Specifications
Current Measure Description:	Patients determined as having prostate cancer who are currently starting or undergoing androgen deprivation therapy (ADT), for an anticipated period of 12 months or greater and who receive an initial bone density evaluation. The bone density evaluation must be prior to the start of ADT or within 3 months of the start of ADT.
Substantive Change:	**Updated definition:** Added: First Androgen Deprivation Therapy - The First Androgen Deprivation Therapy (ADT) is measured as the first order or administration of ADT for an anticipated period of 12 months or greater to a patient with prostate cancer.
Steward:	Oregon Urology Institute
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to add a definition for 'First Androgen Deprivation Therapy' to clarify the timing of the bone density evaluation necessary for numerator compliance.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q462 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.105 Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use

Category	Description
NQF # / eCQM NQF #:	0657 / N/A
Quality#:	464
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.
Substantive Change:	**Updated denominator**: Added telehealth exclusion to patient encounter.
Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to add a telehealth exclusion to the patient encounter as telehealth encounters are not applicable to this measure and these patients should not be included in the denominator.

Comment: One commenter supported the addition of telehealth reporting for measure Q464. The commenter noted that there is an error in the substantive change: "Updated denominator: Added telehealth exclusion to patient encounter." The substantive change should instead read, "Updated denominator: Telehealth exclusion to patient encounter is removed" as telehealth encounters are applicable to this measure and these patients should not be excluded in the denominator.

Response: We agree that the measure specification currently excludes telehealth and the substantive change was to remove the telehealth exclusion as it would be appropriate to include these patients into the measure denominator eligible population.

After consideration of public comments, we are finalizing the changes to measure Q464 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.106 Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	468
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	Percentage of adults aged 18 years and older with pharmacotherapy for opioid use disorder (OUD) who have at least 180 days of continuous treatment.
Substantive Change:	**Updated instructions:** Revised: This measure is to be submitted a minimum of once per performance period for all adults aged 18 years and older with pharmacotherapy for OUD seen during the measurement period that meet additional denominator criteria described below. **The denominator is revised to read:** Adults aged 18 years and older who had a qualifying encounter during the performance year, and a diagnosis of OUD and pharmacotherapy for OUD during the denominator identification period. Eligibility to submit results for a patient requires a qualifying encounter in the performance year, i.e., between January 1, 2021, and December 31, 2021. Solely administering or prescribing OUD medication does not convey eligibility to submit. If a patient has a qualifying encounter within the performance year, the patient is included in the denominator, if the following criteria are met in the denominator identification period between July 1, 2020, and June 30, 2021: • Have a diagnosis of OUD • Receive pharmacotherapy for OUD **Updated denominator definition:** Added: Qualifying Encounter – Encounter during the performance year. Revised: Denominator Identification Period – The period in which eligible adults receive pharmacotherapy for OUD. The denominator identification period is defined as the 12-month period from 07/1/2020 to 6/30/2021. The denominator identification period includes the first 6 months of the reporting year and the last 6 months of the previous year to ensure that all included patients can be observed for at least 180 days of treatment in the reporting year. Patients started on treatment in the second half of the reporting year will be included in the denominator of the subsequent year. The patient must have at least one OUD medication and one visit with a OUD diagnosis during the denominator identification period to be eligible for the measure. **Updated denominator criteria:** Revised: Adults aged ≥ 18 years on date of qualifying encounter. Encounter during the measurement period. **Updated denominator exclusion:** Removed: Pharmacotherapy for OUD initiated after June 30th of 2020. **The numerator note is revised to read:** Numerator compliance is expected to be determined within an 18-month period that includes the measurement period and the 6 months prior to the measurement period (July 1, 2020– December 31, 2021).
Steward:	University of Southern California
High Priority Measure:	Yes
Measure Type:	Process
Rationale:	We proposed to update the measure to ensure the denominator eligible encounter occurs within the current performance period and the initiation of pharmacotherapy for opioid use disorder (OUD) occurs within the denominator identification period to allow for assessment of at least 180 days for continuous pharmacotherapy for OUD. Additionally, we aproposed to update the definitions by adding an additional definition of qualifying encounter to clarify which encounters are denominator eligible and revising the denominator identification period definition to align with and clarify the changes to the denominator in regards to timing and eligibility. The numerator note is being revised to align with these changes outlined above and reiterates the guidance pertaining to the timeframes allowed for clinicians to determine if the patient was on at least 180 days for continuous. pharmacotherapy for OUD
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q468 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.107 Functional Status After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	469
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age and older who had a lumbar fusion procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a)* at one year (9 to 15 months) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q469 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.108 Functional Status After Primary Total Knee Replacement

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	470
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively.
Substantive Change:	**The description is revised to read:** For patients age 18 and older who had a primary total knee replacement procedure, functional status is rated by the patient as greater than or equal to 37 on the Oxford Knee Score (OKS) or a 71 or greater on the KOOS, JR tool at one year (9 to 15 months) postoperatively. **Updated instructions:** Revised: NOTE: This measure is a target-based measure, where the numerator is met by having a one-year postoperative Oxford Knee Score (OKS) greater than or equal to 37 or a KOOS, JR score greater than or equal to 71. It is expressed as a proportion or rate. Patients having received a primary total knee replacement procedure who are not assessed for functional status postoperatively remain in the denominator and are considered as not meeting the target. The measure intent is that MIPS eligible clinicians will submit all denominator eligible procedures for performance calculation. **The numerator is revised to read**: All eligible patients whose functional status is greater than or equal to 37 on the Oxford Knee Score (OKS) or greater than or equal to 71 on the KOOS, JR patient reported outcome tool at one year (9 to 15 months) postoperatively. **Updated numerator definition:** Added: KOOS, JR - The KOOS, JR was developed from the original long version of the Knee injury and Osteoarthritis Outcome Score (KOOS) survey using Rasch analysis. The KOOS, JR contains 7 items from the original KOOS survey. Items are coded from 0 to 4, none to extreme respectively. KOOS, JR is scored by summing the raw response (range 0-28) and then converting it to an interval score using the table provided below. The interval score ranges from 0 to 100 where 0 represents total knee disability and 100 represents perfect knee health. This short form tool was developed by Stephen Lyman, PhD at the Hospital for Specialty Surgery in 2017. https://www.hss.edu/hoos-jr-koos-jr-outcomes-surveys.asp KOOS, JR Target - A patient who is assessed postoperatively at one year (9 to 15 months) after the procedure rates their functional status score as greater than or equal to 71. **The numerator note is revised to read:** The following situations are those in which the numerator targets cannot be reached and Performance Not Met (M1046) is submitted: • Oxford Knee Score (OKS) or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) is not administered postoperatively at one year (9 to 15 Months) • Functional status is measured using a different patient-reported functional status tool or Oxford Knee Score (OKS) version or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) • Postoperative Oxford Knee Score (OKS) or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) is administered less than 9 Months or greater than 15 Months • Postoperative Oxford Knee Score (OKS) is less than 37 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) is less than 71. **The numerator options are revised to read:** **Performance Met:** Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was greater than or equal to 37 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was greater than or equal to 71. **Performance Not Met:** Functional status measured by the Oxford Knee Score (OKS) or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) at one year (9 to 15 months) postoperatively was less than 37. **Performance Not Met:** Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was less than 37 or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was less than 71.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the measure to allow for the inclusion of the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) tool as numerator compliance. The KOOS, JR is recommended by the American Academy of Orthopaedic Surgeons (AAOS) and is part of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation and is an appropriate tool for the purposes of this measure. The language was updated throughout the measure to reflect this update and to define numerator compliance when utilizing the KOOS, JR tool.

We proposed a substantive change to numerator options; however, during the quality measure annual revision process with the measure steward, there was additional language refinement. Therefore, we are finalizing the substantive change to state:
Performance Met: Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was greater than or equal to 37 or Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was greater than or equal to 71.
Performance Not Met: Functional status was not measured by the Oxford Knee Score (OKS) or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR.) at one year (9 to 15 months) postoperatively
Performance Not Met: Functional status measured by the Oxford Knee Score (OKS) at one year (9 to 15 months) postoperatively was less than 37 or the Knee injury and Osteoarthritis Outcome Score Joint Replacement (KOOS, JR) was less than 71.
This additional refinement does not affect the intent of the proposed substantive change, but is in alignment with the updates to the entire measure and the guidance given in the numerator note.

We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q470 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years.

D.109 Functional Status After Lumbar Discectomy/Laminectomy

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	471
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients age 18 and older who had lumbar discectomy/laminectomy procedure, functional status is rated by the patient as less than or equal to 22 OR a change of 30 points or greater on the Oswestry Disability Index (ODI version 2.1a) * at three months (6 to 20 weeks) postoperatively.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q471 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.110 Leg Pain After Lumbar Fusion

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	473
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-Centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	For patients 18 years of age or older who had a lumbar fusion procedure, leg pain is rated by the patient as less than or equal to 3.0 OR an improvement of 5.0 points or greater on the Visual Analog Scale (VAS) Pain* scale at one year (9 to 15 months) postoperatively. * hereafter referred to as VAS Pain.
Substantive Change:	**Updated denominator exclusion**: Revised: Patient had cancer, acute fracture or infection related to the lumbar spine OR patient had neuromuscular, idiopathic or congenital lumbar scoliosis.
Steward:	Minnesota Community Measurement
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to add neuromuscular scoliosis to the denominator exclusion based upon feedback from clinicians following statewide implementation of the measure. We agreed that patients with this type of scoliosis should be removed to help create a more heterogeneous population, which reflects the original intent of this denominator exclusion.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q473 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.111 International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	476
CMS eCQM ID:	CMS771v2
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	eCQM Specifications
Current Measure Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Substantive Change:	**The title is revised from 'International Prostate Symptom Score (IPSS) or American Urological Association-Symptom Index (AUA-SI) Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia' to:** Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia. **Per the 'Telehealth Guidance for Electronic Clinical Quality Measures (eCQMs) for Eligible Professional/Eligible Clinician 2021 Quality Reporting':** Medicare telehealth eligible codes found in any encounter value set must only be used for in-person encounters for the following eCQMs.
Steward:	Large Urology Group Practice Association and Oregon Urology Institute
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to shorten the title to replace the very specific score wording with more general wording to be more consistent with definitions and language used within the measure. We proposed to remove telehealth encounters from the denominator and denominator exclusions as telehealth is not an appropriate setting for this measure. This guidance can be found in a separate document that will be published on the eCQI Resource Center.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q476 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.112 Functional Status Change for Patients with Neck Impairments

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	478
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Person and Caregiver-centered Experience and Outcomes
Current Collection Type:	MIPS CQMs Specifications
Current Measure Description:	This is a patient-reported outcome performance measure (PRO-PM) consisting of a patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients aged 14+ with neck impairments. The change in FS is assessed using the Neck FS PROM.* The measure is risk-adjusted to patient characteristics known to be associated with FS outcomes. It is used as a performance measure at the patient, individual clinician, and clinic levels to assess quality. *The Neck FS PROM is an item-response theory-based computer adaptive test (CAT). In addition to the CAT version, which provides for reduced patient response burden, it is available as a 10-item short form (static/paper-pencil).
Substantive Change:	**The description is revised to read:** This is a patient-reported outcome measure of risk-adjusted change in functional status for patients aged 14 years+ with neck impairments. The change in functional status (FS) is assessed using the FOTO Neck FS patient-reported outcome measure (PROM). The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient level, at the individual clinician level, and at the clinic level to assess quality. The measure is available as a computer adaptive test, for reduced patient burden, or a short form (static/paper-pencil). **The definition is revised to read**: **Functional Deficit** – Limitation or impairment of physical abilities/function resulting in evaluation and inclusion in a treatment plan of care. **Treatment Episode** –A Treatment Episode is defined as beginning with an Initial Evaluation for a functional neck deficit, progressing through treatment without interruption (for example, a hospitalization or surgical intervention), and ending with Discharge signifying that the treatment has been completed. A patient currently under clinical care for a neck deficit remains in a single Treatment Episode until the Discharge is conducted and documented by the MIPS eligible clinician. **Initial Evaluation** – An Initial Evaluation is the first encounter for a functional deficit involving the neck and includes an evaluation (CPT 97161, 97162, 97163, 97165, 97166, 97167, 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 98940, 98941, 98942, or 98943), or an Initial Evaluation Status M-code (M1143). A patient presenting with a neck impairment, who has had an interruption of a Treatment Episode for the same functional neck deficit secondary to an appropriate reason like hospitalization or surgical intervention, is an Initial Evaluation. **Discharge**– Discharge is accompanied by a treatment finalization and evaluation completion M-Code (Mxxx) identifying the close of a Treatment Episode for the same neck deficit identified at the Initial Evaluation and documented by a Discharge report by the MIPS eligible clinician. An interruption in clinical care for an appropriate reason like hospitalization or surgical intervention requires a discharge from the current Treatment Episode. **Encounter** – A visit between the patient and the provider for the purpose of assessing and/or improving a functional deficit. Patient Reported – The patient directly provides answers to the FS measure items using a standardized, reliable and valid, computerized adaptive testing or short form (static/paper and pencil-type) method. If the patient cannot reliably respond independently (for example, in the presence of cognitive deficits), a suitable proxy may provide answers. **The denominator is revised to read**: All patients aged 14 years and older with neck impairments who initiated a Treatment Episode. **Updated denominator criteria**: Revised: All patients aged ≥14 years on date of Initial Evaluation. Added: With a neck impairment and/or diagnosis pertaining to a functional deficit affecting the neck. **Updated denominator** exclusions: Removed: Ongoing care not indicated, patient seen only 1-2 visits (e.g., home program only, referred to another provider or facility, consultation only). Added: Patient unable to complete the Neck FS PROM at Initial Evaluation and/or Discharge due to blindness, illiteracy, severe mental incapacity or language incompatibility, and an adequate proxy is not available. **The numerator is revised to read:** Patients who were presented with the Neck FS PROM at Initial Evaluation (Intake) and at or near Discharge (Status) for the purpose of calculating the patient's Risk-Adjusted Functional Status Change Residual Score. **The numerator definition is revised to read:** **Patient's Functional Status Score** – A functional status score is produced when the patient completes the functional status patient-reported outcome measure (either by short form or computerized adaptive testing administration). The functional status score is continuous and linear. Scores range from 0 to 100 with higher scores meaning higher functional abilities. The measure is standardized, and the scores are validated for the measurement of function for this population. **Patient's Functional Status Change Score** – A functional status change score is calculated by subtracting the Patient's Functional Status Score at Initial Evaluation from the Patient's Functional Status Score at Discharge. **Predicted Functional Status Change Score** – Functional Status Change Scores for patients are risk adjusted using multiple linear regression methods that include the following independent variables: Patient's Functional Status Score at Initial Evaluation, patient age, symptom acuity, surgical history, gender, specific co- morbidities, use of medication for the condition at Initial Evaluation, exercise history, history of previous treatment for the condition and type of post-surgical status. The Patient's Functional Status Change Score is the dependent variable. For each patient completing a functional status assessment at Initial Evaluation (Intake), the regression model provides a risk-adjusted prediction of functional status change at Discharge. **Risk-Adjusted Functional Status Change Residual Score** – The difference between the raw non-risk- adjusted Patient's Functional Status Change Score and the Risk-Adjusted Predicted Functional Status Change Score (raw minus predicted) is the Risk-Adjusted Functional Status Change Residual Score, which is in the same units as the Patient's Functional Status Scores, and should be interpreted as the unit of functional status change different than predicted given the risk-adjustment variables of the patient being treated. As such, the Risk-Adjusted Residual Change Score represents Risk-Adjusted Change corrected for the level

Category	Description
	of severity of the patient. Risk-Adjusted Residual Change Scores of zero (0) or greater (> 0) should be interpreted as functional status change scores that were predicted or better than predicted given the risk- adjustment variables of the patient, and risk-adjusted residual change scores less than zero (< 0) should be interpreted as functional status change scores that were less than predicted given the risk-adjustment variables of the patient. Aggregated Risk-Adjusted Residual Scores allow meaningful comparisons amongst clinicians or clinics. **Updated numerator note:** Removed all. **The numerator options are revised to read:** **Performance Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment successfully calculated and the score was equal to zero (0) or greater than zero (> 0) **Denominator Exceptions:** 1. Ongoing care not clinically indicated because the patient needed a home program only, referral to another provider or facility, or consultation only, as documented in the medical record. 2. Ongoing care not medically possible because the patient was discharged early due to specific medical events, documented in the medical record, such as the patient became hospitalized or scheduled for surgery. 3. Ongoing care not possible because the patient self-discharged early (e.g., financial or insurance reasons, transportation problems, or reason unknown. 4. Patient refused to participate. **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment not measured because the patient did not complete the Neck FS PROM at Initial Evaluation and/or near Discharge, reason not given. **Performance Not Met:** Risk-Adjusted Functional Status Change Residual Score for the neck impairment successfully calculated and the score was less than zero (< 0).
Steward:	Focus on Therapeutic Outcomes, Inc.
High Priority Measure:	Yes
Measure Type:	Patient Reported Outcome
Rationale:	We proposed to update the measure to align with the other Focus on Therapeutic Outcomes, Inc. (FOTO) measures within MIPS. This will lessen MIPS eligible clinician burden when reporting this measure in conjunction with FOTO's other measures as the structure and content will now align. Definitions were inlcuded to add clarity and provide guidance when reporting this measure. Additonal denominator criteria for patients with a neck impairment and/or diagnosis pertaining to a functional deficit affect the neck was included to further define the appropriate patient population for this measure. Additionally, the denominator exclusions and exceptions were updated, along with the other numerator options, to align across all FOTO measures for consistency. In the event the proposed substantive change(s) were finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes.
We received no public comments on the substantive changes proposed for this measure; therefore, we are finalizing the changes to measure Q478 as proposed for the 2021 MIPS performance period/2023 MIPS payment year and future years.	

D.113 Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older

Category	Description
NQF # / eCQM NQF #:	N/A / N/A
Quality#:	048
CMS eCQM ID:	N/A
National Quality Strategy Domain:	Effective Clinical Care
Current Collection Type:	Medicare Part B Claims Measure Specifications, MIPS CQMs Specifications
Current Measure Description:	Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months.
Substantive Change:	**Modified collection type:** MIPS CQMs Specifications
Steward:	National Committee for Quality Assurance
High Priority Measure:	No
Measure Type:	Process
Rationale:	We proposed to remove the Medicare Part B Claims Measure Specifications collection type as it has reached the end of the topped out lifecycle as finalized in 82 FR 53640.
After consideration of public comments received under Table C.2, we are finalizing the removal of measure Q048 as indicated for the 2021 MIPS performance period/2023 MIPS payment year and future years for the Medicare Part B Claims Specifications collection type only. Measure Q048 will remain in the MIPS program for 2021 for the MIPS CQMs Specifications collection type.	

MISCELLANEOUS PUBLIC COMMENTS AND RESPONSES
Note: The following table summarizes public comments received that are general to individual MIPS measures but not specific to newly proposed measures, specialty measure sets, measures proposed for removal, or measures with substantive changes. In addition, some comments summarized below are out-of-scope to our proposed changes to the MIPS quality measure set.
Comment: One commenter was supportive of the proposal to remove 14 quality measures that do not add value to the quality of care, and instead add more meaningful measurements. **Response:** We thank the commenter for supporting the removal of measures from the MIPS program that do not add value to the quality of care.
Comment: One commenter recommended maintaining the existing MIPS quality measures to ensure consistency, reduce a burden, and allow options in the future for MVPs. **Response:** We understand that ensuring there are measures available for future use in MVPs is important; however, we strive to ensure that all measures align with the Meaningful Measures Initiative, which includes removing those measures that are duplicative, extremely topped out or at the end of the topped out lifecycle, no longer in alignment with the current clinical guidelines, or where a meaningful benchmark cannot be created. By removing measures with high performance rates, we are attempting to reduce reporting burden where there is little room for improvement. We encourage stakeholders to submit potential new measures that will align with the Meaningful Measures Initiative and allow MIPS eligible clinicians to maximize their potential performance within MIPS during the annual Call for Measures.
Comment: One commenter stated that CMS is proposing to expand the list of telehealth visits that include quality and cost measures in 2021. The commenter supported having expanded telehealth services. However, inclusion in the denominator across its measures does not translate to numerator compliance. There is certainly impact to administrative burden, and the commenter wanted to ensure data is captured and mapped appropriately for reporting. Use of telemedicine services for important clinical conditions is not yet fully understood. Some types of quality measurements (numerator compliance) may not be easily obtained via telemedicine or require additional infrastructure development such as remote monitoring. There should be additional time for adaptation. **Response:** We thank the commenter for their comment. Each year the measure specifications are revised and reviewed to ensure coding updates and the inclusion of telehealth encounters aligns with the measure's intent, are clinically appropriate and applicable, and are feasible for implementation. The allowance of telehealth for denominator eligibility does not translate into numerator compliance, as some quality actions are not able to be performed via telehealth, however, it is important to ensure a complete patient population is assessed for numerator compliance therefore supporting the assessment of providing quality care. We encourage the commenter to reach out to measure stewards to review expanding telehealth as a possible revision for implementation in future years and review the 2021 MIPS specifications to determine if or how telehealth is included within the measure
Comment: One commenter indicated that in terms of numerator compliance, CMS guidance has stated that there may be instances where the quality action cannot be completed during the telehealth visit. If an eligible clinician is providing services via telehealth but unable to complete the quality action in the numerator via telehealth, the commenter strongly believes that measure should be excluded from the list of telehealth eligible measures. **Response:** We agree that there are some measures available via the eCQM Specifications collection type that include telehealth encounters as denominator eligible with a quality action that cannot be met via telehealth. This decision is driven by how each measure is structured and ensuring a complete and appropriate patient population. Measures that do not require a quality action for every encounter, but allow for patient report, look back periods, or completion at encounter, would be appropriate for inclusion of telehealth. For measures that have defined performance or assessment of the quality action (e.g., measure Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented), telehealth encounters would not be appropriate. We would encourage the commenter to review 2021 eCQM guidance found on the eCQI Resource Center at https://ecqi.healthit.gov/ep-ec?globalyearfilter=2020.
Comment: Current eCQM standards do not allow for the use of modifiers and therefore do not clearly include or exclude telehealth encounters when these "'telehealth-eligible' CPT and HCPCS codes are used. **Response:** We do recognize that value sets by eCQMs do not include codes modifiers and would encourage stakeholders to review the 2021 eCQM guidance found on the eCQI Resource Center. In instances where a modifier is submitted, the code is used by the eCQM, however the modifier is not. As such, eCQM logic and value sets do not differentiate between in-person encounters or telehealth encounters when these "telehealth-eligible" codes are applied. Therefore, it is the eligible professionals' and eligible clinicians' responsibility to make sure they can meet all other aspects of the quality action within the measure specification, including other quality actions that cannot be completed via telehealth when considering which measure to report. And, that the encounter, either in-person or via telehealth, is in alignment with current measure specification level guidance. In instances where a POS modifier is applied for billing and is submitted for the eCQM, only the encounter code is used by the eCQM and the modifier is not used.

APPENDIX 2: IMPROVEMENT ACTIVITIES

NOTE: In this final rule, for the CY 2021 performance period and future years, we are modifying two previously adopted improvement activities in the Inventory, removing one previously adopted improvement activity, and finalizing one improvement activity that was originally adopted in the March 31st COVID-19 IFC (85 FR 19277) and continued with modification in the September 2nd COVID-19 IFC (85 FR 54850 through 54851). These improvement activities are discussed in detail below.

Table A: Changes to Previously Adopted Improvement Activities for the MIPS CY 2021 Performance Period and Future Years

Current Improvement Activity	
Current Activity ID:	**IA_BE_4**
Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Engagement of patient through implementation of improvements in patient portal
Current Activity Description:	Access to an enhanced patient portal that provides up to date information related to relevant chronic disease health, blood pressure control, and includes interactive features allowing patients to enter health information and/or enables bidirectional communication about medication changes and adherence.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2017 QPP final rule (81 FR 77825). This modification would add language to include caregivers as additional potential users of the patient portal, instead of just patients and clinicians, given the important role caregivers can play in bidirectional information exchange regarding the clinical care of the patient. This modification would also add language to clarify that the portal's use should be for "bidirectional information exchange between the patient and their provider" and "the primary use…should be clinical, and not administrative." In addition, the modifications would replace existing description with a nonexhaustive list of examples of bidirectional portal functions that are clinical rather than administrative. The list of examples would include: "brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; and any relevant acute or chronic disease management."
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must provide access to an enhanced patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal include, but are not limited to: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; or any relevant acute or chronic disease management.
Comments:	Several commenters supported the modification of this improvement activity. Several commenters noted that caregivers are a critical component of patient-centered care. A few commenters noted the importance of bidirectional information exchange in the provision of care.
Response:	The modification to this improvement activity includes caregivers in the bidirectional information exchange regarding the clinical care of patients and provides clarity that the portal should be used for bidirectional information exchange that is clinical not administrative in nature.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_BE_4**
Subcategory:	Beneficiary Engagement
Activity Title:	Engagement of patient through implementation of improvements in patient portal

Activity Description:	To receive credit for this activity, MIPS eligible clinicians must provide access to an enhanced patient/caregiver portal that allows users (patients or caregivers and their clinicians) to engage in bidirectional information exchange. The primary use of this portal should be clinical and not administrative. Examples of the use of such a portal include, but are not limited to: brief patient reevaluation by messaging; communication about test results and follow up; communication about medication adherence, side effects, and refills; blood pressure management for a patient with hypertension; blood sugar management for a patient with diabetes; or any relevant acute or chronic disease management.
Weighting:	Medium
Current Improvement Activity	
Current Activity ID:	**IA_AHE_7**
Current Subcategory:	Achieving Health Equity
Current Activity Title:	Comprehensive Eye Exams
Current Activity Description:	To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by providing literature and/or facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign and/or referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA. This activity is intended for: ● Non-ophthalmologists / optometrists who refer patients to an ophthalmologist/optometrist; ● Ophthalmologists/optometrists caring for underserved patients at no cost; or ● Any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams.
Current Weighting:	Medium
Proposed Change and Rationale:	This improvement activity was originally finalized in the CY 2019 PFS final rule (83 FR 59452). This modification would add language that expands the types of services that eligible clinicians can promote to underserved and/or high-risk populations to receive credit for this activity. Specifically, we are proposing to add the following sentence: "promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment." Also, "or vision rehabilitation services" would be added to the end of the activity description. These modifications would broaden this improvement activity to eligible clinicians who promote vision rehabilitation services, if they are serving patients with vision impairments detected during comprehensive eye exams.
Proposed Revised Activity Description:	To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by any one or more of the following: ● providing literature, ● facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign, ● referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA, or ● promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment. This activity is intended for: ● Non-ophthalmologists / optometrists who refer patients to an ophthalmologist/optometrist; ● Ophthalmologists/optometrists caring for underserved patients at no cost; or ● Any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their

	access to comprehensive eye exams or vision rehabilitation services.
Comments:	Several commenters supported the modification of this improvement activity.
Response:	We appreciate the support for this modification. The modification to this improvement activity allows clinicians also to receive credit by providing vision rehabilitation services to patients who are underserved and/or high-risk with vision impairments detected during comprehensive exams.
Final Action:	After consideration of the public comments received, we are finalizing changes to this improvement activity as proposed.
Finalized Improvement Activity	
Activity ID:	**IA_AHE_7**
Subcategory:	Achieving Health Equity
Activity Title:	Comprehensive Eye Exams
Activity Description:	To receive credit for this activity, MIPS eligible clinicians must promote the importance of a comprehensive eye exam, which may be accomplished by any one or more of the following: ● providing literature, ● facilitating a conversation about this topic using resources such as the "Think About Your Eyes" campaign, ● referring patients to resources providing no-cost eye exams, such as the American Academy of Ophthalmology's EyeCare America and the American Optometric Association's VISION USA, or ● promoting access to vision rehabilitation services as appropriate for individuals with chronic vision impairment. This activity is intended for: ● Non-ophthalmologists / optometrists who refer patients to an ophthalmologist/optometrist; ● Ophthalmologists/optometrists caring for underserved patients at no cost; or ● Any clinician providing literature and/or resources on this topic. This activity must be targeted at underserved and/or high-risk populations that would benefit from engagement regarding their eye health with the aim of improving their access to comprehensive eye exams or vision rehabilitation services.
Weighting:	Medium

TABLE B: Improvement Activity for Removal for the MIPS CY 2021 MIPS Performance Period and Future Years

In this final rule, we are finalizing the removal of one previously finalized improvement activity from the MIPS Program for the MIPS CY 2021 performance period/2023 MIPS payment year and future years. This improvement activity is discussed in detail below. Improvement activity removal factors are discussed in the MIPS CY 2020 final rule (84 FR 62568 through 63563).

Current Improvement Activity	
Current Activity ID:	**IA_CC_5**
Current Subcategory:	Care Coordination
Current Activity Title:	CMS Partner in Patients Hospital Engagement Network
Current Activity Description:	Membership and participation in a CMS Partnership for Patients Hospital Engagement Network.
Current Weighting:	Medium
Removal Rationale:	Subsequent to publication of the proposed rule, we became aware that the underlying program, which forms the basis for this improvement activity, has expired. The Partner in Patients Hospital Engagement Network activity description requires membership and participation in a CMS Partnership for Patients Hospital Engagement Network which ended March 31, 2020, and may be found at https://innovation.cms.gov/innovation-models/partnership-for-patients. Because the Partnership for Patients Hospital Engagement Network has ended and performance of this activity will no longer be possible starting with the CY 2021 performance year, this improvement activity is obsolete (Factor 7, 84 FR 62988) and no longer available for clinicians to participate in; therefore, we are finalizing removal of this improvement activity beginning with the CY 2021 performance year/2023 MIPS payment year to avoid any potential confusion.
Comments:	N/A – Not included in the notice of proposed rulemaking.
Response:	N/A – Not included in the notice of proposed rulemaking.
Final Action:	We are finalizing the removal of this improvement activity beginning with the CY 2021 performance year/2023 MIPS payment year.
Finalized Improvement Activity	
Activity ID:	N/A – Removed

Table C: Finalization of Improvement Activity Previously Adopted in the March 31st COVID-19 IFC (85 FR 19277) and Continued with Modification in the September 2nd COVID -19 IFC (85 FR 54850 through 54851) for the MIPS CY 2021 Performance Period

Original Improvement Activity	
Original Activity ID:	**IA_ERP_XX**
Original Subcategory:	Emergency Response and Preparedness
Original Activity Title:	COVID-19 Clinical Trials
Original Activity Description:	To receive credit for this activity, a MIPS eligible clinician must participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study. For more information on COVID-19 clinical trials we refer redears to the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. This improvement activity was finalized for the MIPS CY 2020 performance period only in response to the PHE for COVID-19.
Original Weighting:	High
Original Comments:	Several commenters supported our efforts to encourage and recognize clinician participation in COVID-related clinical trials through the finalization of this improvement activity.
Original Responses:	We appreciate the commenters' support. We believe that clinicians who treat patients diagnosed with COVID-19 and simultaneously submit relevant data regarding that patient to a clinical data registry for COVID-19 research should receive credit. We believe that all clinical data gathered in the treatment of patients diagnosed with COVID-19 may be helpful in finding a solution to end this pandemic. Encouraging clinicians collectively to utilize a clinical data registry for data reporting could facilitate sharing of data for use in additional clinical studies with larger sample sizes. These additional and larger clinical studies are likely to identify efficacy of certain treatments, which in turn could result in wider improvements in health outcomes, including reduced severity and mortality due to COVID-19 across the nation. This could benefit patients nationwide as well as improve clinical practice and care delivery for the patients of the clinician attesting to this improvement activity.
Modified Improvement Activity	
Modified Activity ID:	**IA_ERP_3**
Modified Subcategory:	Emergency Response and Preparedness
Modified Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Change and Rationale:	Following the publication of the March 31st IFC for COVID-19, we received several inquiries through meetings, email correspondence, and Quality Payment Program help desk requesting further information on whether a clinician working with COVID-19 patients who provides their data to a clinical data registry, without participating in a clinical trial, may get credit for this activity. The Quality Payment Program help desk tracks, documents, and resolves inquiries submitted by MIPS eligible clinicians and groups. Stakeholders may submit inquiries to the help desk via 1-866-288-8292 (Monday-Friday 8 a.m.-8 p.m. ET) or email *QPP@cms.hhs.gov*. Some stakeholders believed that clinicians providing care to patients with COVID-19 outside of a clinical trial that report those data through a clinical data registry should receive credit for this activity. It came to our attention that clinical data registries not only collect data as part of clinical trials, but also collect data from clinicians not participating in clinical trials. The improvement activity as written was causing confusion for clinicians and groups attempting to meet the needs of patients and address gaps in research. Since IA_ERP_3 titled "COVID-19 Clinical Trials" was established, this improvement activity has been the subject of approximately 30 percent of the inquiries to the Quality Payment Program help desk, demonstrating the desire for clinicians to improve clinical care and overall outcomes for patients diagnosed with COVID-19 by conducting this improvement activity, but also indicating the need for further clarity in its activity description. As a result, we expanded the improvement activity to include clinicians

	participating in the care of a patient diagnosed with COVID-19 who simultaneously submit their clinical patient data to a clinical data registry for research. Thus, in order to receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) Participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. We also modified the improvement activity title to reflect this change. We had previously added the improvement activity to the Inventory for the CY 2020 performance period only in response to the PHE for COVID-19. In this IFC, we extended the newly modified COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity through the CY 2021 performance period due to the increased rate of COVID-19 infection we were experiencing nationwide. We anticipated the need for COVID-19 clinical trials and data collection/sharing through registries to continue through CY 2021 at which time we would reassess whether there remains a need for additional data sharing or if preventive measures and clinical treatments have advanced to the point where these type of data are not needed. We wanted eligible clinicians to be able to attest to this improvement activity if it is still pertinent. We believed that participation in this improvement activity was likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID-19.
Modified Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data would be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publically available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213. This improvement activity was continued through the CY 2021 performance period.

Modified Weighting:	High
Comments:	In response to the September 2nd COVID-19 IFC (85 FR 54850 through 54851), several commenters supported the proposal to expand this improvement activity to include clinicians participating in the care of a patient diagnosed with COVID-19 who simultaneously submit their clinical patient data to a clinical data registry for research. Commenters noted that this expansion will increase clinician participation in this improvement activity and increase the availability of COVID-19 patient data. One commenter specifically noted this proposal will improve data for a COVID-19 registry focused on cancer patients and appreciated that a cancer registry is acceptable to meet this improvement activity. A few commenters noted support for the extension of this improvement activity into 2021. Additionally, in response to the September 2nd COVID-19 IFC, a few commenters recommended additional clarifications or expansions around the COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity. One commenter requested that CMS clarify whether anyone submitting COVID-19 related data to a registry would qualify for credit for this improvement activity, whether it is a Qualified Registry (QR), Qualified Clinical Data Registry (QCDR), or a data registry that collects clinical data, provided it meets the other outlined criteria. Another commenter recommended that CMS add additional research targets to the improvement activity, including research related to diagnostic and medical devices rather than just therapeutics. One commenter noted that reporting for the COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity represents an opportunity to meet Promoting Interoperability performance category requirements and recommended that CMS coordinate with both the CDC and ONC to develop common electronic case reporting (eCR) standards. In response to the PFS for the CY 2021 performance period and future years NPRM, several commenters also provided support for the COVID-19 Clinical Data Reporting with or without Clinical Trial improvement activity, including extension of this improvement activity until at least the end of the 2021 reporting period. One commenter provided their disappointment that as a group reporter, they would be unable to attest to this improvement activity because they would not be able to have more than 50 percent of their group participate in clinical data reporting.
Response:	We appreciate the commenters support for the improvement activity. We believe that this improvement activity will increase clinical data reporting and ultimately improve the collection of data clinicians use for the care of their patients. We anticipate that clinical data gathered in the treatment of patients with COVID-19 may be helpful in finding a solution to end this pandemic. To clarify, to receive credit for this improvement activity, a MIPS eligible clinician or group must either: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research If the clinician or group is participating in a COVID-19 clinical trial, it must utilize a drug or biological product. On the other hand, the clinician or group could participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. This latter option is more broad and could include use of diagnostics and medical devices. In addition, for purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. We refer readers to the activity description for full details. In many cases, this could include a Qualified Registry (QR), Qualified Clinical Data Registry (QCDR), or a data registry that collects clinical data, so long as it meets the stated requirements. We will take into consideration the recommendation that we coordinate with CDC and ONC to develop common electronic case reporting (eCR) standards related to this improvement activity. We understand the disappointment that this improvement activity is more difficult for group reporters to attest.

Final Action:	After consideration of the public comments received, we are adopting this improvement activity as finalized in the September 2nd COVID-19 IFC (85 FR 54850 through 54851) to apply through the CY 2021 performance year.
Finalized Improvement Activity	
Activity ID:	**IA_ERP_3**
Subcategory:	Emergency Response and Preparedness
Activity Title:	COVID-19 Clinical Data Reporting with or without Clinical Trial
Activity Description:	To receive credit for this improvement activity, a MIPS eligible clinician or group must: (1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or (2) participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research. Data should be submitted to the extent permitted by applicable privacy and security laws. Examples of COVID-19 clinical trials may be found on the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19. In addition, examples of COVID-19 clinical data registries may be found on the National Institute of Health website at https://search.nih.gov/search?utf8=%E2%9C%93&affiliate=nih&query=COVID19+registries&commit=Search. For purposes of this improvement activity, clinical data registries must meet the following requirements: (1) the receiving entity must declare that they are ready to accept data as a clinical registry; and (2) be using the data to improve population health outcomes. Most public health agencies and clinical data registries declare readiness to accept data from clinicians via a public online posting. Clinical data registries should make publically available specific information on what data the registry gathers, technical requirements or specifications for how the registry can receive the data, and how the registry may use, re-use, or disclose individually identifiable data it receives. For purposes of credit toward this improvement activity, any data should be sent to the clinical data registry in a structured format, which the registry is capable of receiving. A MIPS eligible clinician may submit the data using any standard or format that is supported by the clinician's health IT systems, including but not limited to, certified functions within those systems. Such methods may include, but are not limited to, a secure upload function on a web portal, or submission via an intermediary, such as a health information exchange. To ensure interoperability and versatility of the data submitted, any electronic data should be submitted to the clinical data registry using appropriate vocabulary standards for the specific data elements, such as those identified in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213.
Weighting:	High

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Part III

Department of Transportation

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, 173, et al.
Hazardous Materials: Miscellaneous Amendments Pertaining to DOT-Specification Cylinders; Final Rule

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Parts 107, 171, 173, 178 and 180

[Docket No. PHMSA–2011–0140 (HM–234)]

RIN 2137–AE80

Hazardous Materials: Miscellaneous Amendments Pertaining to DOT-Specification Cylinders

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: PHMSA is amending the Hazardous Materials Regulations (HMR) to revise certain requirements applicable to the manufacture, use, and requalification of DOT-specification cylinders. PHMSA is taking this action in response to petitions for rulemaking submitted by stakeholders and agency review of compressed gas cylinder regulations. Specifically, PHMSA is incorporating by reference or updating the references to several Compressed Gas Association publications, amending the filling requirements for compressed and liquefied gases, expanding the use of salvage cylinders, and revising and clarifying the manufacture and requalification requirements for cylinders.

DATES:

Effective date: January 27, 2021.

Incorporation by reference date: The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of January 27, 2021. The incorporation by reference of other publications listed in this rule were previously approved by the Director of the Federal Register as of January 1, 2004 (ASTM E 8–99 and Welding Aluminum: Theory and Practice, Fourth Edition) and May 11, 2020 (Transport Canada TDG Regulations).

Compliance Date: Unless otherwise specified, compliance with the amendments adopted in this final rule is required beginning December 28, 2021.

FOR FURTHER INFORMATION CONTACT: Eamonn Patrick, Standards and Rulemaking Division, and Mark Toughiry, Mechanical Engineer, Engineering and Research Division, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590, at (202) 366–8553.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

Cylinders filled with a Class 2 hazardous material (gas) or other hazardous materials and offered for transportation must comply with various requirements of the Hazardous Materials Regulations (HMR; 49 CFR parts 171–180). These include 49 CFR part 173, subpart G, which sets forth the requirements for preparing and packaging gases; 49 CFR part 178, subpart C, which sets forth the specifications for cylinders (*i.e.,* how they should be constructed); and 49 CFR part 180, subpart C, which sets forth the requirements for repair, maintenance, and periodic requalification of cylinders. Additionally, cylinders must meet other requirements in the HMR, such as regulations that address the modal requirements on cylinders in transportation including general handling, loading, unloading, and stowage.

PHMSA (also referred to herein as ''we'' or ''us''), in response to petitions for rulemaking submitted by stakeholders and an Agency initiated review of the regulations, is making changes to the HMR, including but not limited to the following: Incorporating by reference or updating references to several Compressed Gas Association (CGA) publications; amending the filling requirements for compressed and liquefied gases; expanding the use of salvage cylinders; and revising and clarifying the manufacture and requalification requirements for cylinders. This final rule is also presenting minor and miscellaneous regulatory editorial corrections. These revisions are collectively intended to result in a net reduction of regulatory burdens while maintaining or enhancing the existing level of safety of hazardous materials transported in cylinders. Based on the regulatory impact analysis conducted in support of this final rule, PHMSA estimates that adoption of this final rule will result in net cost savings of approximately $.70 million over 10 years, or $70,000 annualized (undiscounted).

II. ANPRM Background

On May 29, 2012, PHMSA published an Advance Notice of Proposed Rulemaking (ANPRM) to obtain public comment from those likely to be affected by the possible adoption of ten petitions for rulemaking and three special permits (SP) into the HMR (77 FR 31551). Commenters included cylinder manufacturers, cylinder requalifiers, independent inspection agencies, commercial establishments that own and use DOT-specification cylinders and UN pressure receptacles, and individuals who export non-UN/ISO compressed gas cylinders. The ANPRM proposed adopting the petitions for rulemaking and special permits to update and expand the use of currently authorized industry consensus standards; revise the construction, marking, and testing requirements of DOT 4-series cylinders; clarify the filling requirements for cylinders; discuss the handling of cylinders used in a fire suppression system; and revise the requalification and condemnation requirements for cylinders.

The ANPRM comment period closed on August 27, 2012. PHMSA received comments from 13 stakeholders, including compressed gas and/or cylinder manufacturers, cylinder testers, and trade associations representing the compressed gas industry or shippers of hazardous materials. Most comments either answered questions PHMSA posed in the ANPRM or responded to multiple petitions and/or special permits. Regarding the petitions, the comments received were mostly supportive for all of the petitions, with the exception of P–1515. PHMSA received four comments regarding the special permits and all supported their adoption into the HMR. A list of the commenters, along with the related Docket ID Number, is shown in Table 1 below:

TABLE 1—ANPRM COMMENTERS AND ASSOCIATED COMMENT DOCKET NO.

Company	Docket ID No.
Air Products and Chemicals, Inc	PHMSA–2011–0140–0004
	PHMSA–2011–0140–0008
	PHMSA–2011–0140–0018
Bancroft Hinchley	PHMSA–2011–0149–0024
Barlen and Associates, Inc	PHMSA–2011–0140–0019
City Carbonic, LLC	PHMSA–2011–0140–0029
Compressed Gas Association (CGA)	PHMSA–2011–0140–0005
	PHMSA–2011–0140–0012
	PHMSA–2011–0140–0013
	PHMSA–2011–0140–0020
Council on Safe Transportation of Hazardous Articles, Inc. (COSTHA)	PHMSA–2011–0140–0026
CTC Certified Training	PHMSA–2011–0140–0001
	PHMSA–2011–0140–0023
	PHMSA–2011–0140–0030
HMT Associates	PHMSA–2011–0140–0002
	PHMSA–2011–0140–0021
Hydro-Test Products, Inc	PHMSA–2011–0140–0017
Manchester Tank	PHMSA–2011–0140–0016
Norris Cylinder	PHMSA–2011–0140–0025
SodaStream USA, Inc	PHMSA–2011–0140–0027
Worthington Cylinder Corporation	PHMSA–2011–0140–0028

Please see the HM–234 notice of proposed rulemaking (NPRM) published on July 26, 2016 (81 FR 48978) for a detailed discussion of comments made to the ANPRM.

III. NPRM Background

On July 26, 2016, PHMSA published an NPRM to obtain public comment on changes proposed to the HMR (81 FR 48978). The NPRM addressed 20 total petitions, one special permit, and several PHMSA-initiated editorial changes intended to clarify HMR requirements. After publication of the NPRM, PHMSA received comments from 44 stakeholders on the proposed changes. A table of commenters is shown in Table 2 below:

TABLE 2—NPRM COMMENTERS AND ASSOCIATED COMMENT DOCKET NO.

Company	Docket ID No.
Alaska Airlines	PHMSA–2011–0140–0036
Amerex	PHMSA–2011–0140–0061
AmeriGas Propane, L.P	PHMSA–2011–0140–0066
Amtrol	PHMSA–2011–0140–0063
	PHMSA–2011–0140–0058
Bancroft Hinchey Inc	PHMSA–2011–0140–0071
Compressed Gas Association (CGA)	PHMSA–2011–0140–0052
Council on Safe Transportation of Hazardous Articles (COSTHA)	PHMSA–2011–0140–0083
CTC (Certified Training Co.)	PHMSA–2011–0140–0057
	PHMSA–2011–0140–0042
Danko Emergency Equipment Co	PHMSA–2011–0140–0044
Dow Chemical Company	PHMSA–2011–0140–0060
Entegris	PHMSA–2011–0140–0082
FIBA	PHMSA–2011–0140–0074
	PHMSA–2011–0140–0041
Fike Corporation	PHMSA–2011–0140–0077
Fire Suppression Systems Association (FSSA)	PHMSA–2011–0140–0047
Firehouse Hydro Sales and Service	PHMSA–2011–0140–0067
Ford Motor Company	PHMSA–2011–0140–0055
Galiso Incorporated	PHMSA–2011–0140–0062
Hidroprob S.A	PHMSA–2011–0140–0079
HMT Associates, LLC	PHMSA–2011–0140–0049
Honeywell	PHMSA–2011–0140–0084
Hydro-Test Products Inc	PHMSA–2011–0140–0033
Independent Cylinder Training (ICT)	PHMSA–2011–0140–0068
Janus Fire Systems	PHMSA–2011–0140–0069
Kidde-Fenwal, Inc	PHMSA–2011–0140–0065
Manchester Tank	PHMSA–2011–0140–0050
Wesley Scott	PHMSA–2011–0140–0080
Chart, Inc	PHMSA–2011–0140–0078
Guardian Services, Inc	PHMSA–2011–0140–0072
Joshua Blake	PHMSA–2011–0140–0059
Jeff Elliot	PHMSA–2011–0140–0043
David Felkins	PHMSA–2011–0140–0035
W Andrews	PHMSA–2011–0140–0034

TABLE 2—NPRM COMMENTERS AND ASSOCIATED COMMENT DOCKET NO.—Continued

Company	Docket ID No.
Katherine Bowman	PHMSA–2011–0140–0032
National Association of Fire Equipment Distributors	PHMSA–2011–0140–0053
National Propane Gas Association	PHMSA–2011–0140–0070
Noble Gas Solutions	PHMSA–2011–0140–0045
Northeast Pressure Vessel Testing	PHMSA–2011–0140–0046
Praxair	PHMSA–2011–0140–0073
Quality Safety Solutions, LLC	PHMSA–2011–0140–0040
Scuba Do	PHMSA–2011–0140–0081
Steve Gentry	PHMSA–2011–0140–0086
The Chemours Company FC, LLC	PHMSA–2011–0140–0054
Thunderbird Cylinder	PHMSA–2011–0140–0037
Worthington Cylinder	PHMSA–2011–0140–0064

Most comments addressed more than one change proposed in the NPRM. The comments are discussed below in the context of each petition or other proposed changes it addresses.

IV. Petitions for Rulemaking and Comments Received

Table 3 lists the petitions included in the docket for this proceeding. The NPRM addressed 20 total petitions. The table below provides the petition number, the petitioner's name, the docket number on *www.regulations.gov,* a summary of the request(s), the affected 49 CFR sections, whether PHMSA proposed to adopt the petition in the NPRM, and the decision to adopt, adopt in part, or not adopt the petition in this final rule.

TABLE 3—PETITION SUMMARY

Petition No.	Petitioner	Docket No.	Summary	Affected sections	Proposed to adopt?	Adopted?
P–1499	Compressed Gas Association.	PHMSA–2007–28485	Replace the incorporated by reference (IBR) Seventh Edition of the CGA C–6 Standards for Visual Inspection of Steel Compressed Gas Cylinders with the revised Tenth Edition and update the appropriate references throughout the HMR.	§§ 171.7; 172.102 (SP 338); 173.3(d)(9); 173.198(a); 180.205(f)(1); 180.209(c), (b)(1)(iii), (d), (f), (g), (m); 180.211(d)(1)(ii); 180.411(b); 180.510(c).	Proposed to adopt	Adopted.
P–1501	Compressed Gas Association.	PHMSA–2007–28759	Revise the specification requirements for 4B, 4BA, 4BW, and 4E cylinders to provide clarity.	§§ 178.50, 178.51, 178.61, 178.68.	Proposed to adopt in part.	Adopted in part.
P–1515	Certified Training Company.	PHMSA–2008–0101	Adopt changes to the requalification process designed to clarify the regulations in the event CGA Standard C–1, Methods of Pressure Testing Compressed Gas Cylinders, is not incorporated.	§§ 180.203, 180.205, 180.207, 180.209, 180.211, 180.212, 180.213, and 180.215 and appendices C and E to part 180.	Proposed to adopt, except those changes not necessary because of incorporation by reference of CGA C–1 under P–1626.	Adopted in part.
P–1521	Compressed Gas Association.	PHMSA–2008–0152	Allow the use of labels described in CGA C–7–2004 on a cylinder contained in an overpack.	§ 172.400a(a)(1)(i)	Proposed to adopt	n/a; addressed by another rulemaking.
P–1538	The Wicks Group, representing Jetboil Inc.	PHMSA–2009–0138	Allow § 173.306(a)(1) to permit camping stove cylinders containing liquefied petroleum gas in amounts less than four (4) ounces to be shipped as consumer commodity (ORM–D). Define ''capacity'' in § 171.8.	§§ 171.8, 173.306(a)(1)	Not proposed to adopt	Not adopted.
P–1539	Matheson Tri-Gas.	PHMSA–2009–0140	Allow DOT 3A, 3AA, 3AL cylinders in Division 2.2 Services to be retested every 15 years. Allow DOT 3A, 3AA, and 3AL cylinders packaged with Division 2.1 materials to be requalified every 10 years.	§ 180.209(a)	Not proposed to adopt	Not adopted.
P–1540	Compressed Gas Association.	PHMSA–2009–0146	Require newly manufactured DOT 4B, 4BA, 4BW, and 4E cylinders to be marked with the mass weight, tare weight, and water capacity.	§ 178.35(f)	Proposed to adopt	Adopted.
P–1546	GSI Training Services, Inc.	PHMSA–2009–0250	Allow cylinders used as a component of a fixed fire suppression system to be transported under the exceptions applicable to fire extinguishers.	§ 173.309(a)	Proposed to adopt	Adopted in part.

TABLE 3—PETITION SUMMARY—Continued

Petition No.	Petitioner	Docket No.	Summary	Affected sections	Proposed to adopt?	Adopted?
P–1560	Air Products and Chemicals, Inc.	PHMSA–2010–0176	Modify the maximum permitted filling densities for carbon dioxide and nitrous oxide to include 70.3%, 73.2%, and 74.5% in DOT 3A, 3AA, 3AX, 3AAX, and 3T cylinders.	§ 173.304a(a)(2)	Not proposed to adopt. Addressed by revisions made under rulemaking HM–233F [81 FR 3635].	Not adopted.
P–1563	Regulatory Affairs Management Center—3M Package Engineering, Global Dangerous Goods.	PHMSA–2010–0208	Authorize an ''overpack'' as a strong outer package for cylinders listed in the section, except aerosols ''2P'' and ''2Q,'' marked with the phrase ''inner packagings conform to the prescribed specifications''.	§ 173.301(a)(9)	n/a; We asked for further comment.	Not adopted.
P–1572	Barlen and Associates, Inc.	PHMSA–2011–0017	Revise the filling ratio for liquefied compressed gases in MEGCs consistent with Packing Instruction (P200) of the United Nations (UN)—Model Regulations (17th ed. 2011), as specified in § 173.304b; and prohibit liquefied compressed gases in manifolded DOT cylinders from exceeding the filling densities specified in § 173.304a(a)(2).	§§ 173.301(g)(1)(ii) and 173.312.	Proposed to adopt, in part.	Adopted, in part.
P–1580	HMT Associates	PHMSA–2011–0123	Require the burst pressure of the rupture disc on a cylinder ''shall not exceed 80% of the minimum cylinder burst pressure and shall not be less than 105% of the cylinder test pressure'' for DOT 39 cylinders containing oxidizing gas transported by aircraft.	§§ 173.301(f)(4), 173.302(f)(2), 173.304(f)(2).	Proposed to adopt	Adopted.
P–1582	Water Systems Council.	PHMSA–2011–0135	Revise the limited quantity exception for water pump system tanks to authorize transport of tanks manufactured to American National Standards Institute's Water Systems Council Standard PST 2000—2005 (2009).	§ 173.306(g)	Proposed to adopt	Adopted.
P–1592	Compressed Gas Association.	PHMSA–2012–0173	IBR CGA S–1.1, 2011 Pressure Relief Device Standards, Part 1, Cylinder for Compressed Gas, Fourteenth Edition.	§§ 173.301(c), (f) and (g), 173.302a(c), 173.304a(e), 178.75(f).	Proposed to adopt	Adopted.
P–1596	Chemically Speaking, LLC.	PHMSA–2012–0200	Add Class 4 and Class 5 hazardous materials to the hazard classes in an authorized salvage cylinders.	§ 173.3(d)(1)	Proposed to adopt	Adopted.
P–1622	Worthington Cylinder.	PHMSA–2013–0210	Restrict the internal volume of hazardous materials shipped in a DOT-specification 39 cylinder to not exceed 75 cubic inches.	§ 173.304a(a)(2) and (3)	Proposed to adopt	Adopted in part.
P–1626	Compressed Gas Association.	PHMSA–2013–0265	IBR CGA C–1–2009, Methods for Pressure Testing Compressed Gas Cylinders, Tenth Edition (C–1, 2009) as a reference in 49 CFR, and provide for specific language for sections affected.	§§ 171.7, 178.36, 178.37, 178.38, 178.39, 178.42, 178.44, 178.45, 178.46, 178.47, 178.50, 178.51, 178.53, 178.55, 178.56, 178.57, 178.58, 178.59, 178.60, 178.61, 178.65, 178.68, 180.205, 180.209.	Proposed to adopt	Adopted.
P–1628	Compressed Gas Association.	PHMSA–2013–0278	IBR CGA C–3–2005, Reaffirmed 2011, Standards for Welding on Thin-Walled, Steel Cylinders, Seventh Edition.	§§ 171.7, 178.47, 178.50, 178.51, 178.53, 178.55, 178.56, 178.57, 178.58, 178.59, 178.60, 178.61, 178.65, 178.68, 180.211.	Proposed to adopt	Adopted.

TABLE 3—PETITION SUMMARY—Continued

Petition No.	Petitioner	Docket No.	Summary	Affected sections	Proposed to adopt?	Adopted?
P–1629	Compressed Gas Association.	PHMSA–2014–0012 ...	IBR CGA C–14–2005, Reaffirmed 2010, Procedures for Fire Testing of DOT Cylinder Pressure Relief Device Systems, Fourth Edition, as a reference in 49 CFR.	§§ 171.7, 173.301, 173.323.	Proposed to adopt	Adopted.
P–1630	Compressed Gas Association.	PHMSA–2014–0027 ...	Add the term ''recondition'' for DOT–4L welded insulated cylinders and revise language to clarify when a hydrostatic test must be performed on the inner containment vessel after the DOT–4L welded insulated cylinder has undergone repair.	§§ 180.203 and 180.211(c) and (e).	Proposed to adopt	Not adopted.

P–1499

The Compressed Gas Association (CGA) submitted P–1499 requesting that PHMSA incorporate by reference the Tenth Edition of its publication C–6, dated 2005, *Standards for Visual Inspection of Steel Compressed Gas Cylinders* (CGA C–6), replacing the Seventh Edition, and update the appropriate references throughout the HMR. The Tenth Edition of the CGA C–6 provides enhanced guidance for cylinder requalifiers—including guidance on the inspection of Multiple-Element Gas Containers (MEGCs) and thread inspection for cylinders used in corrosive gas service—and clarifies maximum allowable depths and measuring techniques for various types of corrosion.

PHMSA agrees that the CGA C–6 Tenth Edition provides improved and updated guidance on inspecting MEGCs. After the submission of this petition, the Eleventh Edition of the CGA C–6, dated 2013, was made available. PHMSA, therefore, proposed in the NPRM to update the incorporated by reference version of CGA C–6 to the Eleventh Edition. PHMSA determined that the changes from the Tenth to the Eleventh Editions were minor and improved safety, while not imposing any additional burdens on the regulated community.

Comments. Bancroft Hinchey, Worthington Cylinder, the National Association of Fire Equipment Distributors (NAFED) and CGA submitted comments supporting incorporation by reference of the Eleventh Edition of CGA C–6. Thunderbird Cylinder submitted a comment requesting revisions to CGA publication C–6.1, *Standards for Visual Inspection of High Pressure Aluminum Compressed Gas Cylinders* and CGA publication C–11, *Recommended Practices for Inspection of Compressed Gas Cylinders at Time of Manufacture.*

PHMSA response. In this final rule, PHMSA is incorporating by reference the Eleventh Edition of the CGA C–6, as proposed. The Tenth Edition of the CGA C–6 provides enhanced guidance for cylinder requalifiers—including guidance on the inspection of Multiple-Element Gas Containers (MEGCs) and thread inspection for cylinders used in corrosive gas service—and clarifies maximum allowable depths and measuring techniques for various types of corrosion. PHMSA has determined that the changes from the Tenth to the Eleventh Editions were minor and improved safety, while not imposing any additional burdens on the regulated community. The Eleventh edition of CGA C–6 is available for purchase online and will be available for public inspection at the Hazardous Material Information Center after publication of the final rule.

Thunderbird Cylinder's comment is beyond the scope of this rulemaking, but we encourage Thunderbird Cylinder or other interested parties to reach out to CGA regarding potential revisions to its publications and then, if warranted, to submit separate petitions for rulemaking requesting that PHMSA incorporate by reference the revised versions of CGA C–6.1 and C–11, respectively.

P–1501

CGA submitted P–1501 requesting that PHMSA revise the manufacturing requirements for DOT 4B, 4BA, 4BW, and 4E specification cylinders. CGA contends in their petition that the DOT 4-series welded cylinder manufacturing specification standards in the HMR are unclear in some respects and result in varied interpretations of what is required of manufacturers by both manufacturers and enforcement personnel. CGA states in the petition that their proposed changes do not present a significant economic impact to any single manufacturer or user, yet will enhance regulatory clarity, promote consistent manufacturing practices, and create greater uniformity between the specifications for DOT 4-series cylinders and the requirements for welded cylinders found in International Organization for Standardization (ISO) Standard 4706–1, *Gas cylinders—Refillable welded steel cylinders-Part 1: Test pressure 60 bar and below* (ISO 4706–1), which is referenced in the UN Model Regulations. The HMR currently incorporates ISO 4706–1 into § 178.71 as an authorized standard for the design and construction of UN pressure receptacles.

Comments. CGA submitted a comment reiterating their support for adoption of P–1501. Bancroft Hinchey submitted a comment supporting all proposed changes to the manufacturing specifications in §§ 178.36–178.70.

A summary of the specific changes proposed by P–1501, the comments received relative to the proposed changes, if any, and PHMSA's position and/or action are detailed below:

(1) Revise the requirements for DOT-specification 4B, 4BA, 4BW, and 4E cylinders in §§ 178.50(b), 178.51(b), 178.61(b), and 178.68(b), respectively, to ensure material compositions and the heat treatment are within the specified tolerances and are of uniform quality as follows: (1) Require a record of intentionally-added alloying elements, and (2) require materials manufactured outside of the United States to have a ladle analysis confirmed by a check analysis.

Comments. We did not receive any comments regarding either proposal.

PHMSA response. The provision regarding materials manufactured outside the United States having a ladle analysis confirmed by a check analysis is not necessary because § 178.35(c)(2) requires inspectors to verify that the material of construction meets the requirements of the applicable specification by: (1) Making a chemical analysis of each heat of material; (2) obtaining a certified chemical analysis

from the material manufacturer for each heat of material (a ladle analysis is acceptable); or (3) if an analysis is not provided for each heat of material by the material manufacturer, by making a check analysis of a sample from each coil, sheet, or tube. However, we do believe a record of intentionally added alloying elements will be useful for ensuring material compositions are within the specified tolerances. A cylinder made of material within specified tolerances is less susceptible to deterioration or failure from the wear and tear on a cylinder from pressure cycling and exposure to pressurized gases.

PHMSA, therefore, is adopting the requirement for manufacturers to maintain a record of intentionally added alloying elements, as proposed.

(2) Revise the pressure tests for DOT-specification 4B, 4BA, 4BW, and 4E cylinders in §§ 178.50(i), 178.51(i), 178.61(i), and 178.68(h), respectively, to permit use of the volumetric expansion test, a hydrostatic proof pressure test or a pneumatic proof pressure test.

Given the added risk associated with pneumatic testing (*i.e.,* using pressurized gas for testing) and that there are suitable alternatives to determine whether a cylinder has a leak at the time of manufacture, PHMSA did not propose to permit the use of pneumatic proof pressure testing in the NPRM.

Comments. Fike Corporation, the National Propane Gas Association (NPGA), AmeriGas Propane, Amtrol, Worthington Cylinder (Worthington) and Manchester Tank (Manchester) submitted comments opposing PHMSA's decision to not permit the use of pneumatic proof pressure testing. Bancroft Hinchey and NAFED submitted comments supporting our decision to not permit the use of pneumatic proof pressure testing.

PHMSA response. This final rule allows manufacturers to conduct pneumatic proof pressure tests, when proof pressure tests are authorized in part 178, subpart C. PHMSA is convinced by the comments from Fike, NPGA, Amerigas, Amtrol, Worthington, and Manchester that manufacturers currently account for the additional risks created by pneumatic proof pressure testing. PHMSA would like to emphasize that pneumatic proof pressure test systems can present increased risks to test personnel due to the amount of energy stored in a cylinder filled to test pressure with a gas. This stored energy, if released due to a cylinder failure, is sufficient to cause serious injury or death. Manufacturers must take this risk into account and develop systems to prevent the death or injury of their employees in the event of a catastrophic cylinder rupture at test pressure. The use of additional safety equipment such as blast shields, test cages, etc., is advisable to prevent possible injury to testing personnel and equipment.

(3) Revise the physical and flattening tests and retest criteria for DOT-specification 4B, 4BA, 4BW, and 4E cylinders in §§ 178.50, 178.51, 178.61, and 178.68, respectively, for consistency. These revisions would clarify the location on the cylinder from which the test specimens are removed.

(a) Elongation Criteria

Fike Corporation submitted a comment requesting that we review the proposed revisions to the elongation criteria for specimens taken from DOT 4B, 4BA and 4BW cylinders under §§ 178.50, 178.51, and 178.61, based on its opinion that we should not revise the criteria at this time.

PHMSA response. We agree with Fike Corporation's comment that PHMSA should not revise the elongation criteria. In reviewing the proposed changes based on comments received, we solicited comment from Steve Gentry, the original submitter of the elongation criteria modification to CGA, to provide additional justification for changing the elongation requirement to 20 percent for all specimens, regardless of gauge length in making our final determination on the proposed language based on CGA's petition.

Mr. Gentry justified the requested change based on international harmonization and consistency with other elongation criteria calculations in the HMR. However, PHMSA does not believe these justifications warrant making the requested change. First, changing the elongation requirement will not assist in harmonizing with international standards at this time. A review of Transport Canada standard B339–18 shows that Canada has not revised cylinder manufacturing standards to require a 20 percent elongation for all specimens (*e.g.* see CSA B339–18 5.8.3). Second, we believe that changing the elongation criteria will introduce confusion to the detriment of compliance with no measurable safety benefit. Current elongation criteria are well understood in the industry and we do not believe we have enough information at this time to make the requested change.

Additionally, in response to Mr. Gentry's final justification, we do not believe that the current elongation criteria for two inch specimens conflicts with the ''24t'' formula in §§ 178.50(k)(2), 178.51(j)(2), and 178.61(k)(2). In §§ 178.50(k)(2), 178.51(j)(2), and 178.61(k)(2), cylinder manufacturers may choose to conduct elongation tests on cylinder specimens with a set length of eight inches or two inches with width not over 1.5 inches, or use a cylinder specimen with a gauge length of 24 times the thickness of the wall with width not over 6 times the thickness, commonly known as a ''24t'' gauge length. Cylinder specimens with a gauge length of 2 inches must achieve elongation of at least 40 percent, while all other gauge lengths (*i.e.,* the 24t gauge length) must achieve an elongation of at least 20 percent. Mr. Gentry identified several specific instances where a cylinder manufacturer utilizing the 24t gauge length option would use a calculated gauge length very close to 2 inches (*e.g.* a cylinder with a wall thickness of .0835 inches would, using the 24t formula, have a specimen 2.004 inches long) which would be subject to an elongation requirement of 20 percent, rather than the 40 percent requirement for a standard 2-inch gauge specimen. Mr. Gentry believes that the 20 percent elongation requirement for the 2.004 inch x .501-inch specimen calculated using the 24t method conflicts with the 40 percent elongation requirement for the 2 inch x 1½ inch specimen.

A direct elongation comparison between specimens with 24t gauge length (GL) x 6t wide, and 2″ GL x 1½″ width, however, is not valid because the load resisting cross-sectional areas are not the same even when nearly the same gauge lengths are used for both specimens. Essentially the ''24t'' gauge length specimen and the 2-inch specimen cannot be directly compared because their cross-sectional areas are different; therefore, it is correct to have different elongation criteria even when the ''24t'' specimen is very nearly 2 inches long. PHMSA acknowledges that there may be room for improvement of the DOT 4-series cylinder elongation criteria associated with the physical and flattening tests and plans to continue reviewing the criteria for possible changes.

(b) Non-Destructive Examination

Fike Corporation submitted an additional comment opposing the proposed requirement to examine circumferential welds in addition to longitudinal welds using radioscopic or radiographic examination under proposed § 178.61(f), indicating that it believes this is a significant change. Regarding Fike Corporation's comments on radioscopic or radiographic examination applicability, we agree.

The current requirements in § 178.61(d)(3)(ii) require radioscopic or radiographic examination of the longitudinal weld only, except in the case of spot radioscopy or radiography. It was not our intent to impose new weld radioscopy or radiography requirements in this final rule. Therefore, in this final rule we are modifying the requirements in § 178.61(d)(5) to clarify that radioscopic or radiographic examination of the circumferential weld is not required, except as part of spot radioscopy or radiography. Additionally, we are moving the proposed radiography examination language from § 178.61(f) to § 178.61(d)(5) in order to improve the organization of, and therefore, understanding of the section.

(c) Specimen Test Failure

In the NPRM, we proposed to amend the rejected cylinder paragraphs for 4B, 4BA and 4E cylinders to align them with the provisions for 4BW cylinders. Specifically, we proposed to add a provision to §§ 178.50(n), 178.51(m), and 178.68(m) that would allow two additional specimens to be selected from the same lot and subjected to the prescribed test. If either of the two specimens failed the test, the entire lot would be rejected.

No rationale was presented in P–1501 for this change. Moreover, we received no comments on these specific provisions. We do not believe that a change to cylinder rejection criteria is warranted at this time because we do not have enough supporting information to justify the change, and therefore we will not amend the rejected cylinder language in this final rule. We may consider this action in a future rulemaking.

(4) Revise §§ 178.50(n), 178.51(n), and 178.61(o), and 178.68, respectively, for DOT-specification 4B, 4BA, 4BW, and 4E cylinders to permit marking on the footring for cylinders with water capacities up to 30 pounds, instead of 25 pounds.

We received no comments regarding this item and are adopting the revision as proposed.

(5) Add additional options for the location of markings on DOT 4E cylinders in § 178.68.

We received no comments regarding this item and are adopting the addition as proposed.

(6) Determination of Expansion.

Related to P–1501, Worthington Cylinder submitted a comment requesting that we eliminate the requirement to determine expansion for non-spherical 4B, 4BA, and 4BW cylinders at time of manufacture. This comment is beyond the scope of this rulemaking. We encourage Worthington Cylinder or other interested parties to submit petitions on this issue.

(7) Correction.

In the review of the NPRM, PHMSA determined that we inadvertently replaced the word ''rejected'' with ''condemned'' in several places in §§ 178.50, 178.51, 178.61, and 178.68. This was not our intent. In this final rule, we will maintain the HMR's existing language for cylinders rejected during manufacture.

P–1515

The Certified Training Company (CTC) submitted P–1515 requesting that PHMSA make numerous revisions to the requirements for the requalification of DOT-specification cylinders found in 49 CFR part 180, subpart C. Part 180, subpart C includes definitions for terms used in the subpart, references to CGA publications for the visual inspection of cylinders, and requirements for hydrostatically testing cylinders including methods to ensure the accuracy of test equipment. Many changes proposed in P–1515 were intended to align the requirements in part 180, subpart C with an industry standard for the requalification of gas cylinders known as CGA C–1, *Methods for Pressure Testing Compressed Gas Cylinders* (CGA C–1). CTC acknowledged that the preferred outcome would be to incorporate by reference CGA C–1 into part 180, subpart C, but the petitioner presented an option whereby PHMSA could adopt many of the provisions of CGA C–1 into the current structure of the HMR without incorporating CGA C–1.

Many of P–1515's proposed changes were only requested in the event that PHMSA chose not to adopt P–1626. P–1626 requested that PHMSA incorporate by reference CGA C–1 into part 180, subpart C. In the NPRM, PHMSA proposed to incorporate CGA C–1 (Eleventh Edition) into part 180, subpart C in addition to the numerous changes suggested by P–1515. CTC, along with numerous others, submitted extensive comments regarding this action. In this final rule, we will incorporate the Eleventh Edition of CGA C–1 for the requalification of compressed gas cylinders, which renders many of P–1515's proposed changes moot. Please see our discussion of P–1626 for additional discussion of CGA C–1 and revisions to the structure of part 180, subpart C.

(1) Comments Related to the Incorporation by Reference of CGA C–1

(a) Definitions

Certified Training Company (CTC) and Bancroft Hinchey submitted comments opposing our proposed inclusion of additional definitions for cylinder requalification terms in § 180.203, which were intended to bring the HMR into alignment with CGA C–1. CTC also suggested we delete other long-standing definitions in § 180.203 because they did not align with CGA C–1's definitions.

PHMSA response. We agree with CTC and Bancroft Hinchey's comments to remove the definitions of ''Accuracy,'' ''Accuracy grade,'' ''Actual test pressure,'' ''Calibrated cylinder,'' ''Defect,'' ''Elastic expansion,'' ''Error,'' ''Master gauge,'' ''Percent permanent expansion,'' ''Permanent expansion,'' ''Reference gauge,'' ''Rejected,'' ''Service pressure,'' ''Test pressure,'' ''Total expansion,'' ''Visual inspection,'' and ''Volumetric expansion test'' from § 180.203. We are incorporating by reference CGA C–1 into the HMR and these terms are all defined in this industry standard; thus, codification of the definitions in § 180.203 is redundant and this provides us an opportunity to reduce the size of the HMR. However, PHMSA has decided to keep the definition of ''condemn'' because § 180.205(i) will continue to discuss condemnation criteria in greater detail than CGA C–1 does and we believe maintaining the definition in § 180.203 will increase clarity for cylinder requalifiers.

(b) Incorporation of CGA C–1 Into § 180.205(g)

CTC and Bancroft Hinchey noted that the NPRM did not incorporate by reference CGA C–1 into § 180.205(g), which was PHMSA's stated intent in the NPRM preamble. Section 180.205(g) is a crucial paragraph for cylinder requalifications that contains instructions on how to conduct the pressure test that is used to requalify a cylinder for future use or condemn it. By incorporating CGA C–1 into § 180.205(g), we will require cylinder requalifiers to comply with the instructions in CGA C–1 when conducting pressure tests. These instructions offer more guidance and include helpful diagrams and examples that decrease compliance burdens compared to the current instructions in § 180.205(g).

PHMSA response. We agree with CTC and Bancroft Hinchey's comments. It was our intent to incorporate CGA C–1 for the requalification of DOT

specification cylinders, therefore, in this final rule we are including a reference to CGA C–1 (Eleventh Edition) in § 180.205(g).

(c) Streamlining of Existing Regulatory Text

CTC and CGA noted that since we proposed to adopt P–1626, there was an opportunity to streamline the HMR's cylinder requalification instructions significantly by revising § 180.205(g) to require compliance with CGA C–1, rather than maintaining the existing instructions for pressure tests. CTC and CGA commented that maintaining two sets of instructions would generate confusion and frustration.

PHMSA response. We agree with CTC and CGA's comments to revise existing § 180.205(g). This final rule removes the existing language in the HMR on conducting volumetric expansion testing from § 180.205(g) and replaces it with instructions to conduct requalification in accordance with CGA C–1. These revisions will help to reduce confusion and improve compliance without increasing burdens on the regulated community while meeting our stated intent in the NPRM to adopt the CGA C–1 standard as the industry standard for performance of inspection and testing for requalification and continued service of cylinders.

(d) Accuracy Requirements

In the NPRM, PHMSA proposed to align with ISO requirements by requiring the pressure indicating device (PID) to meet ''Industrial Class 1 (±1% deviation from the end value).'' CGA, Hidroprob SA, Bancroft Hinchey, and Galiso identified this change as problematic because it conflicts with the accuracy grade requirements for PIDs found in CGA C–1.

PHMSA response. Hidroprob S.A., Bancroft Hinchey, Galiso, and CGA's comments regarding device accuracy are correct, and contributed to our decision to not adopt the proposed changes in § 180.205(g) and simplify requirements by adopting CGA C–1 into the section. In this final rule, we will not adopt the proposed changes to device accuracy in § 180.205(g). In this final rule, we will maintain the HMR's current PID accuracy requirements in § 180.205(g)(3)(i). Voluntary compliance with CGA C–1 5.3.2.2 is authorized and will meet the HMR's accuracy requirements for PIDs used for cylinder requalification, as will the practice of demonstrating accuracy through maintenance of a calibration certificate showing the gauge has been certified to meet the accuracy requirements at lower points. See discussion of PID accuracy in P–1626 for further information on this decision.

(e) Condemnation Criteria for Repeat Tests

CTC and Bancroft Hinchey submitted comments requesting we revise the condemnation criteria for cylinders that are subjected to a repeated test due to equipment malfunction or operator error to 5 percent permanent expansion, rather than 10 percent. CTC states that increasing the pressure by 10 percent, or 100 psig for the repeat test, is not enough to ensure that an unsafe cylinder exhibits a permanent expansion over 10 percent. Bancroft Hinchey states that an increase of 10 percent/100psi can be insufficient to give measurable plastic deformation and resultant permanent expansion >10 percent due to the gradient of the load/extension curve immediately after yield point. An increase of 100psi at a (minimum) test pressure of 3000 psi (the lowest pressure above 3000) represents a pressure increase of only 3100/3000 = 3.3 percent and is unlikely to give a resultant 10 percent plastic deformation.

PHMSA response. We do not agree with CTC and Bancroft Hinchey's comments to change the condemnation criteria for cylinders in this case. CGA C–1 limits cylinder requalifiers to only two repeated tests in the event of equipment malfunction or operator error, and we do not believe that there is a safety justification to change the condemnation criteria to permanent expansion that is 5 percent of total expansion in cases where a repeat test is conducted. We acknowledge that repeated tests may result in some stretching of the cylinder, resulting in cylinders passing requalification that may have otherwise failed; however, this risk is minimized by limiting requalifiers to a maximum of two repeat tests in the event of equipment failure or operator error. Further, this provision does not authorize the retest of a cylinder otherwise required to be condemned by § 180.205(i). The final rule, therefore, does not change the condemnation criteria for cylinders subjected to a repeat test.

(f) Letters of Interpretation

In P–1515, CTC further requested that PHMSA rescind two letters of interpretation (Reference Nos. 00–0309 and 05–0087) that discuss the number of repeat tests allowed in the event of equipment malfunction and required hold time for pressure tests, respectively. Bancroft Hinchey supports retracting these letters of interpretation.

PHMSA response. We agree that adopting CGA C–1 will eliminate the confusion regarding the number of permitted repeat tests in case of system failure or operator error, as well as the required pressure hold time, that the letters of interpretation attempted to clarify. This final rule supersedes the two letters of interpretation. Affected entities should not rely on 00–0309 and 05–0087 because they are no longer valid and will be removed from our website.

(2) Comments Related to § 180.205

(a) Grinding and Sanding

NPGA and Amerigas opposed the proposed changes in § 180.205(d)(4) and (f)(5) regarding grinding and sanding of cylinders. Bancroft Hinchey submitted a comment supporting the proposed changes in § 180.205(d)(4).

PHMSA response. Our intent in § 180.205(d)(4) and (f)(5) is to address methods of cleaning or repair that remove wall thickness from the cylinder. Cleaning methods, regardless of the tool used, that only remove loose debris or paint from the cylinder while not removing wall thickness are not considered ''grinding.'' In this final rule we modify § 180.205(d)(4) and (f)(5) to clarify our intent and to authorize grinding or sanding performed by any authorized repair facility.

(b) Reordering of Condemnation Criteria

CTC submitted a comment requesting that we swap § 180.205(i)(1)(v) and (vi) in order to have the condemnation criteria for DOT 4E cylinders immediately follow the general requirements in § 180.205(i)(1)(iv).

PHMSA response. We do not agree with CTC's comment to re-order § 180.205(i)(1). Changing the citations for the condemnation criteria section will result in increased confusion and we do not believe it is in the best interest of safety.

(c) Additional Condemnation Criteria

Bancroft-Hinchey commented that we should add one additional criterion to § 180.205(d), *Conditions requiring tests and inspections of cylinders,* for cases where a cylinder is discovered with incorrect markings.

PHMSA response. We are not adopting the suggested change in Bancroft-Hinchey's comment. They did not provide enough information to make a judgement on the merits of the proposal. The public may make a separate petition further explaining the issue.

(3) Comments Related to § 180.207

(a) Deletion of § 180.207(a) and (b)

Certified Training Company (CTC) submitted a comment requesting that we delete § 180.207(a) and (b), because these instructions could be combined with § 180.205(c).

PHMSA response. While we agree with CTC that these paragraphs serve similar purposes, we do not agree with CTC's comment to delete § 180.207(a) and (b) and consolidate them into § 180.205(c). The current structure of the HMR generally separates instructions for DOT specification cylinders and UN ISO pressure receptacles because of differences in their design and construction. These paragraphs in § 180.207 are necessary to provide enforceable instructions for shippers and fillers of UN pressure receptacles separately from shippers and fillers of DOT specification cylinders.

(b) Ultrasonic Examination for High Tensile Strength UN Pressure Receptacles

CTC and Worthington submitted a comment requesting that we remove language from § 180.207(d) that requires ultrasonic examination (UE) of certain UN pressure receptacles.

PHMSA response. We do not agree with CTC and Worthington's comment to remove the requirement that UN cylinders with a tensile strength greater than or equal to 950 MPa must be requalified by UE in accordance with ISO 6406 in § 180.207(d)(1). This requirement serves an important safety purpose. High strength steels exhibit a reduction of fatigue stress endurance during requalification and are therefore unsuitable for pressure testing. In general, the fatigue stress endurance limits increase with increasing ultimate tensile strength (the specifics are alloy dependent). At a certain ultimate tensile strength level, the fatigue stress endurance limit is drastically reduced with increasing tensile strength due to notch sensitivity. Increased notch sensitivity is a result of finer microstructural features that lead microstructural damage evolution (dislocation slips eventually accumulating to micro void coalescence and the initiation of a fatigue crack). Performing UE of high-strength seamless steel during requalification will detect fatigue cracks in cylinders/tubes while hydrostatic testing coupled with visual inspection has a significantly lower probability of detecting any fatigue cracks in cylinders/tubes. Therefore, we are continuing to require UE for UN cylinders with a tensile strength greater than or equal to 950 MPa.

(c) Acetylene Test Interval

During review of the NPRM, we noted that the proposed revisions to § 180.207(d)(3) for dissolved acetylene UN cylinders were not in alignment with the suggested test intervals in ISO 10462(E) or ISO 10462 2013(E). Therefore, in the final rule, we will not make the proposed changes to § 180.207(d)(3).

(4) Comments Related to § 180.209

(a) Revisions to Requalification of Cylinders Table

CTC and Independent Cylinder Training (ICT) submitted comments requesting we replace ''DOT 3'' with ''ICC 3'' and CTC and Bancroft Hinchey's comment to re-insert ''10'' for DOT 3A and 3AA and ''7'' for 4B, 4BA, 4BW cylinders in § 180.209(a) Table 1.

PHMSA response. We agree with CTC, ICT, and Bancroft Hinchey that there are errors in the table in § 180.209(a) Table 1. However, we proposed changes to § 180.209(a) Table 1 in a different rulemaking [1] and will take no action in this rulemaking to avoid potential for complication and confusion.

(b) Foreign Cylinders

CTC and Wesley Scott submitted comments requesting that we change the requalification requirements for foreign cylinders in § 180.209 Table 1.

PHMSA response. We do not agree with CTC and Wesley Scott's comments regarding test pressure of foreign cylinders in § 180.209(a) Table 1. Foreign-marked ISO cylinders are subject to the requirements of § 180.207, and would not be subject to test at 5/3 of service pressure. Therefore, we will not change this requirement in Table 1.

(c) Footnote 1

CTC, ICT, Hydro-Test Products and COSTHA's comments noted that we inadvertently deleted Footnote 1 of Table 1 in § 180.209 and requested that we reinsert the footnote.

PHMSA response. It was not our intent to change the requirements applicable to these small cylinders. In this final rule, we are not making any of the proposed changes to the table in § 180.209 to avoid conflicts with other rulemaking efforts. In this final rule, we are not removing Footnote 1 of Table 1 in § 180.209.

[1] See Response to an Industry Petition to Reduce Regulatory Burden for Cylinder Requalification Requirements, NPRM, 84 FR 38180 (Aug. 6, 2019).

(d) Special Filling Limits (''+'' Mark) Relocation

In P–1515, CTC requested that we move the requirements for special filling limits for DOT 3A, 3AX, 3AA, 3AAX and 3T cylinders found in § 173.302a(b) to § 180.209. We did not propose to take this action in the NPRM. CTC submitted a comment to the NPRM requesting that we reconsider our decision not to propose the change.

PHMSA response. We disagree with CTC's request to move the current requirements in § 173.302a(b) (''Special filling limits for DOT 3A, 3AX, 3AA, 3AAX and 3T cylinders'') to § 180.209. The requirements in § 173.302a(b) deal with filling, and are properly placed in a filling section rather than a requalification section. Moving the requirements to a requalification section in part 180 would create unnecessary confusion. We additionally disagree with CTC's request to modify the language in § 173.302a(b) to remove the table of steel types, average wall stress limitation, and maximum wall stress limitation. We acknowledge that this information can be found in CGA C–5, which is incorporated by reference into the section, but we continue to see value in reproducing the table in the HMR for accessibility purposes. We did not propose this change in the NPRM, and we will not adopt this change in the final rule.

(e) 10-Year Requalification Condition Revisions (''Star'' Mark)

CTC submitted a comment regarding the applicability of the ''star'' marking for 10-year requalification in § 180.209(b), specifically requesting that we modify the change proposed in the NPRM to allow cylinders used in vehicles to continue to take the exception.

PHMSA response. PHMSA is not changing the applicability of the 10-year requalification to prohibit cylinders used in clusters, banks, groups, racks, or vehicles. If fillers are not removing these cylinders from the cluster, bank, group, rack, or vehicle, as stated by CTC in P–1515, then they may not use the exception unless they have been issued a special permit. Changing the applicability of the exception is not an appropriate way to deal with this supposed compliance problem. We encourage cylinder users and fillers to re-familiarize themselves with the conditions for the 10-year requalification for DOT 3A and 3AA cylinders.

(f) 10-Year Requalification Expansion Limit

ICT and Bancroft Hinchey also commented about their opposition to another part of this proposed change to § 180.209(b), namely the new limit of 5 percent permanent expansion for these cylinders.

PHMSA response. In this final rule, we are not modifying the applicability of the exception or creating a new permanent expansion limit. We are, however, modifying the exception by removing the ''hammer test,'' as requested in P–1515 and proposed in the NPRM. The hammer test is outmoded and no longer provides relevant information regarding the continued strength of the cylinder. We may consider further modifying this exception in the future.

(5) Eddy Current Testing

In the NPRM we proposed to change the applicability of the eddy current test, eddy current condemnation criteria, and eddy current record keeping requirements, as requested in P–1515. We do not believe the change and possible increase in cost is justified by data at this time. Therefore, in this final rule, we are not making any changes related to eddy current testing applicability, condemnation criteria, or recordkeeping.

(a) Test Applicability

Currently, eddy current testing is required for 3AL cylinders made of aluminum alloy 6351–T6 in SCUBA, SCBA, or oxygen service. 3AL 6351–T6 cylinders have been shown to be susceptible to sustained load cracking (SLC) in the neck and thread area of the cylinder. Eddy current testing combined with a detailed visual examination can identify SLC before it poses an immediate danger. We have required eddy current testing since the publication of HM–220F (71 FR 51122; 8/29/2006). P–1515 requested that we change the applicability of the eddy current test to any DOT 3AL cylinder made of 6351–T6 alloy with a service pressure at or above 1,800 psig. We received one comment in support of this change from ICT. We did not discuss the proposed change in detail in the preamble to the NPRM, only stating, ''Specifically we plan to revise . . . the paragraph (m) requalification conditions for DOT 3AL cylinders made of 6351–T6 aluminum alloy.'' We are concerned that the change from a gas service-based testing applicability to a pressure-based testing applicability may significantly increase the number of cylinders subject to eddy current testing, without adequate notice to the regulated community or safety justification.

Since the imposition of the eddy current test requirement in 2006, we are not aware of any catastrophic failures of DOT 3AL cylinders involving sustained load cracking. In this final rule, we are not making the proposed change to eddy current test applicability. We welcome further petitions on the matter, but we do not believe the change and possible increase in cost is justified by data at this time.

(b) Condemnation Criteria

Similarly, we are not making any change to eddy current condemnation criteria. The current criteria in the HMR have proved successful in identifying cylinders prone to sustained load cracking, facilitating their removal from service before cracks can cause catastrophic failure. We may consider revising the condemnation criteria in a future rulemaking, but will make no change to eddy current condemnation criteria at this time.

(c) Record-Keeping

In the NPRM, we proposed changes to eddy current recordkeeping requirements. We proposed to move eddy current recordkeeping requirements currently found in appendix C to part 180 to new § 180.215(b)(5). We received a comment from ICT opposed to the relocation of requirements from appendix C to part 180 into § 180.215(b)(5). We agree with ICT and are not making the proposed change to relocate requirements out of appendix C to part 180 at this time. Eddy current testers are familiar with the requirements found in appendix C to part 180 and moving the requirements to a new section would create unnecessary confusion. We may review eddy current recordkeeping requirements in a future rulemaking.

(6) Comments Related to § 180.209(j)

(a) Incorporation by Reference of CGA C–1

CTC commented on the proposed language in § 180.209(j) and stated their opinion that the language was unnecessarily confusing and redundant following the incorporation of CGA C–1.

PHMSA response. We agree with CTC's comment that there are redundant instructions in § 180.209(j), and the requirements could be simplified by referring to the test procedures in CGA C–1. Additionally, COSTHA noted an error in the structure of § 180.209(j), where it appeared the proposed paragraphs (j)(2) and (3) overlapped in applicability and contradicted each other. We appreciate this comment, and have re-structured § 180.209(j) to make clear that paragraph (j)(1)(i) applies to smaller 4B, 4BA, 4B240ET, or 4BW cylinders, paragraph (j)(1)(ii) to larger 4B, 4BA, 4B240ET, or 4BW cylinders, and (j)(2) to 3A, 3AA, or 3AL cylinders.

(b) Increased Pressure for Repeat Tests

ICT commented on our proposed requirement to increase the pressure by 10 percent for a repeated proof pressure test for fire extinguishers, noting this was not in accordance with CGA C–1 requirements.

PHMSA response. We agree, and are removing this provision and replacing it with instructions to conduct the proof pressure test in accordance with CGA C–1.

(c) 4E Cylinders

While reviewing § 180.209(j), we noted erroneous references to DOT 4E cylinder condemnation criteria. DOT 4E cylinders are generally not eligible to be transported or requalified as fire extinguishers, so we have removed the reference to 4E condemnation criteria from § 180.209(j).

In the final rule, we are revising § 180.209(j) as discussed above to simplify and clarify the requirements for the requalification of specification fire extinguishers.

(7) Comments Related to § 180.212

Bancroft Hinchey commented in support of the proposed requirement in § 180.212(a)(3) to require ultrasonic testing (UT) after a repair facility conducts a repair involving grinding.

PHMSA response. In this final rule, we are adopting this requirement as proposed.

(8) Comments Related to § 180.213

(a) Requalification Label Embedded in Epoxy

Numerous commenters, including NPGA, Amerigas, Firehouse Hydro Sales and Service, Joshua Blake, Hydro-Test Products, and Scuba Do noted that we made an error in § 180.213(c) for requalification marking methods by removing the authorization for a label embedded in epoxy.

PHMSA response. The commenters are correct that we inadvertently did not include the provision allowing for applying a label embedded in epoxy. This was not our intent as part of the HM–234 NPRM. Therefore, in this final rule we are including the label in epoxy marking method in § 180.213(c) as is currently allowed under the HMR. We appreciate the commenters' attentiveness in addressing this unintentional omission in the NPRM.

(b) Requalification Marking Location

Independent Cylinder Training (ICT), Amerigas, and NPGA oppose the proposed requirement in § 180.213(c)(1)(i) that would require requalification marks be placed in a specific location adjacent to the original manufacturing markings. ICT, Amerigas, and NPGA state that this requirement is too restrictive, and in certain cases impossible to meet due to the size and type of cylinders involved. Bancroft Hinchey supports a requirement to ''lay out requalification markings neatly and consistently.''

PHMSA response. We agree with the comments submitted by ICT, Amerigas, and NPGA. While we would have liked to provide a consistent location for requalification markings for shippers and fillers, we recognize the diversity of cylinder types and sizes makes this effort difficult. Therefore, in this final rule we are not adopting the change to § 180.213(c) that was proposed in the NPRM. Requalification markings must be applied in a legible and durable manner and may be placed on any portion of the upper end of the cylinder excluding the sidewall. We welcome petitions on this requirement for possible inclusion in a future rulemaking.

(c) Requalification Marking Depth

Bancroft Hinchey commented that § 180.213(c) should be modified to provide guidance on requalification marking depth when the cylinder specification does not provide any information on accepting marking depth.

PHMSA response. While PHMSA agrees that cylinder requalifiers should not mark cylinders to a depth greater than the original manufacturer's markings, we do not agree with Bancroft Hinchey's comment to modify § 180.213(c). PHMSA believes that including the phrase ''or the original manufacturer's markings'' to § 180.213(c) will increase confusion among cylinder requalifiers.

(9) Comments Related to § 180.215

(a) Use of Symbols for Cylinder Dimension

Bancroft Hinchey requested clarification of the revision to § 180.215 to permit use of symbols for actual dimensions.

PHMSA response. The use of a symbol in place of the written dimensions of the cylinder is permitted by § 180.215(b) as long as the symbols on the reference chart available at the requalifier's facility are accurate for the actual measured dimensions of each cylinder requalified. It is PHMSA's understanding that some cylinder requalifiers maintain reference charts with symbols cross-referenced to the actual measured dimensions of common cylinder models. As long as the facility has an accurate reference document that cross-references the symbol entered on the requalification record with the actual measured dimensions of the cylinder requalified, they may use that symbol to meet the requirement to enter the actual dimensions of a cylinder on the requalification record. This will increase flexibility and reduce burdens for requalifiers without compromising safety.

(b) Gas Service and Year of Manufacture

Hydro-Test Products commented on the proposed change to cylinder requalification recordkeeping requirements. They noted that in the NPRM we did not discuss the additional requirement to record the cylinder's year of manufacture or gas service in § 180.215(b)(2). Hydro-Test Products is opposed to the proposed change to cylinder requalification recordkeeping requirements and believes it would impose an undue burden on cylinder requalifiers.

PHMSA response. We disagree with Hydro-Test Products' comment. The requirement for cylinder requalifiers to keep a record of the cylinder's date of manufacture and gas service is useful for several reasons. The eligibility for the ''star'' mark in § 180.209(b), allowing a 10-year requalification period instead of 5 years, depends on the year of manufacture and gas service, as does the ''+'' mark for 10 percent overfilling in § 173.302a(b). The applicability of the option to requalify a cylinder via external visual inspection in § 180.209(g) is also dependent on the particular gas service in which the cylinder is used. The year of manufacture is also helpful in determining whether a 3AL cylinder was constructed from 6351–T6 aluminum alloy, and therefore subject to eddy current examination. Use of 6351–T6 aluminum alloy in DOT 3AL cylinders was discontinued in 1990. We believe that the addition of these two pieces of information to cylinder requalification records creates only a minimal reporting burden on the regulated community while aligning recordkeeping requirements with operational practice. See further discussion in Section VIII.G in this rulemaking document regarding the information collection burden of this requirement. In this final rule, we are adopting the changes as proposed, and modifying § 180.215(b)(2) to require cylinder requalifiers to record the year of manufacture and gas service of each cylinder they requalify.

(10) Reclaimed Refrigerant Gas

Section 180.209(e) authorizes proof pressure testing for DOT 4-series cylinders in non-corrosive gas service. In the NPRM we proposed to add the following sentences to this paragraph: ''However, a cylinder used for reclaiming, recycling, or recovering refrigerant gases must be requalified by volumetric expansion testing every 5 years. Reclaimed, recycled, or recovered refrigerant gases are considered to be corrosive due to contamination.'' In this final rule, we are not adding these sentences to § 180.209(e). Although we believe that cylinders used for reclaimed refrigerant gases are generally not eligible for the exception in § 180.209(e) because of the contaminants encountered in this service, we are uncertain whether this is always the case. Therefore, PHMSA has decided that the most practical regulatory alternative at this time is to leave the § 180.209(e) exception allowing a 10-year testing interval for DOT 4-series cylinders used in non-corrosive gas service unchanged. As provided in § 173.22, it is the shipper's responsibility to classify a hazardous material properly.

(11) RIN Markings for Foreign Cylinders

In the HMR, foreign cylinders not manufactured to a DOT, UN, TC, CTC, BTC or CRC specification may be filled and transported for export or for use on board a vessel in accordance with § 171.23(a)(5) (note that this reference was originally § 171.23(a)(4), and has changed to § 171.23(a)(5) after publication of final rule HM–219C). Requalification for these cylinders is discussed in § 180.209(l), which prohibits the marking of the cylinder with a requalifier's RIN, instead requiring only the month and year of requalification. In the NPRM, we proposed to require a RIN marking for these foreign cylinders, along with the symbol ''EX,'' to reduce confusion among fillers and clarify that these foreign cylinders had been requalified in accordance with part 180, subpart C. We received no comments on this proposal. In this final rule, we will adopt this requirement. We believe that the symbol ''EX'' in association with the RIN provides necessary information to inspectors and users that these cylinders are limited to export or vessel service in accordance with § 171.23(a)(5). The inclusion of a RIN marking, which signifies compliance with part 180 subpart C, will increase clarity for fillers

that the cylinders have been properly requalified.

P–1521

CGA submitted P–1521 requesting that PHMSA modify a provision in § 172.400a(a)(1) (specifically § 172.400a(a)(1)(i) at the time the petition was submitted) to remove the limitation that only allows the use of the neckring markings if a cylinder is not overpacked. The petition would still require the overpack to display the labels in conformance with 49 CFR part 172, subpart E. In the NPRM, PHMSA proposed to revise § 172.400a(a)(1)(i) to remove the limitation that would only allow the use of the neckring markings if the cylinders are not overpacked, as proposed in P–1521. National Association of Fire Equipment Distributors (NAFED) and Worthington Cylinder submitted comments supporting this change.

On January 21, 2016, PHMSA published HM–233F (81 FR 3635), which adopted numerous special permits into the HMR. In particular, we adopted DOT SP 14251, which authorizes the transportation of overpacked cylinders marked in accordance with CGA publication C–7 provided the overpacks are properly labeled. Therefore, the intent of P–1521 has already been accomplished. We appreciate CGA's petition and COSTHA's comment highlighting that HM–233F already addressed this issue.

P–1538

On behalf of Jetboil, Inc., The Wicks Group submitted P–1538 requesting that PHMSA revise § 173.306(a)(1) to permit camping stove cylinders containing liquefied petroleum gas (LPG) in amounts less than 4 ounces but in a container exceeding 4 fluid ounce capacity to be shipped as consumer commodity (ORM–D). Historically, PHMSA has limited the amount of compressed gas in limited quantity packagings to reduce the opportunity and speed of the gaseous product's reaction to an activating event, having found that including non-gaseous materials in the same container with the gas—such as foodstuffs, soap, etc.—slowed this reaction. The Interstate Commerce Commission first adopted the provision for § 173.306(a)(1) (previously § 73.306(a)(1)) in a final rule published July 1, 1966 (31 FR 9067). The provision provided an ''exemption'' (*i.e.,* an exception) from regulations for shipping of compressed gases ''when in containers of not more than 4 fluid ounce water capacity.'' Thus, historically, the provision applies to the capacity of the container and not to the quantity of its contents. This is consistent with design requirements for the capacity of packagings found in part 178 that includes a specification for the water capacity of the packaging (*e.g.,* Specification 3A and 3AX seamless steel cylinders in § 178.36); however, the publication of a final rule on April 15, 1976 (41 FR 15972) inadvertently dropped the term ''water'' from paragraph (a)(1) regardless of there having been no express discussion of the intent to do so or to change the size standard from the originally adopted water capacity to the quantity of the contents.

Furthermore, the definition ''maximum capacity'' was introduced as part of a harmonization effort with international regulations and standards in a final rule published December 21, 1990 (55 FR 52402) for consistency with use of terminology internationally for UN performance oriented packaging. See the part 178, subpart L non-bulk performance oriented packaging sections. Therefore, based on the historical context of capacity as its use in § 173.306(a)(1) to mean water capacity and the adoption of the term ''maximum capacity'' in association with the adoption of UN performance oriented packaging, PHMSA did not propose to adopt the petition. We received one comment on this topic. Worthington Cylinder submitted a comment supporting PHMSA's proposal to deny the petition and not amend § 173.306(a)(1). Therefore, as reasoned in the NPRM, we are not adopting P–1538 in this final rule.

P–1539

Matheson-TriGas submitted P–1539 requesting that PHMSA revise § 180.209, which prescribes requirements for requalifying cylinders. Paragraph (a) of § 180.209 requires each DOT-specification cylinder listed in ''table 1 of this paragraph'' to be requalified and marked in conformance with requirements specified in § 180.209. The petitioner requested that PHMSA extend the 10-year retest period prescribed in this table for DOT 3A, 3AA, and 3AL specification cylinders in Division 2.2 (non-flammable) gas service to once every 15 years. Matheson-TriGas also requested in its petition that PHMSA extend the 5-year retest period prescribed in this table for DOT 3A, 3AA, and 3AL specification cylinders in Division 2.1 (flammable) gas service to once every 10 years. The petitioner states: ''Historically over 99.4 percent of cylinders in the above[-mentioned] services that were [subjected] to the water jacket test pass the test,'' and ''it is more likely . . . the cylinder failed the external or internal visual [test] rather than failing the water jacket test.''

Matheson-TriGas notes PHMSA's statement from an earlier rulemaking (HM–220; 63 FR 58460) regarding the history of the plus rating for steel cylinders resulting from the steel shortage of World War II, which resulted in changes ''that benefitted the industry with no compromise of public safety down to this day.'' Matheson-TriGas extrapolates that we face similar metal shortage challenges in today's economy.

Based on concerns about increasing the risk of cylinder failure by lengthening the timeframe between periodic qualifications, PHMSA did not propose to revise the 10-year requalification period for DOT 3A, 3AA, and 3AL specification cylinders in Division 2.2 (non-flammable) gas service to once every 15 years, nor to revise the 5-year requalification period for DOT 3A, 3AA, and 3AL specification cylinders in Division 2.1 (flammable) gas service to once every 10 years.

We received three comments on this topic. Bancroft Hinchey, NAFED, and CGA all supported our decision not to adopt the petition. Therefore, as reasoned in the NPRM, we are not adopting P–1539.

P–1540

CGA submitted P–1540 requesting that PHMSA require newly manufactured DOT 4B, 4BA, 4BW, and 4E cylinders to be marked with the mass weight or tare weight, and the water capacity. As specified in § 178.35(f), the HMR require DOT-specification cylinders to be permanently marked with specific information, including the DOT-specification, the service pressure, a serial number, an inspector's mark, and the date manufacturing tests were completed. These marks provide vital information to fillers and uniquely identify the cylinder.

Certain DOT 4-series specification cylinders contain liquefied gases filled by weight, so the tare weight (the weight of the empty cylinder and appurtenances) or the mass weight (the weight of the empty cylinder), and the water capacity must be known by the filler to fill the cylinder properly. This information is essential for cylinders filled by weight, as cylinders overfilled with a liquefied gas can become liquid full as the ambient temperature increases. If temperatures continue to rise, pressure in the overfilled cylinder will rise disproportionately, potentially leading to leakage or a violent rupture of the cylinder after only a small rise in temperature. Despite these risks, the HMR do not require tare weight, mass

weight, or water capacity markings on DOT-specification cylinders.

To address this, the CGA petitioned PHMSA to require tare weight or mass weight, and water capacity to be marked on newly constructed DOT 4B, 4BA, 4BW, and 4E specification cylinders. The petition also requests that PHMSA provide guidance on the accuracy of these markings and define the party responsible for applying them. In its petition, CGA notes that PHMSA has incorporated by reference the National Fire Protection Association's ''58-Liquefied Petroleum Gas Code, 2001 edition'' (NFPA 58), which requires cylinders used for liquefied petroleum gases to be marked with the tare weight and water capacity; [2] however, as stated in the petition, NFPA 58 gives no guidance as to the accuracy of these markings or the party required to provide them. The CGA states that this lack of guidance can lead to the overfilling of a cylinder and the potential for unsafe conditions.

While DOT 4B, 4BA, 4BW, and 4E cylinders are often used to transport liquefied compressed gas, we noted in the ANPRM that these are not the only cylinder types used for liquefied compressed gas transport. PHMSA understands that many in the compressed gas industry, especially the liquefied petroleum gas industry, already request manufacturers to mark cylinders with the tare weight or water capacity as an added safety measure. Based on this assumption, PHMSA estimates the impact on the liquefied compressed gas industry will be minimal, as many in the industry are already applying these markings voluntarily.

PHMSA requested comments and supporting data regarding the increased safety benefits and the economic impact of this proposal. With regards to the cost associated with this modification, in the ANPRM, PHMSA asked the following specific questions:

- What is the average total cost per cylinder to complete these markings (*i.e.,* is an estimated cost of $0.10 per character for new markings accurate)?
- What is the estimated quantity of newly manufactured 4B, 4BA, 4BW and 4E cylinders each year? Furthermore, how many of these cylinders already display tare weight and water capacity markings in compliance with NFPA 58 or other codes?
- How many manufacturers of the cylinders mentioned above are considered small businesses by the SBA?

PHMSA sought to identify: (1) The frequency of which the mass weight or tare weight, and water capacity markings are already permissively applied to cylinders, (2) the costs associated with applying these marks, (3) the safety benefits associated with the additional markings, and (4) the alternate methods or safeguards against overfilling of cylinders currently being implemented.

Air Products and Chemicals submitted a comment to the ANPRM that supported the petition but they did not discuss the basis for their support. CGA submitted a comment to the ANPRM supporting the inclusions of tare weight, mass weight, and water capacity requirements on newly constructed DOT 4B, 4BA, 4BW, and 4E specification cylinders at the time of manufacture but did not support—and ''strongly disagrees'' with—PHMSA's consideration of modifying § 178.35 to require all DOT-specification cylinders suitable for the transport of liquefied gases to be marked with the cylinder's tare weight and water capacity. The CGA also believed that the HMR must further clarify that no cylinder may be filled with a liquefied gas unless a mass or tare weight is marked on the cylinder, providing the following justification:

- At the time of manufacture, the manufacturer would not know whether the DOT 3-series cylinders are, or are not, to be used in a liquefied gas service.
- Marking all cylinders, as suggested by DOT, would include every cylinder manufactured in conformance with the specifications set forth in the HMR, which would therefore require cylinders that have been designed and manufactured for a specific permanent gas application to be marked for tare weight and water capacity just because the cylinder could be used (at some time) for liquefiable gas.
- There would be instances on small DOT 3-series cylinders where the additional marking would not fit onto the dome of the cylinder.
- The economic impact estimated for marking all cylinders is significantly greater than the estimates submitted by PHMSA.

Manchester Tank submitted a comment to the ANPRM expressing concern that numerous variations in stamped weights could cause confusion in the field among fillers. They stated that adding mass weight stamping to a cylinder that already has tare weight stamped could lead to incorrect filling if the wrong figure is used. They asked PHMSA to clarify who would have responsibility to assign the duty to mark tare weight to the valve installer and indicated that there are many cylinders that are not valved by the manufacturer, and further declared that those cylinders can be marked correctly with mass weight—but not with tare weight, since the weight of the appurtenance may not be known to the manufacturer of the vessel. In addition, Manchester Tank notes that available space for stamping is limited on some vessels and increased stamping will not allow significant space for retest marking information.

In the NPRM, PHMSA proposed to revise § 178.35(f) to require that tare weight or mass weight, and water capacity be marked on all DOT 4B, 4BA, 4BW, and 4E specification cylinders.

We received nine comments to the NPRM related to this issue. Fike Corporation, Janus Fire Systems, Amerex, NAFED, and FSSA submitted comments opposing the requirement to mark all DOT 4B, 4BA, 4BW, and 4E cylinders with tare weight or mass weight, and water capacity. Bancroft Hinchey, Kidde-Fenwal, Worthington Cylinder and CGA submitted comments generally supportive of the requirement, but requested certain modifications. Bancroft Hinchey requested that § 180.215 be modified to require tare weight be added to a 4-series cylinder if it changes service to liquefied gas. Kidde-Fenwal requested that the marking requirements only apply to cylinders filled with liquefied gas, and not 4-series cylinders used for other services, such as fire extinguishers containing an extinguishing agent and charged with a non-liquefied gas. Worthington Cylinder requested that the requirement only apply to cylinders filled with liquefied gas and that the regulations require specific acronyms for mass weight, tare weight, and water capacity to reduce confusion. CGA requested a minor change to the wording in § 178.35(f)(7)(iii) to ensure proper tolerance requirements as requested in P–1540.

PHMSA response. We agree with the commenters that there is no value in requiring the tare weight or mass weight, and water capacity markings for 4-series cylinders that are not used for liquefied compressed gases, as these materials are not filled by weight. However, we do not agree that relying on voluntary industry standards that may require the tare weight or water capacity on a cylinder label is adequate to alleviate our safety concerns regarding proper filling of liquefied compressed gases. We do not believe that NFPA 58 is universally followed in the cylinder industry. Additionally, the NFPA 58 does not assign a particular

[2] Note that NFPA 58 was not incorporated by reference for marking purposes but for purposes of equipping storage tanks containing LPG or propane with safety devices. See § 173.315(j).

party to apply the marks, or any accuracy requirements for the measurements. Therefore, the creation of a Federal standard for tare weight/mass weight and water capacity markings on DOT 4B, 4BA, 4BW and 4E cylinders used for only liquefied compressed gases provides a higher level of safety and oversight than the NFPA 58 standard while limiting burdens to the cylinder industry.

PHMSA expects this marking requirement to play a role in preventing overfilling incidents, which can result in explosions and fatalities. For example, in 2014, an overfilled propane cylinder ruptured, exploded, and fatally injured two people and injured others in Philadelphia.[3] Specifically, a cylinder filler, using the tare/mass weight and water capacity markings to guide their filling practice, is expected to be significantly less likely to overfill a cylinder. Adding tare weight or mass weight, and water capacity markings is expected to improve safety for cylinder fillers, transporters, and the general public by decreasing the incidence of overfilled cylinders entering transportation. Cylinders filled with liquefied gases must be filled by weight (see § 173.304a(c)). The filler must determine the weight of the cylinder in order to fill the cylinder with the proper amount of liquefied gas. The most direct way to ensure that the filler knows the weight of the cylinder being filled is to require that the cylinder's weight be marked on the cylinder itself.

By requiring these markings, PHMSA will help to eliminate confusion and guesswork while providing a potentially quicker and more efficient way to determine the cylinder weight than relying solely on reference materials listing cylinder weights. Cylinder fillers may not always have easy access to cylinder tare/mass weight and water capacity reference materials; the materials may become outdated; or the reference materials that are available may have been created by a cylinder manufacturer other than the manufacturer of the cylinder being filled.

In addition, providing the markings may prevent a cylinder filler from being required to weigh the purportedly empty cylinder to determine the tare weight, removing errors due to residue material that would overstate the tare weight when weighed manually, and also reducing burden. Further, PHMSA believes that the addition of these markings could reduce the occurrence of non-compliant filling methods, such as informally relying on auditory cues (*e.g.,* shaking the cylinder).

Increasing availability of cylinder weight and capacity information on the cylinder itself will decrease the chances of operator error leading to overfilled cylinders. Therefore, in this final rule, we are modifying the proposed requirement from the NPRM that DOT 4B, 4BA, 4BW and 4E cylinders used for only liquefied compressed gases must be marked with tare weight or mass weight, and water capacity. The details are discussed in the VII. Section-by-Section Review. We are also adopting the upper and lower tolerances for the tare weight/mass weight marking as proposed by CGA. We agree that additional markings on a cylinder may be a source of confusion, but we believe that this can be mitigated by using standardizing abbreviations. Accordingly, in this final rule we are requiring that tare weight be abbreviated ''TW'', mass weight ''MW'', and water capacity ''WC.'' The responsibility for meeting this requirement is placed on the owner of the cylinder, as they are best positioned to understand the eventual use of the cylinder at the time of manufacture. We stress that while cylinder markings are important to ensure the safe filling of liquefied compressed gas, they do not take the place of adequate personnel training, procedures to ensure proper filling, and continued requalification and maintenance of cylinders in preventing incidents.

In accordance with § 173.304a(c), liquefied gases must be filled by weight, or when the gas is lower in pressure than required for liquefaction, a pressure-temperature chart for the specific gas may be used to ensure that the service pressure at 55 °C (131 °F) will not exceed ⅝ of the service pressure at 21 °C (70 °F). An accurate scale must be used to check the weight of liquefied gas filled in the cylinder. These requirements apply to all types of cylinders, not only the 4B, 4BA, 4BW and 4E cylinders whose marking requirements we are amending in this final rule. We believe that by requiring TW, MW and WC markings for these cylinders which are most commonly used for liquefied gases, we will create the greatest safety benefit while minimizing costs to the regulated community.

We note that COSTHA submitted a comment that we left the word ''no'' out of the phrase ''[no] upper [tolerance]'' in the proposed § 178.35(f)(7)(iii) for the criteria for the water capacity marking for a cylinder exceeding 25 pounds. COSTHA is correct in its understanding. This was an inadvertent omission and we are correcting § 178.35(f)(8)(iii) (please note that the original regulatory text proposed in § 178.35(f)(7) has been redesignated as paragraph (f)(8) due to changes made to the HMR since the publication of the HM–234 NPRM) such that it reads ''with a tolerance of minus 0.5 percent and *no* upper tolerance'' in this final rule.

Lastly, we are making an editorial change in the final rule and deleting the metric units from § 178.35(f)(8) to increase clarity and decrease confusion for manufacturers, fillers, and users of these cylinders.

P–1546

GSI Training Services submitted P–1546 requesting that PHMSA allow cylinders that form a component of fire suppression systems to use the proper shipping name ''Fire extinguishers'' when offered for transportation. The Hazardous Materials Table (HMT) in § 172.101 provides a shipping description for cylinders used as fire extinguishers (*i.e.,* ''UN1044, Fire extinguishers, 2.2'') and references § 173.309 for exceptions and non-bulk packaging requirements. Fire extinguishers charged with a limited quantity of compressed gas are excepted from labeling, placarding, and shipping paper requirements under certain conditions if the cylinder is packaged and offered for transportation in conformance with § 173.309.[4] Additionally, fire extinguishers filled in conformance with the requirements of § 173.309 may use non-specification cylinders (*i.e.,* cylinders not manufactured to specifications in part 178). Part 180 also provides special requirements for cylinders used as fire extinguishers (*e.g.,* § 180.209(j) includes different requalification intervals).

PHMSA has written several letters of interpretation regarding the applicability of § 173.309 to fire extinguishers. Notably on March 9, 2005, PHMSA wrote a letter of interpretation (Reference No. 04–0202) to Safecraft Safety Equipment regarding non-specification stainless steel cylinders used as a component in a fire suppression system for installation in

[3] This incident resulted in a Federal judge ordering the company who filled the cylinder to pay a $1 million criminal. In addition, the company entered into an historic civil settlement, agreeing to pay victims and the family of those fatally injured $160 million, plus an additional confidential sum. See Moselle, Aaron. *U-Haul fined $1 million after fatal food truck explosion in North Philly.* May 7, 2019. *WHHY.org.* Available at: *https://whyy.org/articles/uhaul-fined-1-million-after-fatal-food-truck-explosion-in-north-philly/.*

[4] Note that the format of § 173.309 was changed under a final rule published January 7, 2013 (HM–215K; 78 FR 1101) such that the exceptions for limited quantities has been relocated to paragraph (d) of § 173.309.

vehicles and stated that the cylinders used in the fire suppression system appeared to meet the requirements of § 173.309. PHMSA issued another letter of interpretation (Reference No. 06–0101) on May 30, 2008, to Buckeye Fire Equipment stating that the company could not use the shipping name ''Fire extinguishers'' for their cylinders, which served as a component of a kitchen fire suppression system, and must use the proper shipping name that best describes the material contained in the cylinder because these cylinders were not equipped to function as fire extinguishers. This latter clarification effectively required cylinders that are part of a fixed fire suppression system to meet an appropriate DOT-specification.

In response to Reference No. 06–0101, GSI Training Services submitted a petition for rulemaking requesting PHMSA to allow cylinders that form a component of fire suppression systems to use the proper shipping name ''Fire extinguishers'' when offered for transportation, stating that: (1) At least one company manufactured over 39,000 non-specification cylinders for use in fire suppression systems based on the information provided in the March 9, 2005 letter; and (2) the May 30, 2008 clarification effectively placed this company out of compliance. GSI Training Services further suggested that cylinders comprising a component of a fixed fire suppression system will provide an equal or greater level of safety than portable fire extinguishers since cylinders in fire suppression systems are typically installed in buildings where they are protected from damage and not handled on a regular basis.

In the NPRM, PHMSA proposed to revise the § 173.309 introductory text to include ''fire extinguishers for installation as part of a fire suppression system'' as a fire extinguisher type authorized for transport in accordance with authorized packaging requirements as assigned to the HMT entry for fire extinguishers.

Comments. Guardian Services, Inc., Janus Fire Systems, Amerex, Worthington Cylinder and the Fire Suppression Systems Association commented in support of this proposal. Kidde-Fenwal commented in support of the proposal, but also stated that ''not all cylinders intended for use as a component of a fire suppression system should utilize the 'Fire extinguisher, UN 1044 designation' as suppression agents with their own HMT designation (example, UN 3296) should continue to be identified as such.'' That is, those fire suppression agents listed by name should continue to be described and packaged as provided in the HMT rather that as UN1044, Fire extinguishers.

The National Association of Fire Equipment Distributors (NAFED) commented in opposition to the proposal, specifically noting its concerns with allowing high pressure, inert gas cylinders used in ''engineered-type'' fire suppression systems to be transported and requalified as ''UN1044, Fire extinguishers.'' The ''engineered-type'' fire suppression systems that NAFED described are large fire suppression systems used in industrial settings that may consist of a vessel that contains an extinguishing agent and separate compressed gas ''charging'' cylinders that provide the pressure to inject the agent into the system upon activation. Other engineered systems may consist of a fire extinguishing agent pressurized with an inert gas, or consist of cylinders that contain only an inert gas.

PHMSA response. We disagree with Kidde-Fenwal. The classification of ''UN1044, Fire extinguisher'' is based on the intended use of the cylinder, and should not necessarily exclude gases listed by name in the § 172.101 HMT if the conditions of § 173.309 are met. However, we agree with NAFED's concerns regarding ''charging'' cylinders transported separately from fire suppression systems. Our intent in the NPRM was to propose allowing fire extinguishers that are charged with a compressed gas and an extinguishing agent and that are intended for installation into fire suppression systems to be described as ''UN1044, Fire extinguishers.'' We did not intend to allow cylinders charged with an inert gas and used only to pressurize a fire suppression system to be described as ''UN1044, Fire extinguishers'' when offered for transportation separately from the suppression system. These ''charging'' cylinders must be described based on the compressed gas they contain, for example ''UN1066, Nitrogen.'' or ''UN1006, Argon.''

In this final rule, we are adopting the proposed change to § 173.309, and further clarifying our meaning. A fire extinguisher charged with a compressed gas and an extinguishing agent that is intended for installation into a fire suppression system may be described as ''UN1044, Fire extinguisher'' if it meets the conditions of § 173.309. A fire extinguisher charged with a compressed gas that is the sole extinguishing agent in the system that is intended for installation into a fire suppression system may also be described as ''UN1044, Fire extinguisher'' if it meets the conditions of § 173.309. A cylinder charged with a gas and used only to pressurize or expel an extinguishing agent as part of a fire suppression system may not be described as ''UN1044, Fire extinguisher'' for purposes of the HMR.

Section 173.309(a) requires the use of a DOT-specification cylinder, as is generally required for a compressed gas, and further requires the use of dry gas and extinguishing agents that are commercially free from corroding components. The safety and performance of DOT specification cylinders filled with dry gas and an extinguishing agent commercially free of corroding components and requalified as provided in § 180.209(j) is expected to be the same for manual use (*i.e.,* handheld) and for use in fixed fire suppression system service. Section 173.309(b) requires the use of Specification 2P or 2Q non-refillable inside metal containers, filled with a non-corrosive extinguishing agent. DOT 2P and 2Q containers are very limited in size and service pressure by their design specification in §§ 178.33 and 178.33a, and therefore would have limited utility for a fixed fire suppression system. Finally, with respect to authorizing use of non-DOT specification cylinders, we believe the requirements in § 173.309(c) provide for the safe transportation of compressed or liquefied gas regardless of whether the cylinder is equipped for manual use as a fire extinguisher (*i.e.,* handheld) or for use as a fire-extinguishing component of a fire suppression system.

Section 173.309(c) allows the use of non-specification cylinders filled with a non-corrosive extinguishing agent as fire extinguishers. These non-specification cylinders are limited in size to 1,100 cubic inches, or 55 cubic inches if they contain any liquefied compressed gas. The cylinders must be pressure tested to three times (3x) their charged pressure prior to initial shipment, and must be designed with a burst pressure six times (6x) their charged pressure. This exceeds the burst pressure ratio of DOT-specification cylinders authorized under § 173.309(a). These non-DOT specification cylinders must additionally be periodically requalified in accordance with the requirements of the Department of Labor's Occupational Safety and Health Administration regulations pertaining to ''portable fire extinguishers'', 29 CFR 1910.157. The combination of size restriction, higher than normal initial test pressure requirements, and much higher than normal burst pressure capability creates an equivalent level of safety for these non-DOT specification fire extinguishers when compared to DOT

specification cylinders. We expect the same level of safety will be achieved in handheld and fire suppression system service.

Note that the changes made in this final rule do not affect the description and classification of large fire extinguishers (see HM–215M, 80 FR 1075, 1/8/2015 for background), which may contain ''charging'' cylinders when transported as a completed fire extinguishing system provided they meet the conditions of § 173.309.

P–1560

Air Products and Chemicals Inc. (Air Products) submitted a petition for rulemaking (P–1560) requesting that PHMSA revise § 173.304a(a)(2) to adopt the provisions of SP 13599. SP 13599 authorizes additional maximum filling densities for carbon dioxide and nitrous oxide to include 70.3 percent, 73.2 percent, and 74.5 percent respectively in DOT 3A, 3AA, 3AX, 3AAX, 3AL, and 3T cylinders with marked service pressures of 2000, 2265, and 2400 psig, subject to operational controls. In the NPRM, we did not propose to adopt this provision because it was already adopted in the HMR by HM–233F (81 FR 3635).

We received two comments related to P–1560 in this docket. Worthington Cylinder agreed with our determination in the NPRM that we had already adopted these provisions and therefore do not need to address them again. Independent Cylinder Training (ICT) submitted a comment proposing additional changes to § 173.304a(a)(2). ICT requested that cylinders with a service pressure of 2015 psig be authorized for 70.3% fill density, like those with a service pressure of 2000 psig. Additionally, ICT requested that PHMSA add a provision to require that cylinders filled according to fill density be marked with the water weight of the cylinder to aid in the filling process.

PHMSA response. ICT's understanding of filling density requirements for carbon dioxide is not correct. In the scenario it presents, a cylinder with a service pressure of 2015 psig is already authorized for a filling density of 70.3 percent for carbon dioxide. ICT's other proposal regarding marking of water weight on a cylinder is beyond the scope of this rulemaking and we suggest that ICT submit a separate petition for rulemaking on the issue. As previously stated, P–1560 provisions were adopted into the HMR by rulemaking HM–233F, and therefore we are not addressing it in this final rule.

P–1563

3M Corporation submitted P–1563 requesting that PHMSA address the regulatory confusion between marking requirements for overpacks in § 173.25 and outside packages for certain thin-walled cylinders specified in § 173.301(a)(9). The petitioner notes that the differing marking requirements in §§ 173.25 and 173.301(a)(9) create confusion and make training difficult. This petition requests modification of the HMR to permit materials packaged in conformance with § 173.301(a)(9)—except aerosols ''2P'' and ''2Q''—to display the ''OVERPACK'' marking described in § 173.25, in lieu of the current requirement for ''an indication that the inner packaging conforms to prescribed specifications.''

In the NPRM, we recognized that differing marking requirements in §§ 173.25 and 173.301(a)(9) to communicate the same intended meaning may be causing confusion without enhancing safety. In order to address the petition and provide for greater clarity, PHMSA proposed to revise § 173.301(a)(9) to authorize use of the ''OVERPACK'' marking as specified in § 173.25(a)(3) as a method to satisfy the current requirement in paragraph (a)(1) to mark the completed package with an indication that the inner packagings conform to prescribed specifications for the listed cylinders. We agreed with 3M that the issue is more complex for 2P and 2Q containers as specified in §§ 173.304, 173.305, and 173.306, and therefore did not propose to include 2P and 2Q in the allowance for the ''OVERPACK'' marking. We proposed additional instructional language that the combination package is not to be considered an ''overpack.''

We received two comments on this issue. Alaska Air stated their opposition to the proposed changes. Alaska Air states that the proposed change is at variance with the existing § 171.8 definition of combination package, which will result in additional confusion by the hazmat community, and that most shipments marked as proposed will be rejected by air carriers because the ''overpack'' mark will be placed on outer packages that are not overpacks.

COSTHA also submitted comments regarding this issue. COSTHA ''supports this [revision] in principle and agrees with PHMSA and the petitioner, 3M, that the differing marking requirements in § 173.25 and § 173.301(a)(9) to communicate similar conditions may be causing confusion without enhancing safety.'' However, COSTHA also notes that the sentence, ''[d]isplay of the 'Overpack' marking is not an indication that this combination package is an overpack'' is confusing, and recommends that it be deleted.

PHMSA response. PHMSA agrees with Alaska Airlines and COSTHA that the proposed change could result in more confusion than it would resolve and would not promote compliance with the HMR. Upon further consideration, we do not believe a regulatory change is warranted. The marking requirement in § 173.301(a)(9) applies to a completed package. The requirements in § 173.25 apply to an enclosure used to protect or consolidate completed packages. The ''OVERPACK'' applies to the enclosure when specification packages are required and are not visible. We do not view this as overly confusing. Therefore, in this final rule we are not adopting any changes proposed in the NPRM based on P–1563.

P–1572

Barlen and Associates submitted P–1572 requesting that PHMSA explicitly state in § 173.312 that for liquefied compressed gases in Multiple-Element Gas Containers (MEGCs), the filling density of each pressure receptacle must not exceed the values contained in Packing Instruction P200 of the UN Model Regulations, as specified in § 173.304b, and the contents of each DOT-specification cylinder cannot exceed the densities specified in § 173.304a(a)(2).[5] The definition of MEGC in § 171.8 states DOT-specification cylinders are not authorized as part of MEGCs and accordingly, we are not including the petitioned language referring to DOT-specification cylinders in § 173.312. DOT-specification cylinders filled with liquefied compressed gas must be filled in accordance with the instructions found in § 173.304 and § 173.304a, including filling density limitations.

Requirements for shipping MEGCs are specified in § 173.312. Specifically, § 173.312(b) details the filling requirements for MEGCs and states, ''[a] MEGC may not be filled to a pressure greater than the lowest marked working pressure of any pressure receptacle [and a] MEGC may not be filled above its marked maximum permissible gross mass.'' The requirement that each pressure receptacle contained in the MEGC may not be filled above the working pressure of the lowest marked

[5] Note that the petition specifically referenced the 17th edition of the UN Model Regulations; however, we will propose a change that references the edition currently incorporated by reference in § 171.7 because we biennially update the edition for harmonization with international standards.

working pressure of any pressure receptacle is clear for permanent (non-liquefied compressed) gases, which are generally filled by pressure; however, § 173.312(b) does not contain a corresponding requirement addressing pressure receptacles containing a liquefied compressed gas, which are most often filled by weight. This lack of specificity for MEGCs containing liquefied compressed gas has led to some confusion on methods for their proper filling. Therefore, in the NPRM, we proposed to specify the filling ratio requirements for pressure receptacles.

We received comments supporting this proposal from CGA and Worthington Cylinder, and comments requesting modification to the proposed language from FIBA Technologies (FIBA).

(1) Manifolding While Filling

We received a comment from FIBA stating their opposition to the sentence ''Manifolding while filling is not authorized.'' FIBA states there would be no safety benefit to removing the manifold for many MEGCs during filling because the MEGCs can be filled safely with the manifold in place.

PHMSA response. We agree with FIBA's comment. It was not our intent to require the disconnection of the manifold during filling. Rather, our intent is to require that each pressure receptacle is filled individually when loading liquefied compressed gases. We acknowledge that the manifold may remain in place as long as there are measures in place to prevent more than one cylinder from being filled at a time when loading liquefied compressed gas. Therefore, in the final rule we will remove the sentence ''[m]anifolding during filling is not authorized.''

(2) Filling With Non-Liquefied Gases

FIBA also noted that our proposed revision accidently removed the language currently in § 173.312(b)(1) relevant to the filling of MEGCs with ''permanent'' or non-liquefied gas.

PHMSA response. This was not our intent; therefore, in the final rule we will move the current language for permanent gases in § 173.312(b)(1) to new § 173.312(b)(1)(i) and insert the language appropriate for filling with liquefied compressed gases in the new § 173.312(b)(1)(ii). Additionally, we agree with FIBA's suggestion that there is value in specifying that § 173.312(b)(1)(i) applies to filling MEGCs with permanent, non-liquefied compressed gases, which are filled by pressure, while § 173.312(b)(2)(ii) applies to liquefied gases, which are filled by weight.

In this final rule, we are adopting P–1572, with the modifications noted above. PHMSA emphasizes that this change does not impose a new burden, as adoption of this proposal only emphasizes an important safety requirement already stated in § 173.304b for UN pressure receptacles.

P–1580

HMT Associates submitted P–1580 requesting that PHMSA revise §§ 173.302(f)(2) and 173.304(f)(2) to require that the burst pressure of a rupture disc align with CGA S–1.1 for DOT 39 cylinders filled with an oxidizing gas and offered for transportation by air. Specifically, as prescribed in 4.2.2 of CGA S–1.1, the required burst pressure of the rupture disc ''shall not exceed 80 percent of the minimum cylinder burst pressure and shall not be less than 105 percent of the cylinder test pressure.''

Section 173.301(f) states that a cylinder filled with a compressed gas and offered for transportation ''must be equipped with one or more [pressure relief devices (PRDs)] sized and selected as to type, location and quantity and tested in conformance with CGA S–1.1 [*Pressure Relief Device Standards—Part 1—Cylinders for Compressed Gases,* Fourteenth Edition (2005)] and CGA S–7 [*Method for Selecting Pressure Relief Devices for Compressed Gas Mixtures in Cylinders* (2005)].'' Sections 172.302(f)(2) and 172.304(f)(2) specify that the rated burst pressure of a rupture disc for DOT 3A, 3AA, 3AL, 3E, and 39 cylinders, as well as that for UN ISO 9809–1, ISO 9809–2, ISO 9809–3, and ISO 7866 cylinders containing oxygen, compressed; compressed gas, oxidizing, n.o.s.; or nitrogen trifluoride, must be 100 percent of the cylinder minimum test pressure with a tolerance of 'plus zero' to minus 10 percent.

In response to PHMSA's NPRM entitled ''Hazardous Materials: Miscellaneous Amendments'' published on September 29, 2010 (75 FR 60017) under Docket No. PHMSA–2009–0151 (HM–218F), HMT Associates submitted a late-filed comment that identified a potential discrepancy between the HMR and CGA S–1.1. Specifically, this commenter stated the HMR have different PRD settings than CGA S–1.1 for DOT 39 cylinders that make it virtually impossible to comply with both the HMR and CGA S–1.1. Sections 173.302(f)(2) and 173.304(f)(2) require the rated burst pressure of a rupture disc for DOT 3A, 3AA, 3AL, 3E, and DOT 39 cylinders to be 100 percent of the cylinder minimum test pressure with a tolerance of 'plus zero' to minus 10 percent, whereas section 4.2.2 of CGA S–1.1 requires the rated burst pressure of the rupture disc on DOT 39 cylinders to be not less than 105 percent of the cylinder test pressure.

In the NPRM, PHMSA proposed to revise § 173.301(f) as it applies to DOT 39 cylinders to alleviate any confusion and conflict between the PRD requirements in § 173.301(f) and those in §§ 173.302(f)(2) and 173.304(f)(2) with respect to minimum burst pressure of pressure relief devices on a DOT 39 cylinder used for the transport of compressed and liquefied oxidizing gases by air.

We received comments from HMT Associates and Worthington Cylinder regarding P–1580. Both comments correctly noted that in the NPRM we failed to amend the regulatory text in §§ 173.302 and 173.304 as we stated in our NPRM discussion.

PHMSA response. We agree with HMT Associates' comment noting that the proposed language in § 173.301(f)(4)(iv) is not strictly necessary, because by revising §§ 173.302(f)(2) and 173.304(f)(2) we will have brought the HMR into alignment with CGA S–1.1 requirements. However, we will maintain the reference to the new requirements in § 173.301(f)(4)(iv) to increase the visibility of the new requirements. We did not receive any comments opposed to the proposed change. Therefore, in the final rule, we are amending §§ 173.302 and 173.304 to align with CGA S–1.1 requirements for DOT 39 cylinders for oxidizing gases transported by air. To avoid placing cylinders in conformance with the current requirements of §§ 173.302(f)(2) and 173.304(f)(2) out of service, we will allow cylinders filled prior to the effective date of this rulemaking that meet the current requirements of the HMR to remain in service until the end of their useful lives.

P–1582

Water Systems Council submitted P–1582 requesting that PHMSA revise § 173.306(g), which provides a limited quantity exception for water pump system tanks, by permitting tanks manufactured to American National Standards Institute (ANSI)/Water Systems Council (WSC) standard PST 2000–2005 (2009) to be authorized for transport.

The ANSI/WSC standard PST 2000–2005 prescribes minimum performance and construction requirements for pressurized storage tanks for service in water well systems with a maximum factory pre-charge pressure of 40 psig (280 kPa), to be operated in ambient air temperatures up to 120 °F (49 °C), with

maximum working pressures not less than 75 psig (520 kPa) and not greater than 150 psig (1,000 kPa) and tank volumes not exceeding 120 gallons (450 L). The standard was developed by a group of WSC members comprised of leading U.S. manufacturers of pressurized water storage tanks for water wells to define and promote—through voluntary written standards—minimum performance and construction requirements for pressurized water storage tanks for service in water well systems. Aligning the HMR with this industry standard will provide minimum requirements for pressurized water storage tanks for water wells that provide at least an equivalent level of safety as currently provided in the HMR.

The revised requirements for water pump system tanks in this final rule authorize tanks to be tested to the manufacturer's specified maximum working pressure instead of the current one size fits all requirement of 100 psig. Further, it allows water pump system tanks to be charged with helium in addition to the currently authorized nitrogen. The requirements in this final rule allow additional flexibility for manufacturers compared to current requirements. Therefore, PHMSA does not expect this amendment to impose costs. PHMSA received one comment in support of this proposal from Worthington Cylinder.

In the NPRM, we proposed to change the pneumatic test requirement from 100 psig to the manufacturer's specified maximum working pressure because the industry standard allows for maximum working pressures greater than 100 psig (*i.e.,* up to 150 psig as stated above). In this final rule, we will specify that the pneumatic test may not exceed 150 psig, which aligns with ANSI/WSC PST 2000–2005 maximum working pressure for a water pump system tank. Pneumatic pressure tests present additional risks to testing personnel, and this modification is intended to reduce risk by clarifying the maximum test pressure allowed while remaining aligned with the industry standard.

We are making several additional editorial changes to the layout and language of § 173.306(g) in order to clarify the intent of the provision. Specifically, we are modifying the introductory paragraph of § 173.306(g) to clarify our intent to allow the tanks to be filled with air, nitrogen, or helium up to 40 psig at time of manufacture, referred to in ANSI/WSC PST 2000–2005 as a ''pre-charge.'' Further, we are replacing the word ''charged'' with ''pre-charge'' throughout the paragraph to clarify that the manufacturer's pre-charge pressure is the pressure that should be used in calculations, where appropriate.

We are modifying § 173.306(g)(1) to explain clearly the maximum allowable working pressure limits of water pump system tanks. The requirement that these tanks may be operated in ambient air temperatures of up to 49 °C (120 °F) with a maximum working pressure not less than 517.1 kPa (75 psig) and not greater than 1034.2 kPa (150 psig) is taken from the ANSI/WSC PST 2000–2005 standard. Our intent is to impose a limit on the marked maximum working pressure for a water pump tank system at 150 psig, (*i.e.,* the upper end of the maximum working pressure), to ensure pneumatic testing is not conducted above this pressure at time of manufacture to prevent increased dangers for testing employees. Given that the new MAWP limit in § 173.306(g)(1) aligns with the industry standard and is above the limit for water distribution piping operations, PHMSA does not believe that this requirement will introduce any additional burdens on manufacturers.

We are removing the phrase ''concave dome tanks'' from § 173.306(g)(3) for clarity because we consider this language to be redundant to the requirement in § 173.306(g)(1) that requires all tanks to have heads concave to pressure.

Finally, we are not adopting proposed paragraph (g)(4), which discussed a design leakproofness test for composite tanks. We do not believe that requiring this test for composite tanks is necessary in the HMR. Our main transportation safety concern with water pump system tanks remains their burst pressure, and we believe that inclusion of the proposed design hydrostatic leakproofness test for composite tanks will increase confusion. All tanks, steel and composite, are subject to a pneumatic proof pressure test at the manufacturer's maximum allowable working pressure at time of manufacture (see § 173.306(g)(1)). All tank designs, both steel and composite, must also have a burst pressure at least 6x the pre-charge pressure at 21.1 °C (70 °F) or 3x the manufacturer's specified maximum working pressure, whichever is greater, as proposed. These modifications to the proposed language are intended to increase clarity without making any substantive changes to the provisions proposed in the NPRM.

In this final rule, PHMSA will adopt provisions of P–1582 as proposed with the modification noted above.

P–1592

The CGA submitted P–1592 requesting that PHMSA replace the 2005 edition of CGA S–1.1, *Pressure Relief Device Standards—Part 1—Cylinders for Compressed Gases* with the 2011 edition as referenced in the HMR.

CGA S–1.1 provides standards for selecting the correct pressure relief device (PRD) to meet the requirements of § 173.301(f) for over 150 gases. It provides guidance on when a pressure relief device can be optionally omitted and when one's use is prohibited, as well as direction on pressure relief device manufacture, testing, operational parameters, and maintenance. CGA S–1.1 is available for purchase online and will be available for public inspection at the Hazardous Material Information Center after publication of the final rule.

This minor update to the regulations improves the timeliness and clarity of industry standards that are incorporated by reference. It supports the goal of facilitating the use of industry standards and reducing the burdens associated with references to outdated material.

Bancroft Hinchey, Worthington Cylinder, NAFED, CGA and FIBA Technologies submitted comments supporting incorporation by reference of the 2011 edition of CGA S–1.1. FIBA Technologies additionally identified an inconsistency with the HMR and new S–1.1 requirements. FIBA Technologies correctly noted that the requirements for pressure relief devices in § 173.302a(c)(4)(ii) conflict with the 2011 edition of CGA S–1.1 that we are incorporating by reference in this rulemaking. Accordingly, we are amending § 173.302a(c)(4)(ii) to reflect that PRDs are optional for hydrogen tube trailers. Shippers are not required to install PRDs on tubes (cylinders longer than 12 feet) shipped in accordance with this paragraph, however their continued use and installation is authorized. This change maintains regulatory flexibility and alignment with accepted industry practice. This change does not impose any new requirements and increases regulatory flexibility by allowing hydrogen tube trailer shippers the option of continuing to use PRDs. In this final rule, we are incorporating by reference CGA S–1.1, 2011 as proposed.

P–1596

Chemically Speaking, LLC submitted P–1596 which requested that PHMSA revise the HMR pertaining to salvage drums. Specifically, P–1596 proposed amending § 173.3(d) to allow Class 4 and Class 5 materials to be placed in salvage cylinders.

Three commenters commented on this proposal. Dow Chemical Company and Worthington Cylinder supported the adoption of the petition as proposed. CGA opposed the adoption of the petition on the basis of safety, stating that they do not support revising salvage drum provisions in the HMR to allow Class 4 and Class 5 to be placed in salvage vessels because chemically reactive materials may produce pressures exceeding their pressure ratings. CGA suggests that a special permit or approval should be required for this activity.

PHMSA response. We agree with Dow and Worthington and do not agree with CGA's comment. We proposed to allow the use of salvage *cylinders* (emphasis added), which are much more robust packagings than the salvage *drums* that CGA mentions. PHMSA acknowledges that the NPRM discussion of this proposal may have led to CGA's overly broad interpretation PHMSA's intent because we used the term ''drum'' even though the petition only applies to salvage cylinders. There is currently no restriction preventing shippers from placing Class 4 and Class 5 materials in salvage drums. Salvage cylinders are currently authorized to transport liquefied gases (such as carbon dioxide) and many toxic gases (Division 2.3). These materials are both high and low pressure so the salvage cylinders must be constructed and designed to handle the possible pressures of the packaged materials at temperatures up to 55 °C. Salvage cylinder design criteria ensure safety and containment of a leaking cylinder so it can be transported to a disposal facility. Adding Class 4 and Class 5 materials will not create any significant change in the risk when using salvage cylinders as long all the requirements of § 173.3(d) are met. No Class 4 and Class 5 materials can be as toxic as the Division 2.3 or Division 6.1 materials currently allowed, nor can they generate pressure that would exceed the pressures of the Division 2.1, 2.2, or 2.3 materials currently allowed. Thus, we believe adding these materials as authorized in salvage cylinders will maintain the same level of safety established by the regulations.

CGA also suggested allowing Class 4 and Class 5 materials to be placed in salvage cylinders under the provision of an approval.

PHMSA response. We believe a requirement to receive an approval to use a salvage cylinder for Class 4 and Class 5 materials to be impractical in emergency situations. Additionally, as we have not identified any increased risk by providing this general allowance, imposing a burden on users to obtain an approval would also not be practical. We do not believe there will be any decrease in safety by allowing shippers to place Class 4 and Class 5 materials in more robust salvage cylinders. Therefore, we are adopting P–1596 as proposed, and amending § 173.3(d) accordingly.

P–1622

Worthington Cylinder submitted P–1622 requesting that PHMSA limit the internal volume of DOT 39 cylinders containing liquefied flammable gas to 75 cubic inches (in^3), to correct an error dating to 2002.

(1) 75 Cubic Inch Limit

Prior to the publication of HM–220D (67 FR 51626; Aug. 8, 2002), the HMR restricted the internal volume of DOT 39 cylinders to 75 in^3 for all non-liquefied flammable compressed gases and the following flammable liquefied gases: Cyclopropane, ethane, ethylene and liquefied petroleum gas. In the HM–220 NPRM (63 FR 58460; Oct. 30, 1998), we proposed to increase the applicability of this restriction to all flammable liquefied gases, but did not adopt the change on the basis of negative comments in the HM–220D final rule. The HM–220D final rule, however, contained a drafting error that removed the 75 in^3 restriction from liquefied gases completely, which was not our intent.

Worthington Cylinder submitted P–1622 on July 19, 2013, requesting that PHMSA impose a volume restriction of 75 in^3 on DOT 39 cylinders containing the liquefied gases cyclopropane, ethane, ethylene, and liquefied petroleum gas. On October 10, 2014, Worthington Cylinder submitted a supplement to P–1622, requesting that PHMSA restrict the volume of DOT 39 cylinders containing any liquefied flammable gas to 75 cubic inches. In the NPRM, we proposed to adopt this second proposal and restrict the volume of DOT 39 cylinders containing any liquefied flammable gas to 75 cubic inches.

CGA and Worthington Cylinder submitted comments supporting our proposed action to restrict the volume of DOT 39 cylinders containing any liquefied flammable gas to 75 cubic inches. We received comments from Worthington Cylinder, Ford Motor Company, Amtrol, Chemours, COSTHA, and Honeywell requesting that we create an exception to the proposed 75 in^3 limit for ASHRAE A2L ''mildly flammable'' gases. We did not receive any comments directly opposed to the creation of a general 75 in^3 limit for liquefied flammable gases in DOT 39 cylinders. The commenters explained that, in the years since the 75 in^3 restriction was inadvertantly deleted, they have begun safely transporting certain Division 2.1 refrigerant gases in DOT 39 cylinders larger than 75 in^3. They also submitted technical data describing the properties of ASHRAE A2L ''mildly flammable'' gases and demonstrated the performance of a DOT 39 cylinder with a capacity over 75 in^3 filled with an A2L gas in a bonfire test.

PHMSA response. In this final rule, we are modifying our proposed change to § 173.304a and imposing a 75 in^3 limit on the capacity of DOT 39 cylinders containing the following liquefied flammable gases: Cyclopropane, ethane, ethylene and liquefied petroleum gas. This course of action will correct the inadvertent error we made in HM–220D and aligns with PHMSA's safety advisory notice published April 24, 2017 (PHMSA–2016–14; 82 FR 18967). This will also sufficiently address the economic concerns raised by Worthington Cylinder, Ford Motor Company, Amtrol, Chemours, COSTHA, and Honeywell regarding the applicability of the 75 in^3 limit for hydrofluoroolefin and dihalogenoalkane refrigerants.

(2) Chemicals Under Pressure

Dow Chemical Company submitted a comment requesting clarification about the size limitation for chemicals under pressure in § 173.302a(a)(3).

PHMSA response. The limit is only intended to apply to Division 2.1 (flammable gas) chemical under pressure. However, as we noted in the NPRM, the 50 L limit is much larger than the maximum size authorized for the DOT 39 specification in § 178.65. This discrepancy was an unintentional outcome of a harmonization effort with international requirements for non-refillable cylinders, which allow larger sizes than the HMR allow (see Docket No. PHMSA–2012–0027 (HM–215L); 78 FR 988). To reduce confusion introduced by the conflict of the 50 L quantity in § 173.302a(a)(3) and the capacity limts of the specification, we are deleting the reference to ''50 L (3050 in^3)'' and replacing it with reference to the DOT 39 specification capacity limits—1526 in^3 for a service pressure of 500 psig or less, and 277 in^3 for a service pressure of greater than 500 psig.

P–1626

The CGA submitted P–1626 requesting that PHMSA incorporate by reference (IBR) CGA C–1, *Methods for Pressure Testing Compressed Gas Cylinders,* Tenth Edition (2009) and revise the regulations regarding the

retesting of cylinders by the hydrostatic test as they are not only unclear to requalifiers, but also missing necessary information rendering the regulations unenforceable. Although the petition proposed the Tenth Edition, currently there is an Eleventh Edition (2016) available. In the NPRM, PHMSA proposed to incorporate by reference this most current version and requested comment regarding this action. We received no adverse comments related to adoption of the newest edition (*i.e.,* CGA C–1–2016 (11th Ed.)) of the standard versus the Tenth Edition. However, we did receive numerous comments regarding the incorporation by reference of CGA C–1–2016 (11th Ed.) (''CGA C–1'') and associated revisions, which we will discuss in depth as follows.

In this final rule, PHMSA is adopting clarifying language and incorporating by reference the CGA C–1 standard, as proposed in P–1626. CGA C–1 provides more detailed instructions and illustrations for use by cylinder requalifiers and manufacturers than what is possible in the HMR and addresses the deficiencies detailed in the petition. This incorporation by reference applies to the following sections: §§ 178.36, 178.37, 178.38, 178.39, 178.42, 178.44, 178.45, 178.46, 178.47, 178.50, 178.51, 178.53, 178.55, 178.56, 178.57, 178.58, 178.59, 178.60, 178.61, 178.65, 178.68, 180.205, and 180.209. The incorporation of CGA C–1 supports the goal of increasing compliance and improving overall safety as its reference increases clarity and provides enhanced guidance compared to the current language in the HMR. Cylinder requalifiers and manufacturers must comply with CGA C–1 requirements for pressure testing cylinders, as well as equipment accuracy and calibration. Specific clarifications include instructions for performing volumetric expansion tests using both the water-jacket and direct expansion methods, as well as a provision for retesting in case of equipment failure or operator error and re-naming the ''hydrostatic test'' paragraph to ''pressure test'' to align more with industry accepted nomenclature. PHMSA believes that CGA C–1's inclusion of ''operator error'' as a condition allowing a repeated test at a higher pressure will prevent the condemnation of cylinders that are safe for continued use. Revising the HMR to incorporate by reference CGA C–1 will provide the desired clarification without imposing requirements that are potentially costly or unnecessarily difficult.

(1) Response to Hydro-Test Products

We received numerous comments regarding incorporation by reference of CGA C–1, and about interpretation of CGA C–1 requirements. Hydro-Test Products [6] submitted a comment requesting clarification of CGA C–1 requalification requirements compared to the current requalification requirements in part 180, subpart C, of the HMR. Hydro-Test Products states,

> The authors of the CGA C–1 pamphlet have included definitions and examples of calibration and accuracy for Expansion Indicating Devices (EID) and Pressure Indicating Devices (PID) that will restrict most all current licensed cylinder re-qualifiers from performing cylinder re-qualification. Furthermore, there are statements in the C–1 that discriminate against procedures and equipment components that have been utilized in a safe, consistent and accurate manner for many years.

PHMSA response. We disagree with Hydro-Test Products and address the issues they raise below.

(a) Expansion Indicating Device Accuracy

Hydro-Test Products describes a burette arrangement with 4 burettes with full scales of 0–25, 0–50, 0–125 and 0–360 cubic centimeters (cc) and explains their belief that incorporation by reference of CGA C–1 will significantly restrict the usable range of the burettes to half of the burette's scale, instead of the much broader range that they believe are authorized under the current HMR.

PHMSA response. Hydro-Test Products understanding of the HMR's current requirements is not correct. The HMR currently require use of burettes in the same manner prescribed in CGA C–1. Hydro-Test Products misunderstanding appears to be grounded in the final rule published on May 28, 1996, known as HM–220A, (61 FR 26750). HM–220A created the requirement that expansion indicating devices (EID), such as burettes or scales, must be certified as having an accuracy of ±0.5 percent, of its full range, and must be accurate to ±1.0 percent of the total expansion of any cylinder tested or 0.1 cubic centimeter, whichever is larger. These accuracy requirements, as discussed in the HM–220A final rule (61 FR 26751), are separate and distinct from the requirement that the EID permit reading to ±1 percent of the total expansion. The reading requirements are intended to address the resolution of the EID, which is not the same as the accuracy of the EID. In the example of the burette with a full scale of 50 cc, with an accuracy grade of ±0.5 percent and increments of 0.1 cc (mid-point interpolation allowed to 0.05), the resolution would permit reading down to 5 cc (*i.e.,* interpolation to 0.05 is 1 percent of 5 cc), but the accuracy of the device would not. A burette with a full scale of 50 cc and full-scale accuracy of ±0.5 percent has an expected deviation of ±0.25 cc. The device may only be used to measure total expansion greater than 25 cc, because at total expansions lower than 25 cc, the expected deviation will be greater than ±1 percent of the total expansion. Using the 5 cc example, a 0.25 cc deviation (*i.e.,* the expected deviation for a 50 cc burette with an accuracy grade of ±0.5 percent) at a total expansion of 5 cc would be a 5% deviation, and would not meet the requirement that the EID is accurate to ±1% of the total expansion.

Moreover, we do not agree that incorporation by reference of CGA C–1 will impose new cost burdens upon cylinder requalifiers because the current regulatory standard has been in place since 1996, and the requirements will not change with incorporation by reference of CGA C–1. Hydro-Test Products states that a similar issue exists for requalifiers using a scale as their EID. Our response is the same: The current regulatory standard has been in place since 1996, and the requirements will not change with incorporation by reference of CGA C–1.

(b) Total and Permanent Expansion Accuracy

Hydro-Test Products asks how EIDs can be used to measure permanent expansion when that permanent expansion is a much lower value that the total expansion, *i.e.* the permanent expansion is out of the range allowed for the total expansion.

PHMSA response. Hydro-Test Products is correct that permanent expansion values are much lower than total expansion values. The HMR has always accepted a greater accuracy deviation for permanent expansion, and this does not change in CGA C–1. Accuracy requirements for EIDs continue to be expressed in terms of the total expansion value.

(c) Foreknowledge of Total Expansion

Hydro-Test Products asks, ''[s]ince there is no indication of the total expansion value on DOT specification

[6] PHMSA notes that Jeff Elliot, Noble Gas Solutions, Anthony King, W Andrews, and Scuba Do submitted comments supporting the Hydro-Test Products comment and opposing the incorporation of CGA C–1. While the discussion below focuses on the specific comments from Hydro-Test Products, it also addresses the subject matter raised by these other comments supporting the Hydro-Test Products comment.

cylinders, how is a re-qualifier supposed to know what burette or scale is applicable and within the proposed regulations for a given test?''

PHMSA response. If a requalifier is completely unaware of the approximate expected total expansion for a cylinder, the requalifier may pressurize the cylinder at or below 90 percent of test pressure, which will give an approximate value for total expansion, allowing the requalifier to select the proper EID for the test. If the operator errs and the cylinder is tested using an EID that cannot measure the total expansion to ±1 percent, he or she may repeat the test up to two times, in accordance with CGA C–1 section 5.7.1. Note that pressurizing the cylinder at or below 90 percent of test pressure does not constitute a test.

(d) Pressure Indicating Device Accuracy

Hydro-Test Products describes a scenario with four pressure indicating devices (PIDs) with the understanding that CGA C–1 will significantly limit the usable range of the gauges.

PHMSA response. We acknowledge that there are other ways to demonstrate compliance with the accuracy requirements for PIDs (*e.g.* certifying gauges at pressures lower than their manufacturer's rated full scale). We believe this practice is in accordance with the HMR and with CGA C–1 because a gauge calibrator has, in effect, certified a gauge to better than a ±0.5 percent full scale accuracy when he or she calibrates the gauge to demonstrate ±1 percent accuracy at points lower than the normally usable range of the gauge based on the manufacturer's rated accuracy. The ±1 percent accuracy requirement is only a minimum standard, and gauge manufacturers or other entities certifying the accuracy are free to demonstrate that the gauge meets the ±1 percent requirement at other, lower points on the gauge.

The examples provided in CGA C–1 are only a guide, and should not be used to prevent the use of PIDs at lower pressures provided the gauge calibrator documents the calibration points on the calibration certificate. The minimum accuracy and readability standards are such that it limits the use of any PID to (the upper) half the gauge, however, there is no limitation on using a gauge certified to be more accurate across its full range, thus allowing broader use of the gauge. PHMSA reviewed this practice in Letter of Interpretation Ref. No. 14–0112, and at this time we have no reason to believe that this practice is unsafe. To clarify our intent further to continue to allow this practice, in this final rule we are not requiring compliance with CGA C–1 paragraph 5.3.2.2, which discusses accuracy requirements for PIDs, if the required accuracy of the PID can be demonstrated by other recognized means such as calibration certificates.

Rather we are maintaining the HMR's current PID accuracy requirements in § 180.205(g)(3)(i). Voluntary compliance with CGA C–1 5.3.2.2 is authorized and will meet the HMR's accuracy requirements for PIDs used for cylinder requalification, as will the practice of demonstrating accuracy through maintenance of a calibration certificate showing the gauge has been certified to meet the accuracy requirements at lower points. Regardless of the method used to determine the usable range of the gauge, the cylinder requalifier must verify that the system is accurate to within 1 percent of the test pressures to be tested that day, as provided in CGA C–1 paragraph 5.5.

(e) Reference Zero Expansion

Hydro-Test Products requests clarification of the term ''reference zero expansion'' in CGA C–1, sections 3.2.22.

PHMSA response. In the verification process, it is critical that the calibrated cylinder show zero expansion to indicate that the system set-up is accurate and ready for testing. The term ''reference zero expansion'' is intended to clarify that when reading the calibrated cylinder's permanent expansion during verification, an expansion reading of ±0.1cc or ±0.1 percent of total expansion, whichever is larger, is accepted as zero.

(f) Daily Verification

Hydro-Test Products states that the requirement to verify all test equipment to be used that day is impossible for those companies that are utilizing burette systems on the volumetric tester and generally unnecessary.

PHMSA response. We disagree. This is a long-standing requirement that is currently found in the HMR in § 180.205(g)(4). All PIDs, EIDs, and water jackets that are to be used that day must be verified under the current requirements of the HMR. We do not believe any additional costs will be imposed by incorporating CGA C–1 because this industry standard has the same requirements as are already required for cylinder requalifiers under the HMR.

(g) Calibrated Cylinders as Surge Tanks

Hydro-Test Products and Galiso question the reasoning for CGA C–1's prohibition on the use of a calibrated cylinder as a ''surge tank'' used to slow pumping speeds when testing smaller cylinders.

PHMSA response. Observations from PHMSA field investigators suggest that industry already largely complies with this requirement. We have safety concerns that exposure to unregulated pressure surges and high temperatures may render the calibrated cylinder unsuitable for its intended purpose. If repeatedly exposed to unregulated pressure surges, the calibrated cylinder may experience additional permanent expansion, rendering it incapable of being used to verify the system's accuracy on a daily basis. The daily verification process depends on the calibrated cylinder giving a precisely known expansion value at a given pressure. If the calibrated cylinder begins stretching too much, for example, a cylinder requalifier may adjust the equipment so that the reading returns to the expected value, not realizing that he has just brought his equipment out of alignment in his attempt to calibrate with an overstretched cylinder. This would cause inaccurate tests whenever that calibrated cylinder is used to verify the system before a day of tests.

(h) Conclusion

Finally, Hydro-Test Products states, ''[a]s we have hoped to have presented in these comments, the incorporation of the C–1 into the regulations will only confuse cylinder re-qualifiers more, while imposing nearly impossible accuracy requirements at a greater cost with absolutely no benefit in safety.''

PHMSA response. We disagree with Hydro-Test Products' conclusion. As we have shown, incorporation of CGA C–1 will not impose additional regulatory burdens on requalifiers. CGA C–1 combines the HMR's current regulatory requirements for pressure testing with diagrams, illustrations, step-by-step guidelines, trouble-shooting procedures, and technical appendices that provide requalifiers with all the information they need to requalify cylinders safely and successfully. The creation of flexibility for reference zero expansion will decrease the time wasted by requalifiers calibrating their systems every day without compromising accuracy. PHMSA believes, based on experience conducting compliance inspections at cylinder requalification facilities, that the additional guidance provided by CGA C–1 (diagrams, troubleshooting guides, technical appendices) will encourage compliance with cylinder requalification standards.

(2) Response to Other Commenters

(a) System Failure or Operator Error

FIBA submitted a comment requesting that we reevaluate the requirements related to system failures or operator error during the pressure test required after cylinder manufacture.

PHMSA response. We agree that the requirements need further clarification. It was our intention to align with the requirements in CGA C–1, section 5.7.2 for cylinder manufacture. In the event of equipment failure or operator error, cylinders may be repeat tested more than twice at time of manufacture, as long as the actual test pressure does not exceed 110 percent of the minimum test pressure and the stresses developed in the cylinder remain within its specification and design limitations. Therefore, we are inserting a reference to that provision in each cylinder manufacture pressure testing paragraph. Note that this does not apply to 3AL cylinders, which, due to the differences in ductility between aluminum and steel, are limited to a single repeat test.

(b) Clarification of § 178.42(f)

COSTHA submitted a comment requesting grammatical changes to the proposed § 178.42(f) to clarify our intent. Section 178.42 specifies two tests for DOT 3E cylinders. One cylinder from each lot must be burst tested, and must burst at a pressure of 6,000 psig without fragmenting or otherwise showing lack of ductility. Then following a successful burst test, each remaining cylinder in the lot must be examined under pressure of at least 3,000 psig, and not above 4,500 psig, and show no defect. The cylinder manufacturer may only examine the cylinders at a pressure of 3,600 psig or greater if the cylinder that was burst-tested at 7,500 psig or greater.

PHMSA response. We agree with COSTHA's comment that the proposed language in § 178.42(f)(3)(ii) was ambiguous. In this final rule, we are reverting the language in § 178.42(f) to the previous layout and language and adding the incorporation of CGA C–1. In our attempt to clarify the requirements in § 178.42(f) we inadvertently made them more ambiguous.

(c) CGA C–1.1

Hydro-Test Products, Bancroft Hinchey, ICT, Noble Gas Solutions, and FIBA noted that the CGA C–1.1 training material we cited in § 180.205(j), has been retracted by CGA and requested that we remove reference to it.

PHMSA response. We agree with the commenters and will remove reference to CGA C–1.1 from § 180.205(j), as it no longer applies as a resource.

(d) Burst Testing Accuracy

Worthington Cylinder submitted a comment requesting clarification about whether CGA C–1 accuracy requirements apply to PIDs used when burst testing cylinders during manufacturing.

PHMSA response. The answer is yes. In this final rule, we will modify the relevant sections of the part 178 specifications for cylinders to indicate that PIDs used for burst tests must meet the requirements of CGA C–1.

(e) Reference Zero Expansion

Galiso submitted a comment requesting that we accept a value within ±1 percent of readability as zero for daily verification. PHMSA does not agree. The allowance of ±.1 percent of total expansion will decrease time spent by requalifiers during daily verification while ensuring that their system continues to meet accuracy requirements. PHMSA will not consider a new ''zero'' standard in this final rule.

(f) Repeat Tests for System Failure or Operator Error

Galiso submitted a comment requesting an explanation for the limitation of two repeat tests in the case of system failure or operator error. When a cylinder is pressurized, it expands. This property is the basis of the volumetric expansion testing program. Volumetric expansion testing measures the volume of the cylinder at test pressure (elastic expansion), and compares it to the volume of the cylinder after pressure is removed (permanent expansion). When permanent expansion is more than 10 percent (or 12 percent for certain cylinders) of elastic expansion, the cylinder must be condemned. If a cylinder is pressurized to over 90 percent of test pressure and then the system fails or the operator errs, it will not return to its original state, rather it will exhibit permanent expansion and reduced expandability because the metal has been stretched. When the test is repeated the next day, the cylinder will exhibit less permanent expansion than the day before, because it started the test in an expanded state. PHMSA is concerned that allowing more than two repeat tests cycles will allow cylinders that should have been condemned to re-enter transportation.

(3) Corrections

(a) DOT 39 Burst Test

In the review of the NPRM, PHMSA determined that we inadvertently removed the requirements for burst-testing DOT 39 cylinders from § 178.65(f). In this final rule, we are re-inserting burst test requirements with language incorporating CGA C–1 calibration and accuracy requirements for burst testing into § 178.65(f).

(b) Incorrect Usage of the Word ''Condemn''

In the review of the NPRM, PHMSA determined that we inadvertently replaced the word ''rejected'' with ''condemned'' in several cylinder manufacture pressure testing sections, specifically §§ 178.46, 178.47, 178.55, 178.56, and 178.65. This was not our intent. In this final rule, we will maintain the HMR's existing instructions for cylinders rejected during manufacture.

(4) Pneumatic and Hydraulic Proof Pressure Tests

CGA C–1 provides instructions for conducting proof pressure tests both pneumatically (gaseous-based system) and hydraulically (liquid-based system). For the purposes of part 178, subpart C, a manufacturer may choose either system when a proof pressure test is authorized. PHMSA would like to emphasize that pneumatic proof pressure test systems can present increased risks to test personnel due to the amount of energy stored in a cylinder filled to test pressure with a gas. Manufacturers must take this risk into account and develop systems to prevent the injury or death of their employees in the event of a catastrophic cylinder rupture at test pressure. The use of additional safety equipment such as blast shields, test cages, etc., is advisable to prevent possible injury to testing personnel and equipment.

P–1628

CGA submitted P–1628 requesting that PHMSA incorporate by reference (IBR) CGA C–3–2005, Reaffirmed 2011, *Standards for Welding on Thin-Walled, Steel Cylinders,* Seventh Edition into the HMR. Presently, the HMR incorporate the Fourth Edition of this standard, CGA C–3–1994. This publication contains information on welding process qualification, welding operator qualifications, tensile testing, bend testing, and radiographic inspection. The changes between the Fourth Edition and the Seventh Edition were predominantly editorial or technical in nature. The significant technical changes are summarized as follows and

can be reviewed in detail in the docket to petition P–1628:[7]

- Added section to the testing criteria to employ the use of macro etch samples in lieu of weld guided bend test and weld tensile testing when the cylinder size would not permit securing of proper size specimens.
- Clarified the weld bend testing procedure, weld bend testing tooling, and proper clearances that are required in the tooling.
- Clarified definitions for the welding procedure qualification and the welding operator weld qualification.
- Added a tolerance section that indicates the plus and minus tolerances when a specific dimensional tolerance is indicated in the publication.
- Added drawings to illustrate different weld joint designs.

Bancroft Hinchey, Worthington Cylinder, NAFED, and CGA submitted comments supporting the incorporation of the Seventh Edition of CGA C–3. Therefore, in this final rule, PHMSA is incorporating by reference CGA C–3–2005, Reaffirmed 2011, as proposed.

Bancroft Hinchey requested clarification of training requirements for cylinder requalifiers.

PHMSA response. Cylinder requalifiers meet the definition of ''hazmat employee'' found in § 171.8. All hazmat employees must be trained in accordance with 49 CFR part 172, subpart H, including function specific training. An employee working as a cylinder requalifier must be trained to perform that job function properly, including visual inspection of cylinders, but would not necessarily need welding training unless also performing a welding function subject to the HMR.

P–1629

The CGA submitted P–1629 requesting that PHMSA incorporate by reference (IBR) CGA C–14–2005, Reaffirmed 2010, *Procedures for Fire Testing of DOT Cylinder Pressure Relief Device Systems,* Fourth Edition, into the HMR. Presently, the HMR incorporates the First Edition of CGA C–14–1979. Since the incorporation of this edition, CGA has revised the publication in 1992, 1999, 2005, and reaffirmed the publication in 2010.

This standard describes test procedures and apparatus for fire testing compressed gas cylinder safety (pressure) relief devices as was required by former § 173.34(d) and current § 173.301(f) of the HMR. The procedures are designed to provide a means of testing to DOT requirements anywhere with reliable test data and repeatable test results. The changes from the 1979 First Edition to the 2005 and Reaffirmed 2010 editions of CGA C–14 were predominantly editorial or technical in nature. The significant technical changes are summarized as follows and can be reviewed in detail in the docket to petition P–1629:[8]

- Permitted the use of an alternate lading. If the intended lading would present an increased safety hazard during the test procedure (such as the use of poisonous or flammable gas), the cylinder may be charged with a typical liquefied or non-liquefied gas. Gases with essentially similar physical properties may be classified as typical.
- Added the Bonfire Test Method to the publication. This permitted the Board of Explosives (BOE) test method to be used to qualify pressure relief device systems. The Bonfire Test Method was successfully used to qualify pressure relief device systems for decades.
- Clarified what information is to be recorded before and during the actual test.
- Increased the water capacity of a cylinder that can be fire tested from 500 pounds water capacity to 1000 pounds water capacity to permit a test method for all DOT 4-series cylinders.

Worthington Cylinder and CGA submitted comments supporting the adoption of CGA C–14–2005, Reaffirmed 2010. Therefore, in this final rule, PHMSA is adopting CGA C–14–2005, Reaffirmed 2010 as proposed.

P–1630

CGA submitted P–1630 requesting that PHMSA revise the HMR requirements for DOT 4L welded insulated cylinders. Specifically, the CGA requested PHMSA make two changes to add a definition of ''recondition'' to § 180.203 and amend paragraphs §§ 180.211(c) and 180.211(e) to clarify when a hydrostatic test must be performed on the inner containment vessel after the DOT 4L welded insulated cylinder has undergone repair.

CGA submitted a comment to the NPRM requesting that we take no action on their petition. We received no other comments to the proposed changes based on P–1630, and therefore, we see no need to revise the HMR based on this petition and will not adopt any changes proposed by P–1630.

V. Special Permits and Comments Received

This final rule addresses one special permit. In the ANPRM, PHMSA considered proposing revisions to adopt certain special permits into the HMR. Specifically, PHMSA proposed changes based on DOT–SPs 12929, 13318, and 13599. In the NPRM, PHMSA did not propose changes in association with these special permits because: (1) DOT–SP 12929 was determined not suitable for adoption under rulemaking HM–233F (80 FR 5340; January 30, 2015); and (2) DOT–SPs 13318 and 13599 were adopted under HM–233F (81 FR 3635; January 21, 2016).

In the NPRM, we proposed to adopt provisions from DOT–SP 14237 to allow for the transportation of adsorbed gases in DOT specification cylinders by creating a new section, § 173.302d, in the HMR. The HMR currently only authorizes the transportation of adsorbed gases in UN pressure receptacles under the provisions of § 173.302c. The use of DOT cylinders containing adsorbed gases is currently authorized under various special permits. In the NPRM, we proposed to authorize the transportation of adsorbed gases in DOT–3E1800, DOT–3AA2015, and DOT–3AA2265 cylinders with a capacity between 0.4 and 7.3 liters. Additionally, the proposed § 173.302d included a requirement to place the DOT specification cylinder into a non-DOT specification full-opening, hinged-head or fully removable head, steel overpack cylinder constructed to meet the requirements of ASME Code Section VIII, Division 1 with a minimum design margin of 4 to 1.[9]

We received several comments regarding this proposal. Praxair submitted a comment requesting that, rather than adopting DOT–SP 14237, we harmonize DOT cylinder adsorbed gas requirements with UN pressure receptacle requirements found in § 173.302c, authorize all gases for use as adsorbed service instead of the ''short list'' proposed in § 173.302d, eliminate the proposed overpack cylinder requirement, and, if we did not eliminate the overpack requirement, require the overpack be tested in a DOT-approved facility subject to the requirements of part 107, subpart I. CGA submitted a comment suggesting that rather than adopt the proposed special permit, we should align the proposed requirements for adsorbed gases in DOT cylinders in § 173.302d with the existing requirements for adsorbed gases in UN pressure receptacles currently found in § 173.302c. COSTHA submitted a comment supporting the adoption of requirements for adsorbed gases in DOT cylinders, but noted that some of the gas entries we listed in the

[7] PHMSA Docket ID: PHMSA–2013–0278.

[8] PHMSA Docket ID: PHMSA–2014–0012.

[9] These are all provisions carried over from DOT–SP 14237.

proposed table in § 173.302d had separate UN ID numbers for their adsorbed version in the § 172.101 Hazardous Materials Table that should be cited instead of the non-adsorbed gas entry.

Entegris submitted a comment requesting that rather than adopting DOT–SP 14237, we should adopt DOT SP–16485, which allows for transportation of adsorbed gases in DOT–3AA and DOT–3E cylinders in a manner harmonized with the current requirements for UN pressure receptacles in § 173.302c. Entegris noted that the overpack requirement in DOT–SP 14237 was created to address the unique risks associated with transportation by aircraft, and presents a significant obstacle to efficient transportation by other modes. They noted that § 173.302c does not require the use of overpacks for UN pressure receptacles containing adsorbed gas, nor does DOT–SP 16485.

PHMSA response. We appreciate the comments we received on this topic. In this final rule, we are not adopting DOT–SP 14237, nor are we inserting requirements for adsorbed gases in DOT specification cylinders into the HMR in § 173.302c. PHMSA's decision is based on the lack of consensus on this subject and technical concerns we have surrounding the modal requirements, minimum test pressure criteria, and authorized requalification. There are multiple existing DOT SPs that authorize the transportation of adsorbed gases in DOT specification cylinders. These permits authorize different adsorbed gases and utilize different DOT specification cylinders to contain the substrate and adsorbed gas, and have different operational controls. Incorporating the provisions of multiple special permits that authorize different materials, multiple specification and non-specification cylinders, and have differing operational controls, is challenging for PHMSA to attempt at the final rule stage without soliciting comments on the regulatory solution that melds the provisions and conditions of multiple permits together. The incorporation of adsorbed gases presents additional difficulties due to the risks presented by the highly toxic nature of the gases currently transported in adsorbed form, leading us to proceed with caution in adopting a standard into the HMR.

Therefore, PHMSA believes that the most appropriate way to authorize adsorbed gases in DOT specification cylinders in the HMR is to conduct a more thorough review of existing systems authorized by special permit and propose a solution in a separate rulemaking, rather than risk creating imperfect regulatory requirements. We will further evaluate international standards for adsorbed gas transportation and existing DOT special permits for determination on how best to adopt provisions for adsorbed gases in DOT specification cylinders into the HMR. Adsorbed gases may continue to be transported in UN pressure receptacles in accordance with existing instructions in § 173.302c, or in DOT cylinders under the terms of a special permit. We will consider revisiting this issue in a future rulemaking.

VI. Agency Initiated Editorial Corrections

PHMSA regularly reviews and revises the HMR to correct errors and clarify any regulations that are unclear or confusing. PHMSA is making the following changes in this final rule.

Section 107.803

Section 107.803 provides approval procedures for independent inspection agencies (IIA) conducting cylinder inspections and verifications as required by parts 178 and 180. In its application for approval status, the IIA must provide information, including a detailed description of its qualifications and ability both to perform and verify inspections. However, at present, the application information requirements of § 107.803(c)(3) only reference part 178. In the NPRM, PHMSA proposed to revise § 107.803(c)(3) to include part 180, subpart C, for consistency.

We received one comment on this topic. Bancroft Hinchey supports this revision. Therefore, in this final rule are adopting this change as proposed in the NPRM.

Section 107.805

Section 107.805 provides approval procedures for persons to inspect, test, certify, repair, or rebuild a cylinder in accordance with the HMR. PHMSA is revising the requirements for application for approval of cylinder requalifiers to include a reference to the option of having a mobile cylinder requalification unit (*i.e.,* a mobile unit). See § 180.203 for further discussion.

We received one comment on this topic. Bancroft Hinchey supports this revision. Therefore, in this final rule we are adopting this change as proposed in the NPRM.

Section 178.70

Section 178.70 provides approval for the manufacture of UN pressure receptacles (*i.e.,* cylinders). Currently, § 178.70(d) restricts the user (manufacturer) from the flexibility that is provided in the UN/ISO standards. The regulation as constructed results in additional cost and delay without any added safety. The UN/ISO standards are developed based on performance testing and include adequate testing for a wide range of design-type modifications. All UN/ISO standards to which the original design type conforms permit certain modifications to an approved design type. PHMSA has received several requests to revise this regulation to allow an authorized manufacturer to benefit from the UN Model Regulations and produce UN/ISO cylinders. In the NPRM, PHMSA proposed to adopt language consistent with UN/ISO standards to reduce the need for approvals.

We received one comment on this topic. Bancroft Hinchey supports this revision. Therefore, in this final rule we are adopting this change as proposed in the NPRM.

Section 180.203

Section 180.203 specifies definitions that apply to cylinder use, qualification, and maintenance. In the NPRM, PHMSA proposed two revisions to definitions in § 180.203. In this final rule, we are adopting the definition for ''mobile unit'' with modifications based on comments received, and we are not adopting a new definition for ''proof pressure test.''

(1) Define and Adopt ''Mobile Unit'' Requalification Operations

The hazardous materials program procedures of 49 CFR part 107 for approval of cylinder requalifiers do not specify the option of a ''mobile cylinder requalification unit.'' The intent of this type of approval is to allow a cylinder requalifier to perform its requalifying function away from the primary place of business to better serve cylinder owners who need requalification testing and inspection of cylinders. In the NPRM, we proposed to limit the operations of a mobile unit to a 100-mile radius from the primary place of business. Eleven commenters objected to this limit based on economic, safety, and fairness grounds.

PHMSA response. PHMSA will not place a distance limit on the operations of a mobile unit. However, an applicant for a mobile requalifier identification number (RIN) must specify the geographic area(s) in which they are requesting approval to operate. The requirement to provide geographic information on the operating range of a mobile unit is a part of the current approval process for mobile units. However, it is not codified in the language of Part 107 for cylinder

requalification approvals. The intent of this final rule is to codify the geographic information requirement in the text of part 107 to increase clarity, not create a new requirement. A mobile cylinder requalifier must adhere to the requirements in a PHMSA-issued approval letter to operate. Note that a mobile unit owned or operated by a previously approved requalifier must still receive a separate approval.

(2) Revise Definition of Proof Pressure Test for Cylinders

The HMR no longer prescribe modified hydrostatic pressure testing, which has been and continues to be the method of low-pressure testing of fire extinguishers.[10] In the NPRM, we proposed to modify the definition of ''proof pressure test'' to indicate that it could be performed with either liquid or a gas. We received 9 comments opposed to this change, and no comments in support.

Our description of the advantages of pneumatic, or gas-based, proof pressure testing in the NPRM was not entirely correct. In certain instances, pneumatic testing may not be faster, less expensive, less corrosive to the cylinder, or less environmentally harmful than hydrostatic testing. Pressurizing a cylinder to test pressure and then de-pressurizing it with air or another gas may take significantly longer than using water. Regarding corrosion concerns, use of compressed air for a pneumatic proof pressure test will generally introduce water into the cylinder, and use of dry gases would generally be cost-prohibitive except in very limited circumstances. Regarding environmental concerns, as several commenters noted, many cylinder requalifiers recycle the water they use.

PHMSA response. When we removed the modified hydrostatic pressure test from the HMR and added the proof pressure test into part 180, we intended that the test be conducted with a liquid, except in special circumstances subject to a special permit. We do not believe that a general authorization for pneumatic proof pressure tests for cylinder requalification is in the public interest. Companies requesting authorization to perform pneumatic proof pressure tests for cylinder requalification may request special permits that detail the methods put in place to prevent death and serious injury in the event of a cylinder rupture at test pressure (*i.e.,* much more energy is needed to pressurize a cylinder with a gas than liquid, thus presenting a safety risk to persons performing the test should a rupture occur). Therefore, we will not adopt the proposed modified definition of a proof pressure test in § 180.203. Rather, we will modify the definition of the test based on comments to indicate clearly that the test is to be conducted with a liquid medium, unless otherwise authorized by a special permit.

Section 180.207

Section 180.207(d) authorizes the use of ISO 6406 to requalify UN refillable seamless steel cylinders and UN refillable seamless steel tube cylinders. The current ISO 6406 has a limitation of 150 liters for the size of these cylinders, which is substantially less than the maximum volume of a UN refillable seamless steel tube (3,000 liters). Pressure tests and ultrasonic examination are authorized for UN cylinders with tensile strength below 950 MPa, and only ultrasonic examination is authorized for UN cylinders with a tensile strength greater than or equal to 950 MPa. PHMSA has received several requests for interpretation of this regulation and its application to the requalification of UN seamless steel pressure receptacles larger than 150 liters. PHMSA responded to these requests through a letter of clarification issued under Reference No. 13–0146, stating that § 180.207(d)(1) authorizes the requalification of seamless steel UN pressure receptacles larger than 150 liters.

We received two comments on this topic. Bancroft Hinchey supports the revision to include the phrase ''larger than 150 liters.'' FIBA submitted a comment requesting that we delete the reference to MEGCs from § 180.207(d) because pressure receptacles exceeding 150 liters (*e.g.* UN refillable seamless steel tubes) may be used for the transportation of hazardous materials not only in MEGCs, but also in other bulk packages, such as a tube trailer motor vehicle.

PHMSA response. We agree with FIBA that UN seamless steel cylinders larger than 150 liters may be found in other packaging configurations besides MEGCs. Our intent is to clarify that all UN seamless steel cylinders, regardless of size or service must be requalified in accordance with ISO 6406. However, we believe there is value in referencing MEGCs as an example of a scenario where users, fillers, or requalifiers may encounter these larger UN cylinders. Therefore, in this final rule we will amend the proposed § 180.207(d)(1) to indicate that all UN seamless steel pressure receptacles, including those with a capacity over 150 liters, must be requalified in accordance with ISO 6406 whether installed in a MEGC or used in other service.

Section 180.213

Section 180.213 prescribes marking requirements for the visual inspection of cylinders (see 49 CFR 180.213(f)(5), (8), and (9)). In the past, PHMSA has allowed a visual (V) requalifier identification number (''V-number'' or ''VIN'') to be marked in the same manner as a requalifier identification number (RIN) marking per § 180.213. V-number markings have four different options for markings. PHMSA issues approval letters that permit a V number marking, but only provide for three of the four available marking options and do not reference § 180.213.

Including all the marking requirements for V-numbers into § 180.213 will make authorized options for these identification numbers to be placed on a cylinder more widely understood.

Amerigas noted that when we inserted examples of acceptable ways to mark a VIN, we omitted one acceptable marking combination that is found in the VIN approval document. Bancroft Hinchey submitted a comment supporting inserting VIN marking examples into the HMR.

PHMSA response. We agree with Amerigas, and will add the additional method that shows the month and year directly above the VIN. In this final rule, PHMSA is amending § 180.213(g) to include examples of V-number markings, as proposed, as well as the method showing the month and year directly above the VIN.

Section 180.215

Section 180.215(a)(6) requires that a person who requalifies, repairs, or rebuilds cylinders must maintain in their records and report information contained in each applicable CGA or ASTM standard incorporated by reference under § 171.7 of the HMR that applies to requalifier activities. In the NPRM, PHMSA proposed to remove the last sentence of paragraph (a)(6) of this section to reduce confusion, as it essentially repeats what is requested in the first sentence of this paragraph.

We received one comment on this topic. Bancroft Hinchey submitted a comment supporting this change. Therefore, in this final rule we will adopt it as proposed. COSTHA submitted a comment requesting that PHMSA revise the language in § 180.215(c)(2)(vii) to delete the phrase ''(permanent expansion may not exceed ten percent (10 percent) of total

[10] PHMSA removed this from the HMR under HM–220D (67 FR 51626).

expansion)'' because this requirement does not apply to all cylinders. We note the comment but consider it beyond the scope of this rulemaking. We will consider the topic for possible inclusion in a future rulemaking.

VII. Section-by-Section Review

Section 107.803

Section 107.803(c)(3) states that each application to obtain approval to perform duties as an IIA must contain a detailed description of the applicant's qualifications and ability both to perform the inspections and to verify the inspections required by part 178 of the HMR or under the terms of a DOT special permit. In this final rule, we revise § 107.803(c)(3) as proposed to clarify that the applicant's description of his or her ability to perform and verify inspections must include those required under part 180 as well, consistent with the general requirements in paragraph (a) that refer to part 180.

Section 107.805

Section 107.805(c) prescribes additional information an application must contain to obtain approval from PHMSA to requalify cylinders and pressure receptacles. In this final rule, we are adding paragraph (c)(5) as proposed to this section to clarify what information must be added to the application to authorize mobile unit requalifiers and the information necessary to acquire approval. We also make a conforming edit to paragraphs (c)(3) and (4) by moving the ''and'' clause from paragraph (c)(3) to paragraph (c)(4).

Section 171.7

Section 171.7 lists reference standards incorporated by reference into the HMR that are not specifically set forth in the HMR.

Paragraph (n) specifically incorporates into the HMR publications issued by the CGA, an industrial and medical gas association that, among others, develops standards and practices for the safe transportation of gases and their containers. In this final rule, we add the Eleventh edition (2016) of CGA publication C–1, *Methods for Pressure Testing Compressed Gas Cylinders* to § 171.7(n). We also update the editions of CGA publications C–3, C–6, C–14, and S–1.1 already incorporated in the HMR. The remaining changes to paragraph (n) are editorial based on PHMSA's initiative to renumber the list to accommodate the new publications and add missing section number symbols, punctuation, and spaces. The documents are summarized below.

The CGA publications include the following:

(1) CGA C–1, *Methods for Pressure Testing Compressed Gas Cylinders* (2016; Eleventh edition). This publication provides the standard(s) for pressure testing of compressed gas cylinders for many newly manufactured cylinders and requalification of cylinders. This standard contains operating and equipment requirements necessary to perform pressure testing of compressed gas cylinders properly. Tests include the water jacket method, direct expansion method, and proof pressure method.

(2) CGA C–3, *Standards for Welding on Thin-Walled Steel Cylinders* (2005, Reaffirmed 2011; Seventh edition). This publication contains information on welding process qualification, welding operator qualifications, tensile testing, bend testing, and radiographic inspection. Additionally, this publication clarifies dimensional tolerances and when weld macro etch can be used for weld process approval and welder qualification approval.

(3) CGA C–6, *Standards for Visual Inspection of Steel Compressed Gas Cylinders* (2013; Eleventh edition). This publication provides cylinder users (requalifiers, owners, fillers, operators, etc.) with criteria to accept, reject, and condemn steel compressed gas cylinders. This standard does not cover all circumstances for each individual cylinder type and condition of lading. Inspection procedures include preparation of cylinders for inspection; exterior inspection; interior inspection (if required); nature and extent of damage to be looked for; and for some tests, the conditions of the cylinder, etc. A sample inspection report is provided in an appendix.

(4) CGA C–14, *Procedures for Fire Testing of DOT Cylinder Pressure Relief Device Systems* (2005, Reaffirmed 2010; Fourth edition). This publication describes test procedures and apparatus for fire testing compressed gas cylinder safety (pressure) relief devices as required by the HMR. The procedures are applicable for cylinders that have less than 500 lbs. water capacity and designed to provide a means of testing to the HMR anywhere with reliable test data and repeatable test results.

(5) CGA S–1.1, *Pressure Relief Device Standards—Part 1—Cylinders for Compressed Gases* (2011; Fourteenth edition). This publication provides the standard(s) for selection of the correct pressure relief device that is required to meet the requirements of the HMR for over 150 gases. It provides guidance on when a pressure relief device can be optionally omitted, and when the use of a pressure relief device is prohibited. It provides direction and guidance on the manufacture and testing of pressure relief devices as well as the operation parameters and maintenance. In this final rule, we are removing the phrase ''with the exception of paragraph 9.1.1'' from § 171.7(n)(18). Compliance with paragraph 9.1.1 is still not required; however, we have moved this instruction to each place S–1.1 is incorporated in Part 173 and Part 178 for clarity.

All of these CGA standards are available for purchase on the CGA website.[11] Additionally, these standards are available for public inspection at the Hazardous Material Information Center ((202) 366–4488; *infocntr@dot.gov*) by appointment.

The regulatory text of this rule references ASTM E 8–99, The Aluminum Association's ''Welding Aluminum: Theory and Practice, Fourth Edition, 2002'', and Transport Canada's TDG Regulations. These standards are already approved for the sections that are being amended.

Section 171.23

Section 171.23 prescribes requirements for transport of specific materials and packaging under international transportation standards such as the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air. Paragraph (a)(5) outlines requirements for filling of cylinders for export or use onboard a vessel. In this final rule, we revise the marking requirements consistent with changes made to § 180.213.

Section 173.3

Section 173.3(d)(1) prescribes how a damaged or leaking cylinder that contains hazardous material may be transported in a non-DOT-specification fully opening hinged-head or removable head steel salvage cylinder. In this final rule, we are amending § 173.3(d)(1) to permit cylinders that contain Class 4 or 5 materials to use this exception as well. In addition, because of the inclusion of Class 4 or 5 materials as authorized material for salvage cylinders, we are reformatting the regulatory text to reference those materials in damaged or leaked cylinders that are excluded from being allowed to be overpacked in a salvage cylinder rather than listing those that are authorized.

[11] *https://www.cganet.com/what-we-do/standards-publications/.*

Section 173.301

Section 173.301 provides the general requirements for shipment of compressed gases and other hazardous material in cylinders. In this final rule in paragraphs (c) and (f), we make an editorial revision to correct the section citation of CGA S–1.1 to read 9.1.1. Additionally, we are revising paragraph (f) to clarify the pressure relief requirements for DOT 39 cylinders. See the discussion of P–1580 for further details.

Section 173.302

Section 173.302(f) prescribes the requirements for transporting non-liquefied or ''permanent'' oxidizing gases by air. We are amending § 173.302(f)(2)(i) and adding a new § 173.302(f)(2)(iii) to align with CGA S–1.1 requirements for DOT 39 cylinders. See the discussion of P–1580 for further details.

Section 173.302a

Section 173.302a(a)(3) prescribes the filling requirements for DOT 39 cylinders that contain Division 2.1 gas or chemical under pressure. In the NPRM, we proposed to clarify the capacity (internal volume) requirements, to make it clear that the 1.23 liter limit applies to Division 2.1 material, and specification size limits of a DOT 39 cylinder apply to chemicals under pressure classed as Division 2.1 (see 49 CFR 172.102, special provision 362). As we noted in the NPRM, the previous 50 L limit for chemical under pressure in a DOT 39 cylinder is much larger than the actual maximum size authorized for the DOT 39 specification in § 178.65. This discrepancy was an unintentional outcome of a harmonization effort with international requirements for non-refillable cylinders, which allow larger sizes than the HMR (see Docket No. PHMSA–2012–0027 (HM–215L); 78 FR 988). To reduce confusion introduced by the conflict of the 50 L quantity in § 173.302a(a)(3) and the capacity limts of the specification, we are deleting the reference to ''50 L (3050 in^3)'' and replacing it with reference to the DOT 39 specification capacity limits—1526 in^3 for a service pressure of 500 psig or less, and 277 in^3 for a service pressure of greater than 500 psig.

We also proposed an editorial correction to the start of paragraph (a)(3) by removing the non-italicized ''DOT 39.''

Section 173.302a(c) provides special filling limits for DOT 3A, 3AX, 3AA, and 3AAX cylinders filled with hydrogen and mixtures of hydrogen with helium, argon, or nitrogen. We are modifying § 173.302a(c)(4) to harmonize with CGA S–1.1. Shippers are not required to install pressure relief devices on tubes (cylinders longer than 144 inches, or 12 feet) shipped in accordance with this paragraph, however their continued use and installation is authorized. This change maintains regulatory flexibility and alignment with accepted industry practice. See discussion of P–1592 for further details.

Section 173.304

Section 173.304(f) prescribes the requirements for transporting liquefied compressed oxidizing gases by air. In this final rule, we are amending § 173.304(f)(2)(i) and adding a new § 173.304(f)(2)(iii) to align with CGA S–1.1 pressure relieve device requirements for DOT 39 cylinders. See the discussion of P–1580 for further details.

Section 173.304a

Section 173.304a prescribes the maximum permitted filling density and authorized cylinders for specific gases. In the NPRM, we proposed to add new paragraph (a)(3) to § 173.304a to state clearly that the maximum capacity (internal volume) of a DOT 39 cylinder containing liquefied flammable gas is 1.23 liters (75 in^3). We also proposed to require these cylinders to be equipped with a pressure relief valve, as prescribed in CGA S–1.1, unless the material is not listed in CGA S–1.1, in which case a CG–7 pressure relief valve must be used.

In this final rule we are modifying our proposed change to § 173.304a and imposing a 75 in^3 limit on the capacity of DOT 39 cylinders containing the following liquefied flammable gases: Cyclopropane, ethane, ethylene, and liquefied petroleum gas. We are also adopting the requirement that a DOT 39 cylinder containing a liquefied gas not listed by name in CGA S–1.1 must be equipped with a CG–7 pressure relief valve, as proposed. See discussion of P–1622 for further details.

Section 173.306

Section 173.306 provides exceptions from the requirements of the HMR for limited quantities of compressed gas. Paragraph (g) excepts water pump system tanks charged with compressed air or limited quantities of nitrogen to not over 40 psig from labeling and specification packaging when shipped in conformance with the requirements prescribed in the paragraph. In this final rule, we revise § 173.306(g) to authorize composite as well as steel tanks, to require a more flexible testing regime at the manufacturers MAWP rather than a set 100 psig, to allow water pump system tanks to be charged with helium, and to clarify that transportation by aircraft is not an authorized mode of transport. See discussion of P–1582 for more details.

Section 173.309

In the NPRM, we proposed to revise § 173.309 to state that the requirements applicable to fire extinguishers also apply to those cylinders used as part of a fire suppression system. In this final rule, we are adopting the change as proposed, while clarifying our intent as to what is considered a ''fire extinguisher.'' We are allowing cylinders charged with a compressed gas and an extinguishing agent that are intended for installation into fire suppression systems to be described as ''UN1044, Fire extinguishers.'' We are not allowing cylinders charged with an inert gas and used only to pressurize a fire suppression system to be described as ''UN1044, Fire extinguishers'' when offered for transportation separately from the suppression system. See discussion of P–1546 for further details.

Section 173.312

Section 173.312(b)(1) prescribes the filling requirements for multiple element gas containers (MEGCs). In this this final rule, we are clarifying requirements for filling MEGC pressure receptacles containing liquefied compressed gas by weight to emphasize that each pressure receptacle must be filled individually. See discussion of P–1572 for further details.

Section 173.323

Section 173.323 is the packaging section for ethylene oxide. In this final rule, we are making an editorial revision to this section to add a reference to the central IBR section, § 171.7, for the existing references to CGA Pamphlet C–14. CGA C–14 was previously approved for inclusion in this section, but through an oversight, § 171.7 was not referenced as required for approved IBRs. This final rule corrects that oversight.

Section 178.35

Section 178.35(f) prescribes the marking requirements that apply to DOT-specification cylinders. In this final rule, we are adding new paragraph (f)(8) to § 178.35 to require that cylinder tare weight or mass weight, and water capacity be marked on certain DOT-specification cylinders that are filled by weight. See discussion of P–1540 for further details.

Although we did not discuss the above in the petition discussion section,

we note Dow Chemical submitted a comment requesting that we add a paragraph to § 178.35 stating that a cylinder manufactured under this subpart prior to publication of HM–234 may continue to be filled and offered for transportation until its authorized service life has expired. We do not believe such a statement is necessary. Section 173.301(a)(1) addresses this situation by providing that compressed gases must be in UN pressure receptacles built in accordance with the UN standards or in metal cylinders and containers built in accordance with the DOT and ICC specifications and part 178 *in effect at the time of manufacture* or CRC, BTC, CTC or TC specification, and requalified and marked as prescribed in subpart C in part 180, if applicable.

Cylinders manufactured prior to the publication of HM–234 may continue in service, subject to the requalification provisions of part 180, subpart C, and other applicable requirements of the subchapter.

Sections 178.36, 178.37, 178.38, 178.39, 178.42, 178.44, 178.45, 178.46, 178.47, 178.50, 178.51, 178.53, 178.55 178.56, 178.57, 178.58, 178.59, 178.60, 178.61, 178.65, and 178.68

These sections prescribe the DOT-specification requirements for a cylinder type including the performance standards for pressure testing of the cylinder. In this final rule, we require that testing and equipment used to conduct the pressure testing be in conformance with CGA C–1, *Methods for Pressure Testing Compressed Gas Cylinders,* to provide for consistency and clarity in performance of pressure testing. In this final rule, we also revise the format of the pressure testing paragraphs for greater consistency, including adding notification that any pressurization in excess of 90% of test pressure constitutes a test, and that operator error (*i.e.* selecting the wrong test pressure) is an acceptable reason to allow a repeated test in accordance with CGA C–1 requirements. See the discussions of P–1515 and P–1626 for further details on the requirements in CGA C–1. A detailed discussion of changes to each section follows.

Section 178.36 Specification 3A and 3AX Seamless Steel Cylinders

The paragraph (i) title ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference into (i)(1) and (3) for volumetric expansion testing as proposed.

Section 178.37 Specification 3AA and 3AAX Seamless Steel Cylinders

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference into paragraphs (i)(1) and (3) for volumetric expansion testing as proposed.

Section 178.38 Specification 3B Seamless Steel Cylinders

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference into paragraphs (i)(1) and (3) for volumetric expansion testing as proposed. To increase clarity, in this final rule we move the instructions for proof pressure testing of cylinders after a selected cylinder from a lot is volumetrically expansion tested at 3 times service pressure from the proposed paragraph (i)(5) to paragraph (i)(2)(ii) to ensure cylinder manufactures are aware of the requirement when reading through paragraph (i). As a result, we also incorporate CGA C–1 into paragraph (i)(2) for proof pressure testing.

Section 178.39 Specification 3BN Seamless Nickel Cylinders

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference into paragraphs (i)(1) and (3) as proposed.

Section 178.42 Specification 3E Seamless Steel Cylinders

The paragraph (f) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' as proposed. As discussed in our discussion of P–1626 we are not adopting the proposed re-organization of § 178.42(f) based on comments received that the new layout would generate confusion for regulated entities. Further, CGA C–1 is incorporated by reference for burst testing in paragraph (f)(2) and proof pressure testing in paragraph (f)(3).

Section 178.44 Specification 3HT Seamless Steel Cylinders for Aircraft Use

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference into paragraphs (i)(1) and (3) for volumetric expansion testing as proposed.

Section 178.45 Specification 3T Seamless Steel Cylinder

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference into paragraphs (i)(1) and (3) for volumetric expansion testing as proposed.

Section 178.46 Specification 3AL Seamless Aluminum Cylinders

The paragraph (g) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference into paragraphs (g)(1) and (3) for volumetric expansion testing as proposed. The HMR currently only allows one repeat test for 3AL cylinders in the case of equipment failure. As proposed, we maintain this requirement in this final rule. 3AL cylinders may only be subjected to one repeat test, rather than the two allowed under CGA C–1. This is due to the different expansion properties of aluminum compared to steel, which would render the expansion measured during a 2nd repeated test at increased pressure an invalid measurement of the cylinder's suitability.

Section 178.47 Specification 4DS Welded Stainless Steel Cylinders for Aircraft Use

The paragraph (j) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference into paragraphs (j)(1) and (3) for volumetric expansion testing as proposed. As proposed, the final rule adds an option for direct expansion testing for 4DS cylinders. PHMSA believes that including the hydrostatic testing direct expansion method in addition to the water jacket method provides for greater flexibility for the tester by allowing an alternative hydrostatic testing method for determining permanent expansion. PHMSA believes that direct expansion will provide an equivalent level of safety when performed in accordance with CGA C–1.

Section 178.50 Specification 4B Welded or Brazed Steel Cylinders

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraph (i)(1) for volumetric expansion testing of one selected cylinder per lot, and (i)(2) for pressure testing the remainder of the lot as proposed.

Section 178.51 Specification 4BA Welded or Brazed Steel Cylinders

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraph (i)(1) for volumetric expansion testing of one selected cylinder per lot, and paragraph (i)(2) for pressure testing the remainder of the lot as proposed.

Section 178.53 Specification 4D Welded Steel Cylinders for Aircraft Use

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure test*'' and CGA C–1 is incorporated by reference as proposed. In this final rule, we are re-inserting the option to conduct a volumetric expansion test on each cylinder at 2 times service pressure. It was not our intent to remove this option for cylinder manufacturers.

Section 178.55 Specification 4B240ET Welded or Brazed Cylinders

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraph (i)(1) for volumetric expansion testing, paragraph (i)(2) for pressure testing, and paragraph (i)(3) for burst testing as proposed.

Section 178.56 Specification 4AA480 Welded Steel Cylinders

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraph (i)(1) for volumetric expansion testing and paragraph (i)(2) for pressure testing as proposed.

Section 178.57 Specification 4L Welded Insulated Cylinders

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraphs (i)(1) and (3) for pressure testing as proposed.

Section 178.58 Specification 4DA Welded Steel Cylinders for Aircraft Use

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraphs (i)(1) and (3) for volumetric expansion testing as proposed.

Section 178.59 Specification 8 Steel Cylinders With Porous Fillings for Acetylene

The paragraph (h) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated in paragraph (h)(1) for volumetric expansion testing and paragraph (h)(2) for pressure testing as proposed. Additionally, we have editorially revised paragraph (h) to clarify that if the randomly selected cylinder from each lot fails the volumetric expansion test, the remaining cylinders in the lot are not eligible for proof pressure testing and each cylinder must pass a volumetric expansion test at 750 psig to be accepted.

Section 178.60 Specification 8AL Steel Cylinders With Porous Fillings for Acetylene

The paragraph (j) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraph (j)(1) for volumetric expansion testing and paragraph (j)(2) for proof pressure testing as proposed. Additionally, we have editorially revised paragraph (j) to clarify that if the randomly selected cylinder from each lot fails the volumetric expansion test, the remaining cylinders in the lot are not eligible for proof pressure testing and must pass a volumetric expansion test at 750 psig to be accepted.

Section 178.61 Specification 4BW Welded Steel Cylinders With Electric-Arc Welded Longitudinal Seam

The paragraph (i) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraph (i)(1) for volumetric expansion testing and paragraph (i)(2) for pressure testing as proposed.

Section 178.65 Specification 39 Non-Reusable (Non-Refillable) Cylinders

The paragraph (f) ''*Pressure tests*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraph (f)(1) for proof pressure testing and paragraph (f)(2) for burst testing as proposed.

Section 178.68 Specification 4E Welded Aluminum Cylinders

The paragraph (h) ''*Hydrostatic test*'' is renamed ''*Pressure testing*'' and CGA C–1 is incorporated by reference in paragraphs (h)(1) and (2) for volumetric expansion testing and paragraph (h)(3) for pressure testing as proposed.

Sections 178.50, 178.51, 178.61, and 178.68

These sections prescribe DOT 4-series specification requirements. As written these specifications are at times unclear to manufacturers and enforcement personnel. In this final rule, we are revising the specification requirements to promote consistent and uniform manufacturing practices for DOT 4-series cylinders to improve understanding by these entities. See the discussion of P–1501 for further details. Below we will discuss changes to each section in detail.

Section 178.50 Specification 4B Welded or Brazed Steel Cylinders

For steel requirements, we are requiring that manufacturers keep a record of intentionally added alloying elements, as proposed.

For material identification, the final rule makes an editorial clarification that the method used to identify the material must not compromise the integrity of the cylinder, as proposed.

For heat treatment, we are making an editorial clarification to direct cylinder manufacturers to table 1 to appendix A of part 178 for details on suitable heat treatment.

For cylinder attachments, we have moved thread requirements to their own paragraph, (h)(h), without making any changes to thread requirements.

For elongation requirements, we are allowing reduction in elongation percentage based on cylinder tensile strength to align with requirements for DOT 4BA and 4BW cylinder requirements.

For rejected cylinders, we are adopting as proposed heat treatment after seam repairs requirements as follows:

- For cylinders with an outside diameter of less than or equal to six (6) inches, welded seam repairs greater than one (1) inch in length shall require reheat treatment of the cylinder.
- For cylinders greater than an outside diameter of 6 inches, welded seam repairs greater than three (3) inches in length shall require reheat treatment.

The HMR current manufacturing standards require heat treatment after any welding repair, but we believe this additional flexibility for manufacturers will maintain the same high level of safety for repaired cylinders.

Finally, we are removing discussion of embossing the head or sidewall of the cylinder from § 178.50(o)(2). PHMSA has concerns with defining ''embossing.'' Markings must be stamped plainly and permanently on the cylinder as prescribed in § 178.50(o)(1).

Section 178.51 Specification 4BA Welded or Brazed Steel Cylinders

For steel, we are requiring that manufacturers keep a record of intentionally added alloying elements, as proposed.

For material identification, the final rule makes an editorial clarification that the method used to identify the material must not compromise the integrity of the cylinder, as proposed.

For head attachment, we are allowing heads to be attached by welding, as proposed. The previous restriction to brazing only was not PHMSA's intent.

For seams, we are making an editorial revision to paragraph (a) to clarify that longitudinal seams are permitted for cylindrical-type cylinders as proposed.

For welding, we are making an editorial revision to paragraph (e), as proposed, to clarify allowable welding operations on the cylinder.

For yield strengths, tensile strengths, elongations and reduction of area of material, we are re-naming paragraph (j) from ''*Physical tests*'' to ''*Mechanical tests*'' as proposed. Additionally, we are removing the language requiring that the mechanical tests be conducted on a cylinder that has passed the hydrostatic testing because the mechanical tests are unrelated to the pressure test requirements. During our review of the final rule, we noted we inadvertently omitted the requirement that mechanical tests must be conducted after heat treatment. This was not our intent; therefore, we are re-inserting the statement that mechanical tests must be conducted after heat treatment is performed.

For mechanical test samples for spherical cylinders, we are now allowing samples to be taken directly from the formed sphere, if the manufacturer desires, in order ensure the mechanical test samples are as representative as possible of the spheres themselves.

In this final rule, we require that manufacturers remove samples for mechanical tests as provided in appendix A to subpart C of part 178 as proposed in order to improve consistency of cylinder mechanical tests. PHMSA believes that all manufacturers were previously removing samples as recommended in appendix A to subpart C of part 178, therefore this will not create any new burdens for industry.

For rejected cylinders, we are adopting as proposed heat treatment after seam repairs requirements as follows:

- For cylinders with an outside diameter of less than or equal to six (6) inches, welded seam repairs greater than one (1) inch in length shall require reheat treatment of the cylinder.
- For cylinders greater than an outside diameter of 6 inches, welded seam repairs greater than three (3) inches in length shall require reheat treatment.

The HMR current manufacturing standards require heat treatment after any welding repair, but we believe this additional flexibility for manufacturers will maintain the same high level of safety for repaired cylinders.

Finally, we are removing discussion of embossing the head or sidewall of the cylinder from § 178.51(n)(2). PHMSA has concerns with defining ''embossing.'' Markings must be stamped plainly and permanently on the cylinder as prescribed in § 178.51(n)(1).

Section 178.61 Specification 4BW Welded Steel Cylinders With Electric-Arc Welded Longitudinal Seam

For steel, we are requiring that manufacturers keep a record of intentionally added alloying elements, as proposed.

For identification of material, the final rule makes an editorial clarification that the method used to identify the material must not compromise the integrity of the cylinder, and that plates and billets for hotdrawn cylinders must be marked with the heat number, as proposed. PHMSA believes that cylinder manufacturers are already in compliance with this requirement and this does not impose any new burden on industry.

For examination of welds, we are adding reference to radioscopic examination, when conducted in accordance with CGA C–3, to increase flexibility for manufacturers while not compromising examination of welds.

For heat treatment, we are aligning the heat treatment requirements with those for DOT 4BA cylinders and clarifying that heat treatment may occur before, during, or after brazing operations.

For yield strengths, tensile strengths, elongations and reduction of area of material, we are re-naming paragraph (j) from ''*Physical tests*'' to ''*Mechanical tests*'' and adding introductory text as proposed. This editorial change is intended to align the 4BW specification language with the similar DOT 4B and 4BA cylinders language. Additionally, we are requiring that manufacturers remove samples for mechanical tests as provided in appendix A to subpart C of part 178, as proposed, in order to improve consistency of cylinder mechanical tests. PHMSA believes that all manufacturers were previously removing samples as recommended in appendix A to subpart C of part 178, therefore this will not create any new burdens for industry. Finally, for the guided bend test we are aligning the DOT 4BW requirements with the 4BA and allowing specimens to be taken from welded test plates and additional specimen testing if the original specimen fails.

For openings to cylinders, we are aligning the DOT 4BW requirements with the existing requirements for DOT 4B and 4BA cylinders as proposed to promote consistency and simplify compliance for manufacturers producing these similar cylinders. Additionally, we are aligning the 4BW with the 4B specification by adding an allowance to attach brass fittings that are components of handheld fire extinguishers.

For rejected cylinders, we are adopting as proposed heat treatment after seam repairs requirements as follows:

- For cylinders with an outside diameter of less than or equal to six (6) inches, welded seam repairs greater than one (1) inch in length shall require reheat treatment of the cylinder.
- For cylinders greater than an outside diameter of 6 inches, welded seam repairs greater than three (3) inches in length shall require reheat treatment.

The HMR current manufacturing standards require heat treatment after any welding repair, but we believe this additional flexibility for manufacturers will maintain the same high level of safety for repaired cylinders.

For marking, we are adding the following marking locations:

1. On side wall adjacent to top head for side walls not less than 0.090 inch thick.
2. On a cylindrical portion of the shell that extends beyond the recessed bottom of the cylinder constituting an integral and non-pressure part of the cylinder.
3. Neckring.

These new locations for the 4BW are already allowed for the very similar 4BA cylinder, are intended to align the 4BW with the 4BA with no decrease in safety.

Finally, we are removing discussion of embossing the head or sidewall of the cylinder from § 178.61(n)(2). PHMSA has concerns with defining ''embossing.'' Markings must be stamped plainly and permanently on the cylinder as prescribed in § 178.61(n)(1).

Section 178.68 Specification 4E Welded Aluminum Cylinders

For aluminum material in § 178.68(b), we are requiring that manufacturers keep a record of intentionally added alloying elements, as proposed. Additionally, we are revising Note 1 to Table 1 to maintain the requirement to conduct regular analysis of the material. It was our intent for the requirement to record intentionally added alloying elements to complement the regular analysis of the material, not replace it.

For yield strengths, tensile strengths, elongations and reduction of area of material, we are re-naming paragraph (j) from ''*Physical tests*'' to ''*Mechanical tests*'' as proposed. For acceptable results for mechanical tests we are not adding the phrase ''a minimum tensile strength as defined in paragraph (f)(1)(ii)

of this section'' to paragraph (k). This text is unnecessary, therefore we are not adopting it. For the alternate guided bend test, we are revising requirements to align with the standards of the Aluminum Association and similar low-pressure steel cylinders.

Finally, we are removing discussion of embossing the head or sidewall of the cylinder from § 178.68(n)(2). PHMSA has concerns with defining ''embossing.'' Markings must be stamped plainly and permanently on the cylinder as prescribed in § 178.68(n)(1).

Section 178.70

Section 178.70(d) prescribes the requirements to obtain design approval of a UN pressure receptacle. In this final rule, we are revising paragraph (d) as proposed to include language that an approval for a design modification is not required if the specific design modification is covered under the UN/ISO standard for the design type already approved.

In our review of the NPRM, we discovered we inadvertently deleted the sentence ''An audit may be required as part of the process to modify an approval'' from § 178.70(d). This was not our intent, therefore in this final rule we are reinserting this sentence.

Section 178.75

Section 178.75 contains the requirements for construction of Multi-Element Gas Containers (MEGCs). In this final rule, we are making two editorial revisions to § 178.75. First, we are correcting a spacing error that made paragraphs (e)(3)(i) and (ii) appear to be part of the same paragraph. Additionally, we are clarifying that compliance with CGA S–1.1 paragraph 9.1.1 is not required for PRDs installed on MEGCs. This editorial change is necessary because we have removed the phrase ''except 9.1.1'' from the central § 171.7 IBR reference for CGA S–1.1.

Section 180.203

Section 180.203 prescribes definitions that apply to the qualification, maintenance, and use of cylinders under the HMR. In this final rule, we add new definitions for the terms or phrases ''mobile unit'' and ''over-pressurized,'' and revise the definitions for ''commercially free of corrosive components'' and ''proof pressure test.'' We previously discussed the definitions for ''mobile unit'' and ''proof pressure test'' in Section VII. Agency Initiated Editorial Corrections. The revision to ''commerically free of corrosive components'' is an editorial revision to express the allowable water content in parts per million (ppm) rather than dew point. We added a definition for ''over-pressurized'' because it is now included as a condition for condemnation of a cylinder under § 180.205(i)—*i.e.,* a cylinder that is known to have been or shows evidence of being ''over-pressurized.'' We received no comments related to the new definition for ''over-pressurized'' and therefore will adopt as proposed. We delete the definitions for ''defect,'' ''elastic expansion,'' ''permanent expansion,'' ''rejected cylinder,'' ''test pressure,'' ''total expansion,'' ''visual inspection,'' and ''volumetric expansion test.'' These new and revised definitions will clarify the cylinder requirements prescribed in part 180, subpart C. The deletion of definitions is intended to remove conflicts and redundancies with the newly incorporated by reference CGA C–1 definitions. See discussion of P–1515 and P–1626 for further discussion of CGA C–1.

Section 180.205

Section 180.205 prescribes the general requirements for requalifying DOT-specification cylinders. In this final rule, we are revising and adding new regulatory text for clarity, and incorporating CGA C–1 into the HMR. Specifically, we clarify the conditions requiring test and inspection of cylinders under paragraph (d) by including a reference to thermal damage as proposed by P–1515 (discussed above in Section IV) to identify cylinders weakened by exposure to heat and evidence of grinding; revise the paragraph (f) visual inspection requirements to include reference to shot blasting and ''chasing'' of cylinders as proposed by P–1515 in accordance with previous PHMSA guidance; revise the paragraph (g) requirements for pressure tests by incorporating by reference CGA C–1; editorially revise paragraph (h) to clarify that rejected cylinders must be repaired or rebuilt as provided in § 180.211 prior to further use, not just requalified; revise paragraph (i) to clarify the responsibilities of the requalifier and add conditions under which a cylinder must be condemned, including arc burns on aluminium cylinders, known over-pressurization, end of service life, and stamping on sidewalls as proposed by P–1515; and move the reference of training materials to its own paragraph (j). See discussion of P–1515 and P–1626 for additional information on the incorporation of CGA C–1.

Section 180.207

Section 180.207 prescribes requirements for requalifying UN pressure receptacles. In this final rule, we revise and add new regulatory text for clarity. In the NPRM, we proposed to remove language authorizing approvals for the extension of the service life of a composite ISO pressure receptacle and require condemnation in accordance with § 180.205(i)(1)(x). In this final rule, we will not adopt these changes, but we will remove reference to a 15-year service life because it does not apply to all ISO composite cylinders. Approval may still be sought to extend the life of ISO composite pressure receptacles and each request will be considered on a case by case basis. Additionally, we clarify language in the introduction to the requalification table to confirm that UN pressure receptacles must be requalified prior to filling the cylinders beyond the marked requalification date; editorially revise paragraph (d) for clarity; and revise the requalification procedures for seamless steel cylinders to include MEGC and other pressure receptacles larger than 150 liters water capacity.

Section 180.209

Section 180.209 prescribes requirements for requalifying specification cylinders. In this final rule, we are revising and adding new regulatory text for clarity and incorporating by reference the 2016 version of CGA C–1, *Methods for Pressure Testing Compressed Gas Cylinders.* Specifically, we revise: The requirement for a hammer test in § 180.209(b); the paragraph (c) tare weight marking requirements; the paragraph (e) proof pressure testing requirements to incorporate by reference CGA C–1; the paragraph (g) visual inspection requirements to remove the obsolete reference to a delayed compliance period that ended in 2004 and to create an entry for cylinders containing propylene, commercially free from corroding components to be requalified visually as proposed by P–1626; the paragraph (j) requirements for fire extinguisher requalification to align with CGA C–1, including allowing direct expansion tests for 4-series cylinders used as fire extinguishers because we believe the direct expansion method is an equivalent method for requalifying fire extinguishers; and the paragraph (l) requirements for marking foreign cylinders. See discussion of P–1626 and P–1515 for additional information on the incorporation of CGA C–1 and additional editorial revisions to § 180.209.

Section 180.212

Section 180.212(a) prescribes requirements to repair seamless DOT 3-

series specification cylinders and seamless UN pressure receptacles. In this final rule, we are revising paragraph (a) to require an ultrasonic examination on DOT 3-series cylinders and seamless UN pressure receptacles after any grinding is performed on these cylinders. Additionally, we are adopting as proposed prohibitions from removing arc burns from cylinders. The presence of arc burns requires cylinder rejection at time of visual inspection, and repair facilities may not remove this evidence from a cylinder. We are adopting ultrasonic examination requirements when grinding is conducted, as proposed. It is PHMSA's understanding that cylinder repair facilities already regularly conduct ultrasonic examination whenever wall thickness is removed or in question, therefore this requirement should not impose any additional burden on cylinder repairers. Finally, we are adopting as proposed a new marking requirement for repaired cylinders to indicate compliance with the repair requirements.

Section 180.213

Section 180.213 prescribes requirements for marking DOT-specification cylinders and UN pressure receptacles that are successfully requalified. In this final rule, we also clarify the marking requirements for foreign cylinders filled for export under paragraph (d). The final rule includes two new marking requirements under paragraph (f):

- Designation of grinding with ultrasonic wall thickness examination; and
- designation of requalification of a foreign cylinder for export only requalified in conformance with §§ 171.23(a)(5) and 180.209(l) of the HMR. The ''EX'' marking for foreign cylinders requalified for export only should not be confused with explosive approvals numbers.

Finally, we add visual inspection identifier number marking requirements under a new paragraph (g) that codify the requirements already found in visual requalifier approval documents.

Section 180.215

Section 180.215 prescribes reporting and retention requirements for a person who requalifies, repairs, or rebuilds cylinders. In this final rule, we revise what information these documents must contain: For calibration certificates, requalifiers must now retain a copy of the most recent calibration certificate for their pressure indicating device and expansion indicating device, to align with CGA C–1 requirements incorporated by reference under this final rule; correcting an ambiguity in § 180.215(c)(2)(vii) to clarify that records for both proof pressure and volumetric expansion tests after re-building a 4-series cylinder must be preserved; and for DOT 3-series cylinders repaired using grinding, a record of the performance of grinding repairs and ultrasonic examination.

VIII. Regulatory Analyses and Notices

A. Statutory/Legal Authority for This Final Rule

This rulemaking responds to 20 petitions for rulemaking, one special permit, and several agency-identified issues that have a potential effect on hazardous materials transportation safety. Federal Hazardous Materials Transportation Law (49 U.S.C. 5101–5128) authorizes the Secretary of Transportation to ''prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce.'' The Secretary's authority is delegated to PHMSA at 49 CFR 1.97.

B. Executive Order 12866 and DOT Policies and Procedures for Rulemakings

This final rule is not considered a significant regulatory action under section 3(f) of Executive Order (E.O.) 12866, ''Regulatory Planning and Review,'' 58 FR 51735, and was not reviewed by the Office of Management and Budget (OMB). This rule is also not significant under the Department of Transportation's Policies and Procedures for Rulemakings (DOT Order 2100.6; Dec. 20, 2018).

E.O. 12866 requires agencies to design regulations ''in the most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' In this final rule, PHMSA accomplishes the directives of E.O. 12866 by involving the public and exercising its own independent judgment in responding to 20 petitions for rulemaking submitted by stakeholders in the compressed gas industry. The final rule clarifies the regulatory text in the HMR and incorporates widely used consensus standards to addresses specific safety concerns, thus enhancing the safe transportation of compressed gases while limiting the impact on the regulated community. Additionally, some of the provisions will provide shippers and carriers with additional flexibility to comply with established safety requirements, thereby reducing burdens and costs and increasing productivity.

Overall, the issues discussed in this final rule promote the continued safe transportation of hazardous materials while producing net cost savings. PHMSA estimates the net cost savings associated with this rule is approximately $70,000 per year, at a 7 percent discount rate, over a ten-year analysis period from 2019 to 2028. Details on the estimated cost savings of this final rule can be found in the rule's economic analysis, which is available in the public docket.

C. Executive Order 13771

This final rule is considered a deregulatory action under E.O. 13771. Details on the estimated cost savings of this final rule can be found in the rule's Regulatory Impact Analysis, available at *www.regulations.gov.*

D. Executive Order 13132

This final rule was analyzed in accordance with the principles and criteria contained in Executive Order 13132, ''Federalism,'' 64 FR 43255. E.O. 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule may preempt State, local, and Native American tribal requirements but does not propose any regulation that has substantial direct effects on the States, the relationship between the National Government and the States, or the distribution of power and responsibilities among the various levels of government. Therefore, the consultation and funding requirements of Executive Order 13132 do not apply.

The Federal Hazardous Materials Transportation Law contains an express preemption provision, 49 U.S.C. 5125(b), that preempts State, local, and Native American tribal requirements on the following subjects unless the non-Federal requirements are ''substantively the same'' as the Federal requirements:

(1) The designation, description, and classification of hazardous materials;

(2) The packing, repacking, handling, labeling, marking, and placarding of hazardous materials;

(3) The preparation, execution, and use of shipping documents related to hazardous materials and requirements related to the number, contents, and placement of those documents;

(4) The written notification, recording, and reporting of the unintentional release in transportation of hazardous material; and

(5) The design, manufacture, fabrication, marking, maintenance, recondition, repair, or testing of a packaging or container represented, marked, certified, or sold as qualified for use in transporting hazardous material.

This final rule addresses subjects (1), (2), and (5) above. Therefore, this final rule will preempt any State, local, or tribal requirements concerning these subjects unless the non-Federal requirements are ''substantively the same'' as the Federal requirements. PHMSA received no comments on the NPRM regarding the effect of the adoption of the specific proposals would have on State or local governments.

E. Executive Order 13175

This final rule was analyzed in accordance with the principles and criteria contained in Executive Order 13175, ''Consultation and Coordination with Indian Tribal Governments,'' 79 FR 4748. E.O. 13175 requires agencies to assure meaningful and timely input from Indian tribal government representatives in the development of rules that significantly or uniquely affect Tribal communities by imposing ''substantial direct compliance costs'' or ''substantial direct effects'' on such communities or the relationship and distribution of power between the Federal Government and Indian tribes. This final rule is generally directed at offerors and shippers of DOT-specification cylinders and UN pressure receptacles that transport hazardous materials in U.S. commerce. The final rule is also likely to affect cylinder manufacturers; cylinder requalifiers; independent inspection agencies; commercial establishments that own and use DOT-specification cylinders and UN pressure receptacles. It does not impose substantial direct compliance costs and does not have substantial direct effects on Native American tribal governments. Therefore, the funding and consultation requirements of E.O. 13175 do not apply, and a tribal summary impact statement is not required. Further, PHMSA did not receive comments on the tribal implications of the rulemaking.

F. Regulatory Flexibility Act, Executive Order 13272, and DOT Procedures and Policies

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities. Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 68 FR 7990, requires agencies to establish procedures and policies to promote compliance with the Regulatory Flexibility Act and to ''thoroughly review draft rules to assess and take appropriate account of the potential impact'' of the rules on small businesses, governmental jurisdictions and small organizations. This rule was developed in accordance with this E.O. and DOT's procedures and policies to promote compliance with the Regulatory Flexibility Act to ensure that potential impacts on small entities of a regulatory action were properly considered.

Section 603(b) of the Regulatory Flexibility Act requires an analysis of the possible impact of the rule on small entities, including the need for the rule, the description of the action, the identification of potentially affected small entities, the reporting and recordkeeping requirements, the related Federal rules and regulations, and the alternative proposals considered. Such analysis for this final rule is as follows:

1. Need for the Final Rule

Current requirements for the manufacture, use, and requalification of cylinders can be traced to standards first applied in the early 1900s. Over the years, the regulations have been revised to reflect advancements in transportation efficiency and changes in the national and international economic environment. This final rule is part of an agency effort to conduct a retrospective review of existing regulations. The final rule attempts to modify and streamline existing requirements that are outmoded, ineffective, insufficient, or excessively burdensome. As part of this effort, this rulemaking introduces new provisions suggested or developed by industry representatives, groups that develop consensus standards, and international regulatory bodies.

2. Description of Action

This final rule responds to 20 petitions for rulemaking, clarifies other requirements in the HMR, and addresses areas of concern that are currently left out of the HMR. The amendments discussed in this final rule are designed to increase flexibility for the regulated community, promote technological advancement, and facilitate international transportation while maintaining a comparable level of safety.

3. Identification of Potentially Affected Small Entities

The term ''small entities,'' as described in 5 U.S.C. 601, comprises small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and governmental jurisdictions with populations of less than 50,000. The amendments considered here are likely to affect cylinder manufacturers (NAICS code 332420; approximately 568 companies); cylinder requalifiers; independent inspection agencies; commercial establishments that own and use DOT-specification cylinders and UN pressure receptacles; and individuals who export non-UN/ISO compressed gas cylinders (NAICS codes 32512, 336992, 423450, 423850, 423990, 454312, and 541380). Nearly all of these companies, particularly cylinder requalification facilities (approximately 5,000 in total) are small entities based on the criteria developed by the Small Business Administration.

4. Reporting and Recordkeeping Requirements

This final rule includes very minor reporting and recordkeeping requirements.

5. Related Federal Rules and Regulations

The Occupational Safety and Health Administration (OSHA) prescribes requirements for the use, maintenance, and testing of portable fire extinguishers in 29 CFR 1910.157 and requirements for fixed fire suppression systems in 29 CFR 1910.160. The issues discussed in this final rule pertaining to the transportation of fire extinguishers and compressed gas cylinders that are a component of a fixed fire suppression system do not conflict with the requirements in OSHA regulations. With respect to the transportation of compressed gases in cylinders, there are not related rules or regulations issued by other departments or agencies of the Federal government.

6. Alternative Proposals for Small Business

The Regulatory Flexibility Act directs agencies to establish exceptions and differing compliance standards for small businesses, where it is possible to do so and still meet the objectives of applicable regulatory statutes. The proposed changes are generally intended to provide cost savings to industry members. PHMSA received no

comments from small entities on specific small business impacts from these additional requirements.

7. Conclusion

This final rule reduces burdens for most persons and any costs resulting from adoption of new requirements will be minimal and will be offset by cost savings. Additionally, the rule will create additional unquantified ancillary benefits and cost savings derived from increasing regulatory flexibility and improving safety through enhanced clarity.

G. Paperwork Reduction Act

PHMSA has analyzed this rule in accordance with the Paperwork Reduction Act of 1995 (PRA) (Pub. L. 96–511). PHMSA stated in the NPRM that the proposals did not impose new information collection requirements. However, PHMSA did receive a comment from Hydro-Test Products related to proposed changes to § 180.215 on the addition of the date of manufacture to test record forms. The commenter noted that PHMSA did not address the paperwork burden for the proposed requirement in § 180.215. To address this comment PHMSA is accounting for a minor adjustment to information on a requalification test report under OMB control number 2137–0022 titled ''Testing, Inspection, and Marking Requirements for Cylinders.'' PHMSA estimates based on our experience observing the activities of cylinder requalifiers during compliance inspections that it will take one additional second to write the date of manufacture on the cylinder requalification record. PHMSA currently estimates there are 6,790,000 cylinder requalifications conducted each year. The additional one second of burden to these reports will result in additional time burden of 1,886 hours (6,790,000 annual reports × 1 second).

Furthermore, upon review of this rule, PHMSA is accounting for additional burden in this rulemaking. In the NPRM, PHMSA also proposed a requirement in § 178.35 to mark the tare weight, mass weight, and water capacity on DOT 4B, 4BA, 4BW, or 4E cylinders. The language in the final rule will codify language in § 178.35 to require that DOT-specification 4B, 4BA, 4BW, and 4E cylinders used in liquefied compressed gas service manufactured two years after publication of this rule to be marked with the tare weight, mass weight, and water capacity. PHMSA already accounts for the marking of new cylinders under § 178.35 under the previously mentioned OMB Control Number 2137–0022. PHMSA estimates based on our knowledge of modern automated cylinder manufacturing processes from direct observation during compliance inspections that this additional marking information will take an additional 3 minutes, for an increase in approximately 3,472 hours on an annual basis.

Additionally, PHMSA proposed a requirement in § 180.215(b)(4) to require cylinder requalifiers to retain the most recent calibration certificate for their pressure indicating device (PID) and expansion indicating device (EID). PHMSA already accounts for creation of records related to cylinder requalification under § 180.215 under OMB Control Number 2137–0022. After the incorporation of CGA C–1, each requalifier will be required to re-calibrate their PID every 6 months. There are approximately 2,300 cylinder requalifiers approved by PHMSA to conduct pressure tests on cylinders, therefore we estimate that 4,600 PID calibration certificates will be generated each year. We estimate that it will take the gauge calibration facility 5 minutes to generate each certificate, based on our knowledge of the information contained on the certificate. This results in a new information collection burden of approximately 383 hours for gauge calibration facilities. Based on our experience inspecting cylinder requalification facilities, we believe that gauge calibration facilities already provide this record as part of their business practices and there will be no additional cost burden associated with this requirement.

Expansion indicating devices (EIDs) are either burette systems or scale-based systems. Burette systems do not require recalibration because their accuracy is fixed at the time the glass burette tube is measured and printed with volume graduations. CGA C–1 requires that scale-based EID systems are recalibrated as provided in the manufacturer's manual. PHMSA has reviewed a manufacturer's manual for a scale-based system and determined that scale calibration is only required when the scale cannot display an accurate weight when tested with an object of known mass (*e.g.* a 100-gram test weight provided with the system). Based on our experience conducting inspections at cylinder requalification facilities, this is an uncommon occurrence. Based on our experience inspecting cylinder requalification facilities, we estimate that 10% of cylinder requalifiers need to recalibrate their scale-based EID systems each year, resulting in the generation of 230 re-calibration certificates annually. We estimate that it will take the scale calibration facility 5 minutes to generate each certificate, based on our knowledge of the information contained on the certificate, which results in an increase of approximate 19 hours in burden. Based on our experience inspecting cylinder requalification facilities, we believe that scale calibration facilities already provide this record as part of their business practices and there will be no additional cost burden associated with this requirement.

Finally, PHMSA proposed a requirement in §§ 178.50(b), 178.51(b), 178.61(b), and 178.68(b) to require manufacturers of DOT 4B, 4BA, 4BW, and 4E cylinders to keep a record of intentionally added alloying elements in the steel or aluminum used to produce the cylinders. PHMSA already accounts for recordkeeping related to the production of cylinders under OMB Control Number 2137–0022. PHMSA estimates based on our knowledge of cylinder manufacturer practices from direct observation during compliance inspections that this additional recordkeeping will take an additional 23 hours affecting 23 manufacturers.

This rulemaking identifies revised information collection requests that PHMSA will submit to OMB for approval based on the requirements in this final rule. PHMSA has developed burden estimates to reflect changes in this final rule and estimates the information collection and recordkeeping burdens in this rule are as follows:

Annual Increase in Number of Respondents: 4,623.

Annual Increase in Annual Number of Responses: 4,853.

Annual Increase in Annual Burden Hours: 5,783.

H. Regulation Identifier Number (RIN)

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document may be used to cross-reference this action with the Unified Agenda.

I. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act (UMRA) of 1995, Public Law 104–4, establishes significance thresholds for the direct costs of regulations on State, local, or tribal governments or the private sector that trigger certain agency reporting requirements. The statutory thresholds established in UMRA were $50 million for intergovernmental mandates and $100 million for private-

sector mandates in 1996. According to the Congressional Budget Office, the thresholds for 2019, which are adjusted annually for inflation, are $82 million and $164 million, respectively, for intergovernmental and private-sector mandates.[12] This final rule results in cost savings and is the least burdensome alternative that achieves the objective of the rule. It is not significant under UMRA. Therefore, PHMSA is not required to prepare a written statement.

J. Environmental Assessment

The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321–4347), and implementing regulations by the Council on Environmental Quality (CEQ) (40 CFR part 1500), require Federal agencies to consider the consequences of major Federal actions and prepare a detailed statement on actions that significantly affect the quality of the human environment. The CEQ regulations require Federal agencies to conduct an environmental review considering: (1) The need for the proposed action; (2) alternatives to the proposed action; (3) probable environmental impacts of the proposed action and alternatives; and (4) the agencies and persons consulted during the consideration process.

1. Need for the Action

This final rule responds to 20 petitions for rulemaking submitted by the regulated community. The issues discussed in this final rule will update and expand the use of currently authorized industry consensus standards; revise the construction, marking, and testing requirements of DOT 4-series cylinders; clarify the filling requirements for cylinders; discuss the handling of cylinders used in fire suppression systems; and revise the requalification requirements for cylinders.

This final rule discusses the following amendments to the HMR:

- Replace the currently incorporated Seventh Edition of the CGA's publication *C–6 Standards for Visual Inspection of Steel Compressed Gas Cylinders* with the revised Eleventh Edition and update the appropriate references throughout the HMR.
- Revise the manufacturing requirements for certain DOT 4-series cylinders.
- Revise the requirements for the requalification of DOT-specification cylinders by pressure testing found in 49 CFR part 180, subpart C.
- Allow the use of the labels described in the Eighth Edition of CGA's publication C–7 *Guide to the Preparation of Precautionary Labeling and Marking of Compressed Gas Containers* (Tenth edition currently incorporated by reference in the HMR) Appendix A on cylinders contained in overpacks.
- Require manufacturers to mark certain newly manufactured cylinders suitable for the transport of liquefied compressed gas with the mass weight or tare weight, and water capacity.
- Allow non-specification cylinders used in a fixed fire suppression system to be transported under the same exceptions as those provided for fire extinguishers, under certain conditions and limitations.
- Clarify filling limits for a liquefied compressed gas in a manifold or a multiple element gas container (MEGC).
- Clarify the requirements for filling non-specification cylinders for export or use on board a vessel.

2. Alternatives Considered

Alternative (1) No Action: Under this alternative, the current regulatory standards would remain in effect. PHMSA would not adopt any of the petitions or incorporate any of the special permits under consideration. As a result, PHMSA would not update, clarify, and provide relief from certain existing regulatory requirements to promote safer transportation practices, eliminate unnecessary regulatory requirements, and facilitate international commerce. We rejected the no action alternative.

Alternative (2) Preferred Alternative: With this alternative, PHMSA responds to 20 petitions for rulemaking, clarifies other requirements in the HMR, and addresses areas of concern that are currently left out of the HMR.

3. Environmental Impacts

Hazardous materials are substances that may pose a threat to public safety or the environment during transportation because of their physical, chemical, or nuclear properties. Under the HMR, hazardous materials are transported by aircraft, vessel, rail, and highway. The hazardous materials regulatory system is a risk management system that is prevention-oriented and focused on identifying a safety hazard and reducing the probability and quantity of a hazardous material release. The potential for environmental damage or contamination exists when packages of hazardous materials are involved in accidents or en route incidents resulting from cargo shifts, valve failures, package failures, loading, unloading, collisions, handling problems, or deliberate sabotage. The release of hazardous materials can cause the loss of ecological resources (*e.g.,* wildlife habitats) and the contamination of air, aquatic environments, and soil. Contamination of soil can lead to the contamination of ground water. Compliance with the HMR substantially reduces the possibility of accidental release of hazardous materials.

Anticipated Impact under Alternative (1) No Action: Potential for increased releases of hazardous materials due to unclear regulatory language and use of outdated industry standards.

Anticipated Impact under Alternative (2) Preferred Alternative: Decreased releases of hazardous materials due to increased clarity of regulatory requirements and updated industry standards. Specifically, increased clarity for MEGC filling requirements will decrease the chances of pressure receptacle overfill which can result in catastrophic releases of hazardous materials. It is anticipated that the petitions discussed in this final rule would have minimal, if any, environmental consequences.

4. Agencies Consulted

Occupational Safety and Health Administration

National Institute of Standards and Technology

U.S. Environmental Protection Agency

5. Conclusion

PHMSA has conducted a technical review of the amendments discussed in this final rule and determined that no significant environmental impact will result from this final rule. The amendments would provide protection against the release of hazardous materials based on sound scientific methods and would not result in unusual stresses on the cylinders used to contain these hazardous materials or adversely impact human health or the environment. PHMSA received no comments specifically addressing the environmental impacts of changes made in this final rule.

K. Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

[12] *https://www.cbo.gov/publication/51335.*

L. International Trade Analysis and Executive Order 13609

The Trade Agreements Act of 1979 (Pub. L. 96–39), as amended by the Uruguay Round Agreements Act (Pub. L. 103–465), prohibits Federal agencies from establishing any standards or engaging in related activities that create unnecessary obstacles to the foreign commerce of the United States. Pursuant to these Acts, the establishment of standards is not considered an unnecessary obstacle to the foreign commerce of the United States, so long as the standards have a legitimate domestic objective, such as the protection of safety, and do not operate in a manner that excludes imports that meet this objective. The statute also requires consideration of international standards, and where appropriate, that they be the basis for U.S. standards. PHMSA notes the purpose is to ensure the safety of the American public and has assessed the effects of this final rule to ensure that it does not exclude imports that meet this objective. The final rule may have positive impacts on international trade because it increases the level of harmonization between U.S. regulations and international standards, which is also consistent with the policy in Executive Order 13609, ''Promoting International Regulatory Cooperation,'' 77 FR 26413. As a result, this final rule is not considered as creating an unnecessary obstacle to foreign commerce.

M. National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) directs Federal agencies to use voluntary consensus standards in their regulatory activities unless doing so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* specification of materials, test methods, or performance requirements) that are developed or adopted by voluntary consensus standards bodies. This final rule adopts five voluntary consensus standards developed by the Compressed Gas Association, which are discussed in detail in the ''Section-by-Section Review'' for § 171.7.

List of Subjects

49 CFR Part 107

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

49 CFR Part 171

Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Reporting and recordkeeping requirements.

49 CFR Part 173

Hazardous materials transportation, Incorporation by reference, Packaging and containers, Radioactive materials, Reporting and recordkeeping requirements, Uranium.

49 CFR Part 178

Hazardous materials transportation, Incorporation by reference, Motor vehicle safety, Packaging and containers, Reporting and recordkeeping requirements.

49 CFR Part 180

Hazardous materials transportation; Motor carriers, Incorporation by reference, Motor vehicle safety, Packaging and containers, Railroad safety, Reporting and recordkeeping requirements.

In consideration of the foregoing, PHMSA amends 49 CFR chapter I as follows:

PART 107—HAZARDOUS MATERIALS PROGRAM PROCEDURES

■ 1. The authority citation for part 107 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410, Section 4; Pub. L. 104–121, Sections 212–213; Pub. L. 104–134, Section 31001; Pub. L. 114–74, Section 4 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97; 33 U.S.C. 1321.

■ 2. In § 107.803, revise paragraph (c)(3) to read as follows:

§ 107.803 Approval of an independent inspection agency (IIA).

* * * * *

(c) * * *

(3) Detailed description of the applicant's qualifications and ability to perform the inspections and to verify the inspections required by parts 178 and 180 of this chapter; or those required under the terms of a special permit issued under this part.

* * * * *

■ 3. In § 107.805, revise paragraphs (c)(3) and (4) and add paragraph (c)(5) to read as follows:

§ 107.805 Approval of cylinder and pressure receptacle requalifiers.

* * * * *

(c) * * *

(3) A certification that the facility will operate in compliance with the applicable requirements of subchapter C of this chapter;

(4) The signature of the person making the certification and the date on which it was signed; and

(5) For a mobile unit operation (as defined in § 180.203 of subchapter C of this chapter), the type of equipment to be used, the specific vehicles to be used, the geographic area the applicant is requesting to operate within, and any differences between the mobile operation and the facility operation as described under paragraph (c)(2) of this section.

* * * * *

PART 171—GENERAL INFORMATION, REGULATIONS, AND DEFINITIONS

■ 4. The authority citation for part 171 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; Pub. L. 101–410, Section 4; Pub. L. 104–134, Section 31001; Pub. L. 114–74, Section 4 (28 U.S.C. 2461 note); 49 CFR 1.81 and 1.97.

■ 5. In § 171.7:

■ a. Revise paragraph (a)(2)(ii);

■ b. Remove paragraph (n)(16) and redesignate paragraphs (n)(1) through (15) as paragraphs (n)(2) through (16);

■ c. Add new paragraph (n)(1) and revise newly redesignated paragraphs (n)(2), (4), and (13) and paragraph (n)(18).

The revisions and addition read as follows:

§ 171.7 Reference material.

(a) * * *

(2) * * *

(ii) The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

* * * * *

(n) * * *

(1) CGA C–1—2016, Methods for Pressure Testing Compressed Gas Cylinders, Eleventh edition, copyright 2016, into §§ 178.36, 178.37, 178.38, 178.39, 178.42, 178.44, 178.45, 178.46, 178.47; 178.50; 178.51; 178.53; 178.55; 178.56; 178.57; 178.58; 178.59; 178.60; 178.61; 178.65; 178.68; 180.205, 180.209.

(2) CGA C–3—2005 (Reaffirmed 2011), Standards for Welding on Thin-Walled Steel Cylinders, Seventh edition, copyright 2005, into §§ 178.47; 178.50; 178.51; 178.53; 178.55; 178.56; 178.57; 178.58; 178.59; 178.60; 178.61; 178.65; 178.68; 180.211.

* * * * *

(4) CGA C–6—2013, Standards for Visual Inspection of Steel Compressed

Gas Cylinders, Eleventh edition, copyright 2013, into §§ 172.102, 173.3, 173.198, 180.205, 180.209, 180.211, 180.411, 180.519.

* * * * *

(13) CGA C–14—2005 (Reaffirmed 2010), Procedures for Fire Testing of DOT Cylinder Pressure Relief Device Systems, Fourth edition, copyright 2005, into §§ 173.301; 173.323.

* * * * *

(18) CGA S–1.1—2011, Pressure Relief Device Standards—Part 1—Cylinders for Compressed Gases, Fourteenth edition, copyright 2011, into §§ 173.301; 173.304a; 178.75.

* * * * *

■ 6. In § 171.23, revise paragraph (a)(5)(i) to read as follows:

§ 171.23 Requirements for specific materials and packagings transported under the ICAO Technical Instructions, IMDG Code, Transport Canada TDG Regulations, or the IAEA Regulations.

* * * * *

(a) * * *

(5) * * *

(i) The cylinder has been requalified and marked in accordance with subpart C of part 180 of this subchapter, or has been requalified as authorized by the Associate Administrator;

* * * * *

PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS

■ 7. The authority citation for part 173 continues to read as follows:

Authority: 49 U.S.C. 5101–5128, 44701; 49 CFR 1.81, 1.96 and 1.97.

■ 8. In § 173.3, revise paragraph (d)(1) to read as follows:

§ 173.3 Packaging and exceptions.

* * * * *

(d) * * *

(1) Except for Class 1, Division 6.2, Class 7, or acetylene material, a cylinder containing a hazardous material may be overpacked in a salvage cylinder.

* * * * *

■ 9. In § 173.301:

■ a. In paragraphs (c) and (f), remove ''9.1.1.1'' and add in its place ''9.1.1'' in each place it appears; and

■ b. Revise paragraph (f)(4).

The revision reads as follows:

§ 173.301 General requirements for shipment of compressed gases and other hazardous materials in cylinders, UN pressure receptacles and spherical pressure vessels.

* * * * *

(f) * * *

(4)(i) A pressure relief device is required on a DOT 39 cylinder regardless of cylinder size or filled pressure.

(ii) A DOT 39 cylinder used for liquefied Division 2.1 materials must be equipped with a metal pressure relief device.

(iii) Fusible pressure relief devices are not authorized on a DOT 39 cylinder containing a liquefied gas.

(iv) A pressure relief device for oxidizing gases transported by air in a DOT 39 cylinder must meet the requirements of § 173.302(f)(2)(iii) of this subpart for permanent gases and § 173.304(f)(2)(iii) for liquefied compressed gases.

* * * * *

■ 10. In § 173.302, revise paragraphs (f)(2)(i) and (ii) and add paragraph (f)(2)(iii) to read as follows:

§ 173.302 Filling of cylinders with nonliquefied (permanent) compressed gases or adsorbed gases.

* * * * *

(f) * * *

(2) * * *

(i) The rated burst pressure of a rupture disc for DOT 3A, 3AA, 3AL, and 3E cylinders, and UN pressure receptacles ISO 9809–1, ISO 9809–2, ISO 9809–3 and ISO 7866 cylinders must be 100% of the cylinder minimum test pressure with a tolerance of plus zero to minus 10%;

(ii) The rated burst pressure of a rupture disc for a DOT 3HT cylinder must be 90% of the cylinder minimum test pressure with a tolerance of plus zero to minus 10%; and

(iii) The rated burst pressure of a rupture disc for a DOT 39 cylinder must be not more than 80 percent of cylinder burst pressure but not less than 105 percent of cylinder test pressure. Cylinders filled and offered for transportation in accordance with the requirements of the section before January 27, 2021 may continue to be used for the life of the packaging.

* * * * *

■ 11. In § 173.302a, revise paragraphs (a)(3) and (c)(4)(i) and (ii) and add paragraph (c)(4)(iii) to read as follows:

§ 173.302a Additional requirements for shipment of nonliquefied (permanent) compressed gases in specification cylinders.

(a) * * *

(3) DOT 39 cylinders. When the cylinder is filled with a Division 2.1 flammable gas, the internal volume of the cylinder may not exceed 1.23 L (75 in^3). For chemical under pressure (see § 172.102 of this subchapter (special provision 362)), the internal volume may not exceed the size limits of the specification as provided in § 178.65(a)(1) of this subchapter.

* * * * *

(c) * * *

(4) * * *

(i) Cylinders less than 1.7 m (65 inches) in length must be equipped with fusible metal backed frangible disc devices;

(ii) Cylinders 1.7 m (65 inches) or greater in length and 24.5 cm (9.63 inches) in diameter or larger must be equipped with fusible metal backed frangible disc devices or frangible disc devices, except as provided in paragraph (c)(4)(iii) of this section. Cylinders with a diameter of 0.56 m (22 inches) or larger must be equipped with frangible disc devices except as provided in paragraph (c)(4)(iii) of this section.

(iii) Cylinders greater than 3.66 m (144 inches) in length that are horizontally mounted on a motor vehicle, in an ISO framework, or other framework of equivalent structural integrity are not required to be equipped with pressure relief devices. If such devices are installed, they must be selected in accordance with § 173.301(f).

* * * * *

■ 12. In § 173.304, revise paragraphs (f)(2)(i) and (ii) and add paragraph (f)(2)(iii) to read as follows:

§ 173.304 Filling of cylinders with liquefied compressed gases.

* * * * *

(f) * * *

(2) * * *

(i) The rated burst pressure of a rupture disc for DOT 3A, 3AA, 3AL, and 3E cylinders, and UN pressure receptacles ISO 9809–1, ISO 9809–2, ISO 9809–3, and ISO 7866 cylinders must be 100% of the cylinder minimum test pressure with a tolerance of plus zero to minus 10%;

(ii) The rated burst pressure of a rupture disc for a DOT 3HT cylinder must be 90% of the cylinder minimum test pressure with a tolerance of plus zero to minus 10%; and

(iii) The rated burst pressure of a rupture disc for a DOT 39 cylinder must be not more than 80 percent of cylinder burst pressure but not less than 105 percent of cylinder test pressure. Cylinders filled and offered for transportation in accordance with the requirements of the section before January 27, 2021 may continue to be used for the life of the packaging.

■ 13. In § 173.304a:

■ a. Revise paragraph (a)(2); and

■ b. Add paragraph (a)(3); and

■ c. Revise paragraph (d)(3)(i).

The revisions and addition read as follows:

§ 173.304a Additional requirements for shipment of liquefied compressed gases in specification cylinders.

(a) * * *

(2) For the gases named, the requirements in table 1 to paragraph (a)(2) apply (for cryogenic liquids, see § 173.316):

TABLE 1 TO PARAGRAPH (a)(2)

Kind of gas	Maximum permitted filling density (percent) (see Note 1)	Packaging marked as shown in this column or of the same type with higher service pressure must be used, except as provided in §§ 173.301(l), 173.301a(e), and 180.205(a) (see notes following table)
Anhydrous ammonia	54	DOT–3A480; DOT–3AA480; DOT–3A480X; DOT–4AA480; DOT–3; DOT–3E1800; DOT–3AL480.
Bromotrifluoromethane (R–13B1 or H–1301)	124	DOT–3A400; DOT–3AA400; DOT–3B400; DOT–4AA480; DOT–4B400; DOT–4BA400; DOT–4BW400; DOT–3E1800; DOT–39; DOT–3AL400.
Carbon dioxide (see Notes 4, 7, and 8)	68	DOT–3A1800; DOT–3AX1800; DOT–3AA1800; DOT–3AAX1800; DOT–3; DOT–3E1800; DOT–3T1800; DOT–3HT2000; DOT–39; DOT–3AL1800.
Carbon dioxide (see Notes 4, 7, and 8)	70.3	DOT–3A2000, DOT–3AA2000, DOT–3AX2000, DOT–3AAX2000, DOT–3T2000.
Carbon dioxide (see Notes 4, 7, and 8)	73.2	DOT–3A2265, DOT–3AA2265, DOT–3AX2265, DOT–3AAX2265, DOT–3T2265.
Carbon dioxide (see Notes 4, 7, and 8)	74.5	DOT–3A2400, DOT–3AA2400, DOT–3AX2400, DOT–3AAX2400, DOT–3T2400.
Carbon dioxide, refrigerated liquid (see paragraph (e) of this section).		DOT–4L.
Chlorine (see Note 2)	125	DOT–3A480; DOT–3AA480; DOT–3; DOT–3BN480; DOT–3E1800.
Chlorodifluroethane or 1-Chloro-1, 1-difluoroethane (R–142b).	100	DOT–3A150; DOT–3AA150; DOT–3B150; DOT–4B150; DOT–4BA225; DOT–4BW225; DOT–3E1800; DOT–39; DOT–3AL150.
Chlorodifluoromethane (R–22) (see Note 8)	105	DOT–3A240; DOT–3AA240; DOT–3B240; DOT–4B240; DOT–4BA240; DOT–4BW240; DOT–4B240ET; DOT–4E240; DOT–39; DOT–3E1800; DOT–3AL240.
Chloropentafluorethane (R–115)	110	DOT–3A225; DOT–3AA225; DOT–3B225; DOT–4BA225; DOT–4B225; DOT–4BW225; DOT–3E1800; DOT–39; DOT–3AL225.
Chlorotrifluoromethane (R–13) (see Note 8)	100	DOT–3A1800; DOT–3AA1800; DOT–3; DOT–3E1800; DOT–39; DOT–3AL1800.
Cyclopropane (see Notes 8 and 9)	55	DOT–3A225; DOT–3A480X; DOT–3AA225; DOT–3B225; DOT–4AA480; DOT4B225; DOT–4BA225; DOT–4BW225; DOT–4B240ET; DOT–3; DOT–3E1800; DOT–39; DOT–3AL225.
Dichlorodifluoromethane (R–12) (see Note 8)	119	DOT–3A225; DOT–3AA225; DOT–3B225; DOT–4B225; DOT–4BA225; DOT–4BW225; DOT–4B240ET; DOT–4E225; DOT–39; DOT–3E1800; DOT–3AL225.
Dichlorodifluoromethane and difluoroethane mixture (constant boiling mixture) (R–500) (see Note 8).	Not liquid full at 131 °F	DOT–3A240; DOT–3AA240; DOT–3B240; DOT–3E1800; DOT–4B240; DOT–4BA240; DOT–4BW240; DOT–4E240; DOT–39.
1,1-Difluoroethane (R–152a) (see Note 8)	79	DOT–3A150; DOT–3AA150; DOT–3B150; DOT–4B150; DOT–4BA225; DOT–4BW225; DOT–3E1800; DOT–3AL150.
1,1-Difluoroethylene (R–1132A)	73	DOT–3A2200; DOT–3AA2200; DOT–3AX2200; DOT–3AAX2200; DOT–3T2200; DOT–39.
Dimethylamine, anhydrous	59	DOT–3A150; DOT–3AA150; DOT–3B150; DOT–4B150; DOT–4BA225; DOT–4BW225; ICC–3E1800.
Ethane (see Notes 8 and 9)	35.8	DOT–3A1800; DOT–3AX1800; DOT–3AA1800; DOT–3AAX1800; DOT–3; DOT–3E1800; DOT–3T1800; DOT–39; DOT–3AL1800.
Ethane (see Notes 8 and 9)	36.8	DOT–3A2000; DOT–3AX2000; DOT–3AA2000; DOT–3AAX2000; DOT–3T2000; DOT–39; DOT–3AL2000.
Ethylene (see Notes 8 and 9)	31.0	DOT–3A1800; DOT–3AX1800; DOT–3AA1800; DOT–3AAX1800; DOT–3; DOT–3E1800; DOT–3T1800; DOT–39; DOT–3AL1800.
Ethylene (see Notes 8 and 9)	32.5	DOT–3A2000; DOT–3AX2000; DOT–3AA2000; DOT–3AAX2000; DOT–3T2000; DOT–39; DOT–3AL2000.
Ethylene (see Notes 8 and 9)	35.5	DOT–3A2400; DOT–3AX2400; DOT–3AA2400; DOT–3AAX2400; DOT–3T2400; DOT–39; DOT–3AL2400.
Hydrogen chloride, anhydrous	65	DOT–3A1800; DOT–3AA1800; DOT–3AX1800; DOT–3AAX1800; DOT–3; DOT–3T1800; DOT–3E1800.
Hydrogen sulfide (Note 10)	62.5	DOT–3A; DOT–3AA; DOT–3B; DOT–4B; DOT–4BA; DOT–4BW; DOT–3E1800; DOT–3AL.

TABLE 1 TO PARAGRAPH (a)(2)—Continued

Kind of gas	Maximum permitted filling density (percent) (see Note 1)	Packaging marked as shown in this column or of the same type with higher service pressure must be used, except as provided in §§ 173.301(l), 173.301a(e), and 180.205(a) (see notes following table)
Insecticide, gases liquefied (see Notes 8 and 12)	Not liquid full at 131 °F	DOT–3A300; DOT–3AA300; DOT–3B300; DOT–4B300; DOT–4BA300; DOT–4BW300; DOT–3E1800.
Liquefied nonflammable gases, other than classified flammable, corrosive, toxic & mixtures or solution thereof filled w/nitrogen, carbon dioxide, or air (see Notes 7 and 8)..	Not liquid full at 131 °F	Specification packaging authorized in paragraph (a)(1) of this section and DOT–3HT; DOT–4D; DOT–4DA; DOT–4DS.
Methyl acetylene-propadiene, mixtures, stabilized; (see Note 5)..	Not liquid at 131 °F	DOT–4B240 without brazed seams; DOT–4BA240 without brazed seams; DOT–3A240; DOT–3AA240; DOT–3B240; DOT–3E1800; DOT–4BW240; DOT–4E240; DOT–4B240ET; DOT–3AL240.
Methyl chloride	84	DOT–3A225; DOT–3AA225; DOT–3B225; DOT–4B225; DOT–4BA225; DOT–4BW225; DOT–3; DOT–3E1800; DOT–4B240ET. Cylinders complying with DOT–3A150; DOT–3B150; and DOT–4B150 manufactured prior to Dec. 7, 1936 are also authorized.
Methyl mercaptan	80	DOT–3A240; DOT–3AA240; DOT–3B240; OT–4B240; DOT–4B240ET; DOT–3E1800; DOT–4BA240; DOT–4BW240.
Nitrosyl chloride	110	DOT–3BN400 only.
Nitrous oxide (see Notes 7, 8, and 11)	68	DOT–3A1800; DOT–3AX1800; DOT–3AA1800; DOT–3AAX1800; DOT–3; DOT–3E1800; DOT–3T1800; DOT–3HT2000; DOT–39; DOT–3AL1800.
Nitrous oxide (see Notes 7, 8, and 11)	70.3	DOT–3A2000, DOT–3AA2000, DOT–3AX2000, DOT–3AAX2000, DOT–3T2000.
Nitrous oxide (see Notes 7, 8, and 11)	73.2	DOT–3A2265, DOT–3AA2265, DOT–3AX2265, DOT–3AAX2265, DOT–3T2265.
Nitrous oxide (see Notes 7, 8, and 11)	74.5	DOT–3A2400, DOT–3AA2400, DOT–3AX2400, DOT–3AAX2400, DOT–3T2400.
Nitrous oxide, refrigerated liquid (see paragraph (e) of this section.).		DOT–4L.
Refrigerant gas, n.o.s. or Dispersant gas, n.o.s. (see Notes 8 and 13).	Not liquid full at 130 °F	DOT–3A240; DOT–3AA240; DOT–3B240; DOT–3E1800; DOT–4B240; DOT–4BA240; DOT–4BW240; DOT–4E240; DOT–39; DOT–3AL240.
Sulfur dioxide (see note 8)	125	DOT–3A225; DOT–3AA225; DOT–3B225; DOT–4B225; DOT–4BA225; DOT–4BW225; DOT–4B240ET; DOT–3; DOT–39; DOT–3E1800; DOT–3AL225.
Sulfur hexafluoride	120	DOT–3A1000; DOT–3AA1000; DOT–AAX2400; DOT–3; DOT–3AL1000; DOT–3E1800; DOT–3T1800.
Sulfuryl fluoride	106	DOT–3A480; DOT–3AA480; DOT–3E1800; DOT–4B480; DOT–4BA480; DOT–4BW480.
Tetrafluoroethylene, stabilized	90	DOT–3A1200; DOT–3AA1200; DOT–3E1800.
Trifluorochloroethylene, stabilized	115	DOT–3A300; DOT–3AA300; DOT–3B300; DOT–4B300; DOT–4BA300; DOT–4BW300; DOT–3E1800.
Trimethylamine, anhydrous	57	DOT–3A150; DOT–3AA150; DOT–3B150; DOT–4B150; DOT–4BA225; DOT–4BW225; DOT–3E1800.
Vinyl chloride (see Note 5)	84	DOT–4B150 without brazed seams; DOT–4BA225 without brazed seams; DOT–4BW225; DOT–3A150; DOT–3AA150; DOT–3E1800; DOT–3AL150.
Vinyl fluoride, stabilized	62	DOT–3A1800; DOT–3AA1800; DOT–3E1800; DOT–3AL1800.
Vinyl methyl ether, stabilized (see Note 5)	68	DOT–4B150, without brazed seams; DOT–4BA225 without brazed seams; DOT–4BW225; DOT–3A150; DOT–3AA150; DOT–3B1800; DOT–3E1800.

Note 1 to paragraph (a)(2): ''Filling density'' means the percent ratio of the weight of gas in a packaging to the weight of water that the container will hold at 16 °C (60 °F). (1 lb of water = 27.737 in^3 at 60 °F.).

Note 2 to paragraph (a)(2): Cylinders purchased after Oct. 1, 1944, for the transportation of chlorine must contain no aperture other than that provided in the neck of the cylinder for attachment of a valve equipped with an approved pressure relief device. Cylinders purchased after Nov. 1, 1935, and filled with chlorine may not contain over 68.04 kg (150 lb) of gas.

Note 4 to paragraph (a)(2): Special carbon dioxide mining devices containing a heating element and filled with not over 2.72 kg (6 lb) of carbon dioxide may be filled to a density of not over 85 percent, provided the cylinder is made of steel with a calculated bursting pressure in excess of 39000 psig, fitted with a frangible disc that will operate at not over 57 percent of that pressure, and is able to withstand a drop of 10 feet when striking crosswise on a steel rail while under a pressure of at least 3000 psig. Such devices must be shipped in strong boxes or must be wrapped in heavy burlap and bound by 12-gauge wire with the wire completely covered by friction tape. Wrapping must be applied so as not to interfere with the functioning of the frangible disc pressure relief device. Shipments must be described as ''liquefied carbon dioxide gas (mining device)'' and marked, labeled, and certified as prescribed for liquefied carbon dioxide.

Note 5 to paragraph (a)(2): All parts of valve and pressure relief devices in contact with contents of cylinders must be of a metal or other material, suitably treated if necessary, that will not cause formation of any acetylides.

Note 7 to paragraph (a)(2): Specification 3HT cylinders for aircraft use only, having a maximum service life of 24 years. Authorized only for nonflammable gases. Cylinders must be equipped with pressure relief devices of the frangible disc type that meet the requirements of § 173.301(f). Each frangible disc must have a rated bursting pressure that does not exceed 90 percent of the minimum required test pressure of the cylinder. Discs with fusible metal backing are not permitted. Cylinders may be offered for transportation only when packaged in accordance with § 173.301(a)(9).

Note 8 to paragraph (a)(2): See § 173.301(a)(9).

Note 9 to paragraph (a)(2): When used for shipment of flammable gases, the internal volume of a specification 39 cylinder must not exceed 75 cubic inches.

Note 10 to paragraph (a)(2): Each valve outlet must be sealed by a threaded cap or a threaded solid plug.

Note 11 to paragraph (a)(2): Must meet the valve and cleaning requirements in § 173.302(b).

Note 12 to paragraph (a)(2): For an insecticide gas that is nontoxic and nonflammable, see § 173.305(c).

Note 13 to paragraph (a)(2): For a refrigerant or dispersant gas that is nontoxic and nonflammable, see § 173.304(d).

(3) A DOT 39 cylinder shall be equipped with a pressure relief device as defined by the commodity in CGA S–1.1, excluding paragraph 9.1.1 (IBR; see § 171.7 of this subchapter). If the commodity is not listed in CGA S–1.1, a CG–7 pressure relief valve must be used.

* * * * *

(d) * * *

(3) * * *

(i) DOT 3, 3A, 3AA, 3B, 3E, 3AL, 4B, 4BA, 4B240ET, 4BW, 4E, or 39 cylinders. The internal volume of a Specification 39 cylinder must not exceed 75 cubic inches. Shipments of flammable gases in DOT 3AL cylinders are authorized only when transported by motor vehicle, rail car, or cargo-only aircraft.

* * * * *

■ 14. In § 173.306, revise paragraph (g) to read as follows:

§ 173.306 Limited quantities of compressed gases.

* * * * *

(g) *Water pump system tank.* Water pump system tanks pre-charged at time of manufacture with compressed air or limited quantities of nitrogen or helium to not over 275.79 kPa gauge pressure (40 psig) for single-trip shipment to installation sites are excepted from labeling, and the specification packaging requirements of this subchapter when shipped under the following conditions. In addition, shipments of these tanks are not subject to the placarding requirements of subpart F of part 172 of this subchapter, and not subject to parts 174 (except § 174.24) and 177 (except § 177.817) of this subchapter.

(1) The tank must be of steel or composite construction, with heads concave to pressure, having a rated water capacity not exceeding 455 L (120 gallons) and with an outside diameter not exceeding 61 cm (24 inches). These tanks may be operated in ambient air temperatures of up to 49 °C (120 °F) with a maximum working pressure not less than 75 psig and not greater than 150 psig. Safety relief devices are not required.

(2) Each tank must be pneumatically tested to the manufacturer's specified maximum working pressure. The test pressure must be permanently marked on the tank. In any case, the pneumatic test must not be conducted to a pressure exceeding 150 psig.

(3) The stress at prescribed pressure for steel tanks must not exceed 20,000 psig (or 25,000 psig for deep-draw steel), using the formula:

$S = Pd/2t$

Where:

S = wall stress in psi;

P = prescribed pressure for the tank is at least the manufacturer's rated maximum working pressure or three (3) times the pre-charged pressure at 21.1 °C (70 °F), whichever is greater;

d = inside diameter in inches; and

t = minimum wall thickness, in inches.

(4) For steel and composite tanks, the burst pressure must be at least six (6) times the pre-charge pressure at 21.1 °C (70 °F) or three (3) times the manufacturer's specified maximum working pressure, whichever is greater.

(5) Each tank must be over-packed in a strong outer packaging in conformance with § 173.301(h).

(6) Transportation is limited to motor vehicle, railcar, and vessel. Transportation by aircraft is not authorized.

* * * * *

■ 15. In § 173.309, revise the introductory text to read as follows:

§ 173.309 Fire extinguishers.

This section applies to portable fire extinguishers for manual handling and operation, fire extinguishers for installation in aircraft, fire extinguishers for installation as part of a fire suppression system, and large fire extinguishers. Fire extinguishers for installation as part of a fire suppression system include cylinders charged with either a compressed gas and an extinguishing agent or a gas which comprises the sole fire extinguishing agent in the system. A fire extinguisher does not include cylinders pressurized with a gas for purposes of expelling a separately stored extinguishing agent in the fire suppression system. Large fire extinguishers include fire extinguishers mounted on wheels for manual handling; fire extinguishing equipment or machinery mounted on wheels or wheeled platforms or units transported similar to (small) trailers; and fire extinguishers composed of a non-rollable pressure drum and equipment, and handled, for example, by fork lift or crane when loaded or unloaded. Cylinders filled with a compressed gas whose purpose is to expel a separately stored extinguishing agent may not be transported under this section when offered for transportation or transported apart from a suppression system.

* * * * *

■ 16. In § 173.312, revise paragraph (b)(1) to read as follows:

§ 173.312 Requirements for shipment of MEGCs.

* * * * *

(b) * * *

(1) A MEGC may not be filled above its marked maximum permissible gross mass. Additionally, MEGCs must be filled in accordance with the following:

(i) A MEGC being filled with non-liquefied (permanent) compressed gas may not be filled to a pressure greater than the lowest marked working pressure of any cylinder (pressure receptacle).

(ii) An MEGC being filled with a liquefied compressed gas must have each pressure receptacle filled separately by weight and must be filled by a means to ensure that only one pressure receptacle is filled at a time.

(iii) The filling density for UN pressure receptacles may not exceed the values in accordance with § 173.304b(b).

* * * * *

§ 173.323 [AMENDED]

■ 17. In § 173.323(b)(2), immediately following the words ''Pamphlet C–14'' in the last sentence, add the phrase ''(IBR, see § 171.7 of this subchapter)''.

PART 178—SPECIFICATIONS FOR PACKAGINGS

■ 18. The authority citation for part 178 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 19. In § 178.35, add paragraph (f)(8) to read as follows:

§ 178.35 General requirements for specification cylinders.

* * * * *

(f) * * *

(8) *Tare weight or mass weight, and water capacity marking.* DOT-specification 4B, 4BA, 4BW, and 4E cylinders used in liquefied compressed gas service manufactured after December 28, 2022, must be marked with the tare weight or mass weight. Additionally, the cylinder must be permanently marked with the water capacity. The owner of the cylinder must ensure it is marked with the following information, as applicable:

(i) *Tare weight.* The tare weight for a cylinder 25 pounds or less at the time of manufacture, with a lower tolerance of 3 percent and an upper tolerance of 1 percent; or for a cylinder exceeding 25 pounds at the time of manufacture, with a lower tolerance of 2 percent and an upper tolerance of 1 percent. The tare weight marking must be the actual weight of the fully assembled cylinder, including the valve(s) and other permanently affixed appurtenances. Removable protective cap(s) or cover(s) must not be included in the cylinder tare weight. Tare weight shall be abbreviated ''TW''; or

(ii) *Mass weight.* The mass weight for a cylinder 25 pounds or less at the time of manufacture, with a lower tolerance of 3 percent and an upper tolerance of 1 percent; or the mass weight marking for a cylinder exceeding 25 pounds at the time of manufacture, with a lower tolerance of 2 percent and an upper tolerance of 1 percent. The mass weight marking must be the actual weight of the fully assembled cylinder, excluding valve(s) and removable protective cap(s) or cover(s). Mass weight shall be abbreviated ''MW''; and

(iii) *Water capacity.* The water capacity for a cylinder 25 pounds water capacity or less, with a tolerance of minus 1 percent and no upper tolerance; or for a cylinder exceeding 25 pounds water capacity, with a tolerance of minus 0.5 percent and no upper tolerance. The marked water capacity of the cylinder must be the capacity of the cylinder at the time of manufacture. Water capacity shall be abbreviated ''WC''.

* * * * *

■ 20. In § 178.36, revise paragraph (i) to read as follows:

§ 178.36 Specification 3A and 3AX seamless steel cylinders.

* * * * *

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Each cylinder must be tested to a minimum of 5/3 times service pressure.

(3) The minimum test pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(4) Permanent, volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

* * * * *

■ 21. In § 178.37, revise paragraph (i) to read as follows:

§ 178.37 Specification 3AA and 3AAX seamless steel cylinders.

* * * * *

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Each cylinder must be tested to a minimum of 5/3 times service pressure.

(3) The minimum test pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(4) Permanent, volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

* * * * *

■ 22. In § 178.38, revise paragraph (i) to read as follows:

§ 178.38 Specification 3B seamless steel cylinders.

* * * * *

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as defined in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Cylinders must be tested as follows:

(i) Each cylinder to at least two (2) times its service pressure; or

(ii) One (1) cylinder out of each lot of 200 or fewer to at least three (3) times its service pressure. When one (1) cylinder out of each lot of 200 or less is tested to at least 3 times service pressure, the balance of the lot must be pressure tested by the proof pressure, water-jacket or direct expansion test method as prescribed in CGA C–1. The cylinders must be subjected to at least 2 times service pressure and show no defect. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

(3) When each cylinder is tested to the minimum test pressure, the minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(4) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

* * * * *

■ 23. In § 178.39, revise paragraph (i) to read as follows:

§ 178.39 Specification 3BN seamless nickel cylinders.

* * * * *

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure

indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Each cylinder must be tested to a minimum of at least two (2) times its service pressure.

(3) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(4) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

* * * * *

■ 24. In § 178.42, revise paragraph (f) to read as follows:

§ 178.42 Specification 3E seamless steel cylinders.

* * * * *

(f) *Pressure testing.* Cylinders must be tested as follows:

(1) One cylinder out of each lot of 500 or fewer must be subjected to a hydrostatic test pressure of 6,000 psig or higher.

(2) The cylinder referred to in paragraph (f)(1) of this section must burst at a pressure higher than 6,000 psig without fragmenting or otherwise showing lack of ductility, or must hold a pressure of 12,000 psig for 30 seconds without bursting. In which case, it must be subjected to a flattening test without cracking to six times wall thickness between knife edges, wedge shaped 60 degree angle, rounded out to a ½ inch radius. The inspector's report must be suitably changed to show results of latter alternate and flattening test. The testing equipment must be calibrated as prescribed in CGA C–1 (IBR, see § 171.7 of this subchapter). All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(3) The remaining cylinders of the lot must be pressure tested by the proof pressure water-jacket or direct expansion test method as prescribed in CGA C–1. Cylinders must be examined under pressure of at least 3,000 psig and not to exceed 4,500 psig and show no defect. Cylinders tested at a pressure in excess of 3,600 psig must burst at a pressure higher than 7,500 psig when tested as specified in paragraph (f)(2) of this section. The pressure must be maintained for at least 30 seconds and sufficiently longer to ensure complete examination. The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

* * * * *

■ 25. In § 178.44, revise paragraph (i) to read as follows:

§ 178.44 Specification 3HT seamless steel cylinders for aircraft use.

* * * * *

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Each cylinder must be tested to minimum of 5⁄3 times service pressure.

(3) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(4) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

* * * * *

■ 26. In § 178.45, revise paragraph (g) to read as follows:

§ 178.45 Specification 3T seamless steel cylinder.

* * * * *

(g) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Each cylinder must be tested to minimum of 5⁄3 times service pressure.

(3) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(4) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

* * * * *

■ 27. In § 178.46, revise paragraph (g) to read as follows:

§ 178.46 Specification 3AL seamless aluminum cylinders.

* * * * *

(g) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) The minimum test pressure must be the greater of the following:

(i) 450 psig regardless of service pressure;

(ii) Two (2) times the service pressure for cylinders having service pressure less than 500 psig; or

(iii) 5⁄3 times the service pressure for cylinders having a service pressure of 500 psig or greater.

(3) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2, however, if a second failure to maintain the test pressure occurs the cylinder being tested must be rejected.

(4) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

* * * * *

■ 28. In § 178.47, revise paragraph (j) to read as follows:

§ 178.47 Specification 4DS welded stainless steel cylinders for aircraft use.

* * * * *

(j) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Each cylinder must be tested to a minimum of at least two (2) times its service pressure.

(3) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(4) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(5) The cylinder must then be inspected. Any wall thickness lower than that required by paragraph (f) of this section must be cause for rejection. Bulges and cracks must be cause for rejection. Welded joint defects exceeding requirements of paragraph (k) of this section are cause for rejection.

* * * * *

■ 29. Revise § 178.50 to read as follows:

§ 178.50 Specification 4B welded or brazed steel cylinders.

(a) *Type, size, pressure, and application.* A DOT 4B is a welded or brazed steel cylinder with longitudinal seams that are forged lap-welded or brazed and with water capacity (nominal) not over 1,000 pounds and a service pressure of at least 150 but not over 500 psig. Cylinders closed in by spinning process are not authorized.

(b) *Steel.* Open-hearth, electric or basic oxygen process steel of uniform quality must be used. Content percent may not exceed the following: Carbon, 0.25; phosphorus, 0.045; sulphur, 0.050. The cylinder manufacturer must maintain a record of intentionally added alloying elements.

(c) *Identification of material.* Pressure-retaining materials must be identified by any suitable method that does not compromise the integrity of the cylinder. Plates and billets for hotdrawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Exposed bottom welds on cylinders over 18 inches long must be protected by footrings. Welding procedures and operators must be qualified in conformance with CGA C–3 (IBR, see § 171.7 of this subchapter). Seams must be made as follows:

(1) *Brazing materials.* Brazing materials must be by copper brazing, by copper alloy brazing, or by silver alloy brazing. Copper alloy composition must be: Copper, 95 percent minimum; Silicon, 1.5 percent to 3.85 percent; Manganese, 0.25 percent to 1.10 percent.

(2) *Brazed circumferential seams.* Heads attached by brazing must have a driving fit with the shell, unless the shell is crimped, swedged, or curled over the skirt or flange of the head, and be thoroughly brazed until complete penetration by the brazing material of the brazed joint is secured. Depth of brazing of the joint must be at least four (4) times the minimum thickness of shell metal.

(3) *Welded circumferential seams.* Circumferential seams are permitted by the welding process.

(4) *Longitudinal seams in shells.* Longitudinal seams must be a forged lap joint design. When brazed, the plate edge must be lapped at least eight (8) times the thickness of the plate, laps being held in position, substantially metal to metal, by riveting or electric spot-welding; brazing must be done by using a suitable flux and by placing brazing material on one side of seam and applying heat until this material shows uniformly along the seam of the other side.

(e) *Welding or brazing.* Only the attachment of neckrings, footrings, handles, bosses, pads, and valve protection rings to the tops and bottoms of cylinders by welding or brazing is authorized. Attachments and the portion of the cylinder to which they are attached must be made of weldable steel, the carbon content of which may not exceed 0.25 percent except in the case of 4130X steel, which may be used with proper welding procedure.

(f) *Wall thickness.* The wall thickness of the cylinder must comply with the following requirements:

(1) For cylinders with outside diameters over 6 inches, the minimum wall thickness must be 0.090 inch. In any case, the minimum wall thickness must be such that calculated wall stress at minimum test pressure (paragraph (i)(4) of this section) may not exceed the following values:

(i) 24,000 psig for cylinders without longitudinal seam.

(ii) 22,800 psig for cylinders having copper brazed or silver alloy brazed longitudinal seam.

(iii) 18,000 psig for cylinders having forged lapped welded longitudinal seam.

(2) Calculation must be made by the formula:

$$S = [P(1.3D^2 + 0.4d^2)]/(D^2 - d^2)$$

Where:

S = wall stress in psig;

P = minimum test pressure prescribed for water jacket test or 450 psig whichever is the greater;

D = outside diameter in inches; and

d = inside diameter in inches.

(g) *Heat treatment.* Cylinder heads, bodies or the completed cylinder, formed by drawing or pressing, must be uniformly and properly heat treated by an applicable method shown in table 1 of appendix A of this part before tests.

(h) *Opening in cylinders.* Openings in cylinders must comply with the following:

(1) Any opening must be placed on other than a cylindrical surface.

(2) Each opening in a spherical type of cylinder must be provided with a fitting, boss, or pad of weldable steel securely attached to the cylinder by fusion welding.

(3) Each opening in a cylindrical type cylinder, except those for pressure relief devices, must be provided with a fitting, boss, or pad, securely attached to container by brazing or by welding.

(4) If threads are used, they must comply with the following:

(i) Threads must be clean cut, even without checks, and tapped to gauge.

(ii) Taper threads must be of a length not less than as specified for American Standard taper pipe threads.

(iii) Straight threads, must have at least four (4) engaged threads, must have tight fit and a calculated shear strength at least ten (10) times the test pressure of the cylinder; gaskets are required for straight threads and must be of sufficient quality to prevent leakage.

(iv) A brass fitting may be brazed to the steel boss or flange on cylinders used as component parts of handheld fire extinguishers.

(5) The closure of a fitting, boss, or pad must be adequate to prevent leakage.

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows: (1) *Lot testing.* (i) At least one (1) cylinder randomly selected out of each lot of 200 or fewer must be

tested by the water jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested to a minimum of 2 times service pressure.

(iii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iv) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(2) *Pressure testing.* (i) The remaining cylinders in the lot must be tested by the proof pressure, water-jacket, or direct expansion test method as prescribed in CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. Further, all testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, sections 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

(ii) Each cylinder must be tested to a minimum of at least two (2) times service pressure and show no defect.

(j) *Mechanical test.* A mechanical test must be conducted to determine yield strength, tensile strength, elongation as a percentage, and reduction of area of material as a percentage as follows:

(1) Testing is required on two (2) specimens removed from one (1) cylinder, or part thereof, heat-treated as required, as illustrated in appendix A to this subpart. For lots of 30 or fewer, mechanical tests are authorized to be made on a ring at least 8 inches long removed from each cylinder and subjected to the same heat treatment as the finished cylinder.

(2) Specimens must comply with the following:

(i) When a cylinder wall is 3⁄16 inch thick or less, one the following gauge lengths is authorized: A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with a width not over 1½ inches, or a gauge length at least twenty-four (24) times the thickness with a width not over six (6) times the thickness.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When the size of a cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are taken and prepared using this method, the inspector's report must show detailed information regarding such specimens in connection with the record of mechanical tests.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM E 8 (IBR, see § 171.7 of this subchapter).

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load'') corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For strain measurement, the initial strain reference must be set while the specimen is under a stress of 12,000 psig, and strain indicator reading must be set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(v) The yield strength must not exceed 73 percent of the tensile strength.

(k) *Elongation.* Mechanical test specimens must show at least a 40 percent elongation for a 2-inch gauge length or at least 20 percent in other cases. However, elongation percentages may be reduced numerically by 2 percent for 2-inch specimens, and by 1 percent in other cases, for each 7,500 psig increase of tensile strength above 50,000 psig. The tensile strength may be incrementally increased by four increments of 7,500 psig for a maximum total of 30,000 psig.

(l) *Flattening test*—(1) *Cylinders.* After pressure testing, a flattening test must be performed on one cylinder taken at random out of each lot of 200 or fewer by placing the cylinder between wedge-shaped knife edges having a 60 degree included angle, rounded to a half-inch radius. The longitudinal axis of the cylinder must be at a 90-degree angle to knife edges during the test. For lots of 30 or fewer, flattening tests are authorized to be performed on a ring of at least 8 inches long removed from each cylinder and subjected to the same heat treatment as the finished cylinder.

(2) *Pipes.* When cylinders are constructed of lap welded pipe, an additional flattening test is required, without evidence of cracking, up to six (6) times the wall thickness. In such case, the rings (crop ends) removed from each end of the pipe, must be tested with the weld 45 °F or less from the point of greatest stress.

(m) *Acceptable results for flattening tests.* There must be no evidence of cracking of the sample when it is flattened between flat plates to no more than six (6) times the wall thickness. If this test fails, one additional sample from the same lot may be taken. If this second sample fails, the entire lot must be rejected.

(n) *Rejected cylinders.* Reheat treatment is authorized for a rejected cylinder in accordance with this paragraph (n). After reheat treatment, a cylinder must pass all prescribed tests in this section to be considered acceptable. Repair of brazed seams by brazing and welded seams by welding is authorized. For cylinders with an outside diameter of less than or equal to six (6) inches, welded seam repairs greater than one (1) inch in length shall require reheat treatment of the cylinder. For cylinders greater than an outside diameter of 6 inches, welded seam repairs greater than three (3) inches in length shall require reheat treatment.

(o) *Markings.* (1) Markings must be as required as in § 178.35 and in addition must be stamped plainly and permanently in any of the following locations on the cylinder:

(i) On shoulders and top heads whose wall thickness is not less than 0.087-inch thick;

(ii) On side wall adjacent to top head for side walls which are not less than 0.090 inch thick;

(iii) On a cylindrical portion of the shell that extends beyond the recessed bottom of the cylinder, constituting an integral and non-pressure part of the cylinder;

(iv) On a metal plate attached to the top of the cylinder or permanent part thereof; sufficient space must be left on the plate to provide for stamping at least six retest dates; the plate must be at least 1/16-inch thick and must be attached by welding, or by brazing. The brazing rod must melt at a temperature of 1100 °F. Welding or brazing must be along all the edges of the plate;

(v) On the neck, neckring, valve boss, valve protection sleeve, or similar part permanently attached to the top of the cylinder; or

(vi) On the footring permanently attached to the cylinder, provided the water capacity of the cylinder does not exceed 30 pounds.

(2) Embossing the cylinder head or sidewall is not permitted.

■ 30. Revise § 178.51 to read as follows:

§ 178.51 Specification 4BA welded or brazed steel cylinders.

(a) *Type, size, pressure, and application.* A DOT 4BA cylinder is a cylinder, either spherical or cylindrical design, with a water capacity of 1,000 pounds or less and a service pressure range of 225 to 500 psig. Closures made by the spinning process are not authorized.

(1) Spherical type cylinder designs are permitted to have only one circumferentially welded seam.

(2) Cylindrical type cylinder designs must be of circumferentially welded or brazed construction; longitudinally brazed or silver-soldered seams are also permitted.

(b) *Steel.* The steel used in the construction of the cylinder must be as specified in table 1 of appendix A to this part. The cylinder manufacturer must maintain a record of intentionally added alloying elements.

(c) *Identification of material.* Pressure-retaining material must be identified by any suitable method that does not compromise the integrity of the cylinder. Plates and billets for hotdrawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart. No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface finish is required. Exposed bottom welds on cylinders over 18 inches long must be protected by footrings.

(1) Seams must be made as follows:

(i) Minimum thickness of heads and bottoms must be not less than 90 percent of the required thickness of the side wall.

(ii) Circumferential seams must be made by welding or by brazing. Heads attached by brazing must have a driving fit with the shell unless the shell is crimped, swedged, or curled over the skirt or flange of the head and must be thoroughly brazed until complete penetration by the brazing material of the brazed joint is secured. Depth of brazing from end of the shell must be at least four (4) times the thickness of shell metal.

(iii) Longitudinal seams in shells must be made by copper brazing, copper alloy brazing, or by silver alloy brazing. Copper alloy composition must be: Copper 95 percent minimum, Silicon 1.5 percent to 3.85 percent, Manganese 0.25 percent to 1.10 percent. The melting point of the silver alloy brazing material must be in excess of 1,000 °F. The plate edge must be lapped at least eight times the thickness of plate, laps being held in position, substantially metal to metal, by riveting or by electric spot-welding. Brazing must be done by using a suitable flux and by placing brazing material on one side of seam and applying heat until this material shows uniformly along the seam of the other side. Strength of longitudinal seam: Copper brazed longitudinal seam must have strength at least 3/2 times the strength of the steel wall.

(2) Welding procedures and operators must be qualified in conformance with CGA C–3 (IBR, see § 171.7 of this subchapter).

(e) *Welding or brazing.* Welding or brazing of any attachment or opening to the heads of cylinders is permitted provided the carbon content of the steel does not exceed 0.25 percent except in the case of 4130 × steel, which may be used with proper welding procedure.

(f) *Wall thickness.* The minimum wall thickness of the cylinder must meet the following conditions:

(1) For any cylinder with an outside diameter of greater than 6 inches, the minimum wall thickness is 0.078 inch. In any case, the minimum wall thickness must be such that the calculated wall stress at the minimum test pressure may not exceed the lesser value of any of the following:

(i) The value shown in table 1 of appendix A to this part, for the material under consideration;

(ii) One-half of the minimum tensile strength of the material determined as required in paragraph (j) of this section;

(iii) 35,000 psig; or

(iv) Further provided that wall stress for cylinders having copper brazed longitudinal seams may not exceed 95 percent of any of the above values. Measured wall thickness may not include galvanizing or other protective coating.

(2) Cylinders that are cylindrical in shape must have the wall stress calculated by the formula:

$$S = [P(1.3D^2 + 0.4d^2)]/(D^2 - d^2)$$

Where:

S = wall stress in psig;

P = minimum test pressure prescribed for water jacket test;

D = outside diameter in inches; and

d = inside diameter in inches.

(3) Cylinders that are spherical in shape must have the wall stress calculated by the formula:

$$S = PD/4tE$$

Where:

S = wall stress in psig;

P = minimum test pressure prescribed for water jacket test;

D = outside diameter in inches;

t = minimum wall thickness in inches;

E = 0.85 (provides 85 percent weld efficiency factor which must be applied in the circumferential weld area and heat affected zones which zone must extend a distance of 6 times wall thickness from center line of weld); and

E = 1.0 (for all other areas).

(4) For a cylinder with a wall thickness less than 0.100 inch, the ratio of tangential length to outside diameter may not exceed 4.1.

(g) *Heat treatment.* Cylinders must be heat treated in accordance with the following requirements:

(1) Each cylinder must be uniformly and properly heat treated prior to test by the applicable method shown in table 1 of appendix A to this part. Heat treatment must be accomplished after all forming and welding operations, except that when brazed joints are used, heat treatment must follow any forming and welding operations, but may be done before, during or after the brazing operations (see paragraph (m) of this section for weld repairs).

(2) Heat treatment is not required after the welding or brazing of weldable low carbon parts to attachments of similar material which have been previously welded or brazed to the top or bottom of cylinders and properly heat treated, provided such subsequent welding or brazing does not produce a temperature in excess of 400 °F in any part of the top or bottom material.

(h) *Openings in cylinders.* Openings in cylinders must comply with the following requirements:

(1) Any opening must be placed on other than a cylindrical surface.

(2) Each opening in a spherical type cylinder must be provided with a fitting, boss, or pad of weldable steel securely attached to the container by fusion welding.

(3) Each opening in a cylindrical type cylinder must be provided with a fitting,

boss, or pad, securely attached to container by brazing or by welding.

(4) If threads are used, they must comply with the following:

(i) Threads must be clean-cut, even, without checks and tapped to gauge.

(ii) Taper threads must be of a length not less than that specified for American Standard taper pipe threads.

(iii) Straight threads, having at least 4 engaged threads, must have a tight fit and a calculated shear strength of at least 10 times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) *Lot testing.* (i) At least one (1) cylinder randomly selected out of each lot of 200 or fewer must be tested by water jacket or direct expansion method as prescribed in CGA C–1 (IBR, see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) The selected cylinder must be tested to a minimum of two (2) times service pressure.

(iii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iv) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(2) *Pressure testing.* (i) The remaining cylinders in the lot must be tested by the proof pressure, water-jacket, or direct expansion test method as prescribed in CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. Further, all testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested to a minimum of two (2) times service pressure and show no defect. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

(j) *Mechanical test.* (1) A mechanical test must be conducted to determine yield strength, tensile strength, elongation as a percentage, and reduction of area of material as a percentage, as follows:

(i) *Cylinders.* Testing is required on two (2) specimens removed from one cylinder or part thereof taken at random out of each lot of 200 or fewer. Samples must be removed after heat treatment as illustrated in appendix A to this subpart.

(ii) *Spheres.* Testing is required on two (2) specimens removed from the sphere or flat representative sample plates of the same heat of material taken at random from the steel used to produce the spheres. Samples (including plates) must be taken from each lot of 200 or fewer. The flat steel from which two specimens are to be removed must receive the same heat treatment as the spheres themselves. Samples must be removed after heat treatment as illustrated in appendix A to this subpart.

(2) Specimens must comply with the following:

(i) When a cylinder wall is 3⁄16 inch thick or less, one the following gauge lengths is authorized: A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with a width not over 1½ inches, or a gauge length at least twenty-four (24) times the thickness with a width not over six (6) times the thickness.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within one inch of each end of the reduced section.

(iii) When size of the cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are so taken and prepared, the inspector's report must show with the record of physical tests detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''offset'' method or the ''extension under load'' method as prescribed in ASTM E 8 (IBR, see § 171.7 of this subchapter).

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load''), corresponding to the stress at which the 0.2 percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2 percent offset.

(iii) For strain measurement, the initial strain reference must be set while the specimen is under a stress of 12,000 psig, and the strain indicator reading must be set at the calculated corresponding strain.

(k) *Elongation.* Mechanical test specimens must show at least a 40 percent elongation for a 2-inch gauge length or at least 20 percent in other cases. However, elongation percentages may be reduced numerically by 2 percent for 2-inch specimens, and by 1 percent in other cases, for each 7,500 psig increase of tensile strength above 50,000 psig. The tensile strength may be incrementally increased by four increments of 7,500 psig for a maximum total of 30,000 psig.

(l) *Tests of welds.* Except for brazed seams, welds must be tested as follows:

(1) *Tensile test.* A specimen must be removed from one cylinder of each lot of 200 or fewer, or welded test plate. The welded test plate must be of one of the heats in the lot of 200 or fewer which it represents, in the same condition and approximately the same thickness as the cylinder wall except that in no case must it be of a lesser thickness than that required for a quarter size Charpy impact specimen. The weld must be made by the same procedures and subjected to the same heat treatment as the major weld on the cylinder. The specimen must be taken from across the major seam and must be prepared and tested in conformance with and must meet the requirements of CGA C–3. Should this specimen fail to meet the requirements, one additional specimen must be taken from two additional cylinders or welded test plates from the same lot and tested. If either of these latter two specimens fail to meet the requirements, the entire lot represented must be rejected.

(2) *Guided bend test.* A root bend test specimen must be removed from the cylinder or welded test plate that was used for the tensile test specified in paragraph (l)(1) of this section. The specimen must be taken from across the circumferential seam and must be prepared and tested in conformance with and must meet the requirements of CGA C–3. Should this specimen fail to meet the requirements, one additional

specimen must be taken from two additional cylinders or welded test plates from the same lot and tested. If either of these latter two specimens fail to meet the requirements, the entire lot represented must be rejected.

(3) *Alternate guided-bend test.* This test may be used and must be as required by CGA C–3. The specimen must be bent until the elongation at the outer surface, adjacent to the root of the weld, between the lightly scribed gage lines a to b, must be at least 20 percent, except that this percentage may be reduced for steels having a tensile strength in excess of 50,000 psig, as provided in paragraph (k) of this section. Should the specimen fail to meet the requirements, one additional specimen must be taken from two additional cylinders or welded test plates from the same lot and tested. If any of these latter two specimens fail to meet the requirements, the entire lot represented must be rejected.

(m) *Rejected cylinders.* Reheat treatment is authorized for a rejected cylinder in accordance with this paragraph (m). After reheat, a cylinder must pass all prescribed tests in this section to be acceptable. Repair of brazed seams by brazing and welded seams by welding is considered authorized. For cylinders with an outside diameter of less than or equal to six (6) inches, welded seam repairs greater than one (1) inch in length shall require reheat treatment of the cylinder. For cylinders greater than an outside diameter of six (6) inches, welded seam repairs greater than three (3) inches in length shall require reheat treatment.

(n) *Markings.* (1) Markings must be as required in § 178.35 and in addition must be stamped plainly and permanently in one of the following locations on the cylinder:

(i) On shoulders and top heads whose wall thickness is not less than 0.087 inch thick;

(ii) On side wall adjacent to top head for side walls not less than 0.090 inch thick;

(iii) On a cylindrical portion of the shell that extends beyond the recessed bottom of the cylinder constituting an integral and non-pressure part of the cylinder;

(iv) On a plate attached to the top of the cylinder or permanent part thereof; sufficient space must be left on the plate to provide for stamping at least six retest dates; the plate must be at least 1/16 inch thick and must be attached by welding, or by brazing at a temperature of at least 1100 °F., throughout all edges of the plate;

(v) On the neck, neckring, valve boss, valve protection sleeve, or similar part permanently attached to the top of the cylinder; or

(vi) On the footring permanently attached to the cylinder, provided the water capacity of the cylinder does not exceed 30 pounds.

(2) [Reserved]

■ 31. In § 178.53, revise paragraph (h) to read as follows:

§ 178.53 Specification 4D welded steel cylinders for aircraft use.

* * * * *

(h) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) *Lot testing.* (i) At least one cylinder selected at random out of each lot of 200 or fewer must be tested by water-jacket or direct expansion as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) The selected cylinder must be tested to a minimum of three (3) times service pressure.

(iii) The minimum test pressure must be maintained be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iv) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(2) *Pressure testing.* (i) The remaining cylinders in each lot must be tested by the proof pressure water-jacket or direct expansion test method as prescribed in CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. Further, all testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1. Determination of expansion properties is not required.

(ii) Each cylinder must be tested to a minimum of two (2) times service pressure and show no defect. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2, as appropriate.

(3) *Alternative volumetric expansion testing.* As an alternative to the testing prescribed in paragraphs (h)(1) and (2) of this section, every cylinder may be volumetrically expansion tested by the water jacket or direct expansion test method. The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(i) Each cylinder must be tested to a minimum of at least two (2) times its service pressure.

(ii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and previous to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iii) Permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

* * * * *

■ 32. In § 178.55, revise paragraph (i) to read as follows:

§ 178.55 Specification 4B240ET welded or brazed cylinders.

* * * * *

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) *Lot testing.* (i) At least one (1) cylinder selected at random out of each lot of 200 or fewer must be tested by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested to a minimum of two (2) times service pressure.

(iii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iv) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(2) *Pressure testing.* (i) The remaining cylinders in each lot must be tested by the proof pressure water-jacket or direct expansion test method as prescribed in

CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested to a minimum of two (2) times service pressure and show no defect. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2. Determination of expansion properties is not required.

(3) *Burst testing.* (i) For purposes of burst testing, each 1,000 cylinders or fewer successively produced each day constitutes a lot. All cylinders of a lot must be of identical size, construction heat treatment, finish, and quality.

(ii) One cylinder must be selected from each lot and be hydrostatically pressure tested to destruction. If this cylinder bursts below five (5) times the service pressure, then two additional cylinders from the same lot as the previously tested cylinder must be selected and subjected to this test. If either of these cylinders fails by bursting below five (5) times the service pressure then the entire lot must be rejected. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

* * * * *

■ 33. In § 178.56, revise paragraph (i) to read as follows:

§ 178.56 Specification 4AA480 welded steel cylinders.

* * * * *

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) *Lot testing.* (i) At least one (1) cylinder selected at random out of each lot of 200 or fewer must be tested by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) The selected cylinder must be tested to a minimum of two (2) times service pressure.

(iii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iv) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(v) If the selected cylinder fails, then two (2) additional specimens must be selected at random from the same lot and subjected to the prescribed testing. If either of these fails the test, then each cylinder in that lot must be tested as prescribed in paragraph (i)(l) of this section.

(2) *Pressure testing.* (i) The remaining cylinders in each lot must be tested by the proof pressure, water-jacket, or direct expansion test method as prescribed in CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. Further, all testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested to a minimum of two (2) times service pressure and show no defect. A cylinder showing a defect must be rejected unless it may be requalified under paragraph (m) of this section. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

* * * * *

■ 34. In § 178.57, revise paragraph (i) to read as follows:

§ 178.57 Specification 4L welded insulated cylinders.

* * * * *

(i) *Pressure testing.* Each cylinder, before insulating and jacketing, must successfully withstand a pressure test as follows:

(1) The cylinder must be tested by the proof pressure, water-jacket, or direct expansion test method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Each cylinder must be tested to a minimum of two (2) times service pressure.

(3) The minimum test pressure must be maintained at least 30 seconds. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2. Determination of expansion properties is not required.

(4) There must be no evidence of leakage, visible distortion or other defect.

* * * * *

■ 35. In § 178.58, revise paragraph (i) to read as follows:

§ 178.58 Specification 4DA welded steel cylinders for aircraft use.

* * * * *

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) The test must be by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(2) Each cylinder must be tested to a minimum of two (2) times service pressure.

(3) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(4) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

* * * * *

■ 36. In § 178.59, revise paragraph (h) to read as follows:

§ 178.59 Specification 8 steel cylinders with porous fillings for acetylene.

* * * * *

(h) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) *Lot testing.* (i) At least one (1) cylinder selected at random out of each lot of 200 or fewer must be tested by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) The selected cylinder must be tested to a minimum of 750 psig.

(iii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iv) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(v) If the selected cylinder passes the volumetric expansion test, each remaining cylinder in the lot must be pressure tested in accordance with paragraph (h)(2) of this section. If the selected cylinder fails, each cylinder in the lot must be tested by water-jacket or direct expansion method as prescribed in CGA C–1 at 750 psig. Each cylinder with a permanent expansion that does not exceed 10% is acceptable.

(2) *Pressure testing.* (i) If the selected cylinder passes the water-jacket or direct expansion test, the remaining cylinders in each lot must be pressure tested by the proof pressure, water-jacket or direct expansion test method as prescribed in CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. Further, all testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested between 500 and 600 psig and show no defect. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 section 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

* * * * *

■ 37. In § 178.60, revise paragraph (j) to read as follows:

§ 178.60 Specification 8AL steel cylinders with porous fillings for acetylene.

* * * * *

(j) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) *Lot testing.* (i) At least one (1) cylinder selected at random out of each lot of 200 or less must be tested by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR; see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) The selected cylinder must be tested to a minimum of 750 psig.

(iii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iv) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(v) If the selected cylinder passes the volumetric expansion test, each remaining cylinder in the lot must be pressure tested in accordance with paragraph (h)(2) of this section. If the selected cylinder fails, each cylinder in the lot must be tested by water-jacket or direct expansion method as prescribed in CGA C–1 at 750 psig. Each cylinder with a permanent expansion that does not exceed 10% is acceptable.

(2) *Pressure testing.* (i) If the selected cylinder passes the water-jacket or direct expansion test, the remaining cylinders in each lot must be pressure tested by the proof pressure water-jacket or direct expansion test method as prescribed in CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. Further, all testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested between 500 and 600 psig and show no defect. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 section 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

* * * * *

■ 38. Revise § 178.61 to read as follows:

§ 178.61 Specification 4BW welded steel cylinders with electric-arc welded seam.

(a) *Type, size, pressure, and application.* A DOT 4BW cylinder has a spherical or cylindrical design, a water capacity of 1,000 pounds or less, and a service pressure range of 225 to 500 psig. Closures made by the spinning process are not authorized.

(1) Spherical designs are permitted to have only one circumferentially electric-arc welded seam.

(2) Cylindrical designs must be of circumferentially welded electric-arc construction; longitudinally electric-arc welded seams are permitted.

(b) *Steel.* (1) The steel used in the construction of the cylinder must be as specified in table 1 of appendix A to this part. The cylinder manufacturer must maintain a record of intentionally added alloying elements.

(2) Material for heads must meet the requirements of paragraph (b)(1) of this section or be open hearth, electric or basic oxygen carbon steel of uniform quality. Content percent may not exceed the following: Carbon 0.25, Manganese 0.60, Phosphorus 0.045, Sulfur 0.050. Heads must be hemispherical or ellipsoidal in shape with a maximum ratio of 2:1. If low carbon steel is used, the thickness of such heads must be determined by using a maximum wall stress of 24,000 psi in the formula described in paragraph (f)(2) of this section.

(c) *Identification of material.* Pressure-retaining materials must be identified by any suitable method that does not compromise the integrity of the cylinder. Plates and billets for hotdrawn cylinders must be marked with the heat number.

(d) *Manufacture.* Cylinders must be manufactured using equipment and processes adequate to ensure that each cylinder produced conforms to the requirements of this subpart and the following:

(1) No defect is permitted that is likely to weaken the finished cylinder appreciably. A reasonably smooth and uniform surface is required. Exposed bottom welds on cylinders over 18 inches long must be protected by footrings. Minimum thickness of heads may not be less than 90 percent of the required thickness of the sidewall. Heads must be concave to pressure.

(2) Circumferential seams must be by electric-arc welding. Joints must be butt with one member offset (joggle butt) or with a lap joint. Joints must have a minimum overlap of at least four (4) times nominal sheet thickness.

(3) Longitudinal electric-arc welded seams (in shells) must be of the butt welded type. Welds must be made by a machine process including automatic feed and welding guidance mechanisms. Longitudinal seams must have complete joint penetration, and must be free from undercuts, overlaps or abrupt ridges or valleys. Misalignment of mating butt edges may not exceed 1/6 inch of nominal sheet thickness or 1/32 inch whichever is less. All joints with nominal sheet thickness up to and including 1/8 inch must be tightly butted. When nominal sheet thickness is

greater than ⅛ inch, the joint must be gapped with maximum distance equal to one-half the nominal sheet thickness or 1/32 inch whichever is less. Joint design, preparation, and fit-up must be such that requirements of this paragraph (d) are satisfied.

(4) Welding procedures and operators must be qualified in accordance with CGA C–3 (IBR, see § 171.7 of this subchapter).

(5)(i) Welds of the cylinders must be subjected to radioscopic or radiographic examination as follows:

(ii) Radioscopy or radiography must be in conformance with CGA C–3 (IBR; see § 171.7 of this subchapter). Maximum joint efficiency will be 1.0 when each longitudinal seam is examined completely. Maximum joint efficiency will be 0.90 when one cylinder from each lot of 50 consecutively welded cylinders is spot examined. In addition, one out of the first five cylinders welded following a shutdown of welding operations exceeding four hours must be spot examined. Spot radiographs, when required, must be made of a finished welded cylinder and must include the circumferential weld for 2 inches in both directions from the intersection of the longitudinal and circumferential welds and include at least 6 inches of the longitudinal weld. Maximum joint efficiency of 0.75 will be permissible without radiography or radioscopy. When fluoroscopic examination is used, permanent film records need not be retained. Circumferential welds need not be examined, except as part of spot examination.

(e) *Welding of attachments.* The attachment to the tops and bottoms only of cylinders by welding of neckrings, footrings, handles, bosses, pads and valve protection rings is authorized provided that such attachments and the portion of the container to which they are attached are made of weldable steel, the carbon content of which may not exceed 0.25 percent.

(f) *Wall thickness.* (1) For outside diameters over 6 inches the minimum wall thickness must be 0.078 inch. In any case, the minimum wall thickness must be such that the wall stress calculated by the formula listed in paragraph (f)(2) of this section may not exceed the lesser value of any of the following:

(i) The value referenced in paragraph (b) of this section for the particular material under consideration.

(ii) One-half of the minimum tensile strength of the material determined as required in paragraph (j) of this section.

(iii) 35,000 psig.

(2) Stress must be calculated by the following formula:

$$S = [2P(1.3D^2 + 0.4d^2)]/[E(D^2 - d^2)]$$

Where:
S = wall stress, psig;
P = service pressure, psig;
D = outside diameter, inches;
d = inside diameter, inches; and
E = joint efficiency of the longitudinal seam (from paragraph (d) of this section).

(3) For a cylinder with a wall thickness less than 0.100 inch, the ratio of tangential length to outside diameter may not exceed 4 to 1 (4:1).

(g) *Heat treatment.* Cylinders must be heat treated in accordance with the following requirements:

(1) Each cylinder must be uniformly and properly heat treated prior to test by the applicable method referenced in table 1 of appendix A to this part. Heat treatment must be accomplished after all forming and welding operations, except that when brazed joints are used, heat treatment must follow any forming and welding operations, but may be done before, during or after the brazing operations (see paragraph (n) of this section for weld repairs).

(2) Heat treatment is not required after welding of weldable low-carbon parts to attachments of similar material which have been previously welded to the top or bottom of cylinders and properly heat treated, provided such subsequent welding does not produce a temperature in excess of 400 °F in any part of the top or bottom material.

(h) *Openings in cylinders.* Openings in cylinders must comply with the following requirements:

(1) All openings must be in heads or bases.

(2) Each opening in a spherical-type cylinder must be provided with a fitting, boss, or pad of weldable steel securely attached to the cylinder by fusion welding.

(3) Each opening in a cylindrical-type cylinder must be provided with a fitting, boss, or pad securely attached to the cylinder by welding.

(4) If threads are used, they must comply with the following:

(i) Threads must be clean cut, even, without checks, and tapped to gauge.

(ii) Taper threads must be of length not less than as specified for American Standard Taper Pipe Threads.

(iii) Straight threads, having at least four (4) engaged threads, must have a tight fit and calculated shear strength at least ten (10) times the test pressure of the cylinder. Gaskets, adequate to prevent leakage, are required.

(iv) A brass fitting may be brazed to the steel boss or flange on cylinders used as component parts of handheld fire extinguishers.

(i) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) *Lot testing.* (i) At least one (1) cylinder randomly selected out of each lot of 200 or fewer must be tested by the water-jacket or direct expansion method as prescribed in CGA C–1 (IBR, see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each selected cylinder must be tested to a minimum of two (2) times service pressure.

(iii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iv) Permanent volumetric expansion may not exceed 10 percent of the total volumetric expansion at test pressure.

(2) *Pressure testing.* (i) The remaining cylinders in each lot must be pressure tested by the proof pressure, water-jacket or direct expansion test method as prescribed in CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. Further, all testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested to a minimum of two (2) times service pressure and show no defect. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

(3) *Burst testing.* One finished cylinder selected at random out of each lot of 500 or less successively produced must be hydrostatically tested to four (4) times service pressure without bursting. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(j) *Mechanical tests.* Mechanical tests must be conducted to determine yield strength, tensile strength, elongation as a percentage, and reduction of area of material as a percentage, as follows:

(1) Specimens must be taken from one cylinder after heat treatment as

illustrated in appendix A to this subpart, chosen at random from each lot of 200 or fewer, as follows:

(i) One specimen must be taken longitudinally from the body section at least 90 degrees away from the weld.

(ii) One specimen must be taken from either head on a cylinder when both heads are made of the same material. However, if the two heads are made of differing materials, a specimen must be taken from each head.

(iii) If due to welded attachments on the top head there is insufficient surface from which to take a specimen, it may be taken from a representative head of the same heat treatment as the test cylinder.

(2) Specimens must conform to the following:

(i) When a cylinder wall is 3⁄16 inch thick or less, one the following gauge lengths is authorized: A gauge length of 8 inches with a width not over 1½ inches, a gauge length of 2 inches with a width not over 1½ inches, or a gauge length at least twenty-four (24) times the thickness with a width not over six (6) times the thickness.

(ii) The specimen, exclusive of grip ends, may not be flattened. Grip ends may be flattened to within 1 inch of each end of the reduced section.

(iii) When size of the cylinder does not permit securing straight specimens, the specimens may be taken in any location or direction and may be straightened or flattened cold, by pressure only, not by blows. When specimens are taken, and prepared in this manner, the inspector's report must show, in connection with the record of physical tests, detailed information in regard to such specimens.

(iv) Heating of a specimen for any purpose is not authorized.

(3) The yield strength in tension must be the stress corresponding to a permanent strain of 0.2 percent of the gauge length. The following conditions apply:

(i) The yield strength must be determined by either the ''off-set'' method or the ''extension under load'' method as prescribed in ASTM E 8 (IBR, see § 171.7 of this subchapter).

(ii) In using the ''extension under load'' method, the total strain (or ''extension under load''), corresponding to the stress at which the 0.2-percent permanent strain occurs may be determined with sufficient accuracy by calculating the elastic extension of the gauge length under appropriate load and adding thereto 0.2 percent of the gauge length. Elastic extension calculations must be based on an elastic modulus of 30,000,000. In the event of controversy, the entire stress-strain diagram must be plotted and the yield strength determined from the 0.2-percent offset.

(iii) For strain measurement, the initial strain reference must be set while the specimen is under a stress of 12,000 psig, and the strain indicator reading must be set at the calculated corresponding strain.

(iv) Cross-head speed of the testing machine may not exceed ⅛ inch per minute during yield strength determination.

(k) *Elongation.* Mechanical test specimens must show at least a 40 percent elongation for a 2-inch gauge length or at least 20 percent in other cases. However, elongation percentages may be reduced numerically by 2 percent for 2-inch specimens, and by 1 percent in other cases, for each 7,500 psi increase of tensile strength above 50,000 psig. The tensile strength may be incrementally increased by four increments of 7,500 psig for a maximum total of 30,000 psig.

(l) *Tests of welds.* Welds must be subjected to the following tests:

(1) *Tensile test.* A specimen must be removed from one cylinder of each lot of 200 or fewer. The specimen must be taken from across the longitudinal seam and must be prepared and tested in conformance with the requirements of CGA C–3 (IBR, see § 171.7 of this subchapter).

(2) *Guided bend test.* A root bend test specimen must be removed from the cylinder or welded test plate used for the tensile test specified in paragraph (m)(1) of this section. Specimens must be taken from across the longitudinal seam and must be prepared and tested in conformance with the requirements of CGA C–3. If the specimen fails to meet the requirements, one specimen each must be taken from two additional cylinders or welded test plates from the same lot as the previously tested cylinder or added test plate and tested. If either of these latter two specimens fails to meet the requirements, the entire lot represented must be rejected.

(3) *Alternate guided bend test.* This test may be used and must be as required by CGA C–3. The specimen must be bent until the elongation at the outer surface, adjacent to the root of the weld, between the lightly scribed gauge lines a to b, must be at least 20 percent, except that this percentage may be reduced for steels having a tensile strength in excess of 50,000 psig, as provided in paragraph (k) of this section. Should this specimen fail to meet the requirements, one additional specimen must be taken from two additional cylinders or welded test plates from the same lot and tested as the previously tested cylinder or added test plate. If either of these latter two specimens fails to meet the requirements, the entire lot represented must be rejected.

(m) *Rejected cylinders.* (1) Unless otherwise stated, if a sample cylinder or specimen taken from a lot of cylinders fails the prescribed test, then two additional specimens must be selected from the same lot and subjected to the prescribed test. If either of these fails the test, then the entire lot must be rejected.

(2) *Reheat treatment of rejected cylinders.* Reheat treatment is authorized for a rejected cylinder in accordance with this paragraph (m)(2). After reheat treatment, a cylinder must pass all prescribed tests in this section to be considered acceptable. Repair of welded seams by welding is authorized. For cylinders less than or equal to an outside diameter of 6 inches, welded seam repairs greater than 1 inch in length shall require reheat treatment of the cylinder. For cylinders greater than an outside diameter of 6 inches, welded seam repairs greater than 3 inches in length shall require reheat treatment.

(n) *Markings.* (1) Markings must be as required in § 178.35 and in addition must be stamped plainly and permanently in one of the following locations on the cylinder:

(i) On shoulders and top heads whose wall thickness is not less than 0.087 inch thick.

(ii) On side wall adjacent to top head for side walls not less than 0.090 inch thick.

(iii) On a cylindrical portion of the shell that extends beyond the recessed bottom of the cylinder constituting an integral and non-pressure part of the cylinder.

(iv) On a plate attached to the top of the cylinder or permanent part thereof; sufficient space must be left on the plate to provide for stamping at least six retest dates; the plate must be at least 1⁄16-inch thick and must be attached by welding at a temperature of 1,100 °F, throughout all edges of the plate.

(v) On the neck, neckring, valve boss, valve protection sleeve, or similar part permanently attached to the top of the cylinder.

(vi) On the footring permanently attached to the cylinder, provided the water capacity of the cylinder does not exceed 30 pounds.

(2) Embossing the cylinder head or side wall is not permitted.

(o) *Inspector's report.* In addition to the information required by § 178.35, the inspector's report must indicate the type and amount of radiography.

■ 39. In § 178.65, revise paragraph (f) to read as follows:

§ 178.65 Specification 39 non-reusable (non-refillable) cylinders.

* * * * *

(f) *Pressure testing.* (1) Each cylinder must be proof pressure tested as prescribed in CGA C–1 (IBR, see § 171.7 of this subchapter). The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(i) The leakage test must be conducted by submersion under water or by some other method that will be equally sensitive.

(ii) If the cylinder leaks, evidences visible distortion or evidences any other defect while under test, it must be rejected (see paragraph (h) of this section).

(iii) If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA, C–1 section 7.1.2.

(2) One cylinder taken from the beginning of each lot, and one from each 1,000 or less successively produced within the lot thereafter, must be hydrostatically tested to destruction. The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1. The entire lot must be rejected (see paragraph (h) of this section) if:

(i) A failure occurs at a gage pressure less than 2.0 times the test pressure;

(ii) A failure initiates in a braze or a weld or the heat affected zone thereof;

(iii) A failure is other than in the sidewall of a cylinder longitudinal with its long axis; or

(iv) In a sphere, a failure occurs in any opening, reinforcement, or at a point of attachment.

(3) A ''lot'' is defined as the quantity of cylinders successively produced per production shift (not exceeding 10 hours) having identical size, design, construction, material, heat treatment, finish, and quality.

* * * * *

■ 40. In § 178.68:

■ a. Revise paragraphs (b), (e), (h), (j) introductory text, (j)(1), and (k) through (m);

■ b. Redesignate paragraph (n) as paragraph (o); and

■ c. Add new paragraph (n).

The revisions and addition read as follows:

§ 178.68 Specification 4E welded aluminum cylinders.

* * * * *

(b) *Authorized material.* (1) The cylinder must be constructed of aluminum of uniform quality. The following chemical analyses are authorized:

TABLE 1 TO PARAGRAPH (b)(1)—AUTHORIZED MATERIALS

Designation	Chemical analysis—limits in percent 5154
Iron plus silicon	0.45 maximum.
Copper	0.10 maximum.
Manganese	0.10 maximum.
Magnesium	3.10/3.90.
Chromium	0.15/0.35.
Zinc	0.20 maximum.
Titanium	0.20 maximum.
Others, each	0.05 maximum.
Others, total	0.15 maximum.
Aluminum	remainder.

(2) The aluminum used in the construction of the cylinder must be as specified in Table 1 to paragraph (b)(1) of this section. Analyses must regularly be made only for the elements specifically mentioned in the table. If, however, the presence of other elements is indicated in the course of routine analysis, further analysis should be made to determine conformance with the limits specified for other elements. The cylinder manufacturer must maintain a record of intentionally added alloying elements.

* * * * *

(e) *Welding.* The attachment to the tops and bottoms only of cylinders by welding of neckrings, flanges, footrings, handles, bosses, pads, and valve protection rings is authorized. However, such attachments and the portion of the cylinder to which it is attached must be made of weldable aluminum alloys.

* * * * *

(h) *Pressure testing.* Each cylinder must successfully withstand a pressure test as follows:

(1) *Pressure test.* All cylinders with a wall stress greater than 18,000 psig must be tested by water-jacket or direct expansion method as prescribed in CGA C–1 (IBR, see § 171.7 of this subchapter). The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(i) Each cylinder must be tested to a minimum of two (2) times service pressure.

(ii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(iii) Permanent volumetric expansion may not exceed 12 percent of the total volumetric expansion at test pressure.

(2) *Lot testing.* (i) Cylinders with a wall stress of 18,000 psig or less may be lot tested. At least one (1) cylinder randomly selected out of each lot of 200 or less must be tested by the water-jacket or direct expansion method as prescribed in CGA C–1. The testing equipment must be calibrated as prescribed in CGA C–1. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1, section 5.7.2.

(ii) Each selected cylinder must be tested to a minimum of two (2) times service pressure.

(iii) The minimum test pressure must be maintained at least 30 seconds and sufficiently longer to ensure complete expansion. Any internal pressure applied after heat-treatment and prior to the official test may not exceed 90 percent of the test pressure.

(iv) Permanent volumetric expansion may not exceed 12 percent of the total volumetric expansion at test pressure.

(3) *Pressure testing.* (i) For cylinders with a wall stress of 18,000 psig or less, the remaining cylinders of the lot must be pressure tested by the proof pressure, water-jacket, or direct expansion test method as defined in CGA C–1. The minimum test pressure must be maintained for the specific timeframe and the testing equipment must be calibrated as prescribed in CGA C–1. Further, all testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

(ii) Each cylinder must be tested to a minimum of two (2) times service pressure and show no defect. If, due to failure of the test apparatus or operator error, the test pressure cannot be maintained, the test may be repeated in accordance with CGA C–1 5.7.2 or 7.1.2, as appropriate. Determination of expansion properties is not required.

(4) *Burst testing.* One (1) finished cylinder selected at random out of each lot of 1000 or less must be hydrostatically tested to four (4) times

service pressure without bursting. Inability to meet this requirement must result in rejection of the lot. All testing equipment and pressure indicating devices must be accurate within the parameters defined in CGA C–1.

* * * * *

(j) *Mechanical test.* A mechanical test must be conducted to determine yield strength, tensile strength, elongation as a percentage, and reduction of area of material as a percentage as follows:

(1) The test is required on two (2) specimens removed from one cylinder or part thereof as illustrated in appendix A to this subpart taken at random out of each lot of 200 or fewer.

* * * * *

(k) *Acceptable results for mechanical tests.* An acceptable result of the mechanical test requires at least 7 percent and yield strength not over 80 percent of tensile strength.

(l) *Weld tests.* Welds of the cylinder are required to pass the following tests successfully:

(1) *Reduced section tensile test.* A specimen must be removed from the cylinder used for the mechanical tests specified in paragraph (j) of this section. The specimen must be taken from across the seam; edges must be parallel for a distance of approximately 2 inches on either side of the weld. The specimen must be fractured in tension. The actual breaking stress must be a minimum of 30,000 psi. The apparent breaking stress calculated on the minimum design wall thickness must be a minimum of two (2) times the stress calculated under paragraph (f)(2) of this section. If the specimen fails to meet the requirements, the lot must be rejected except that specimens may be taken from two (2) additional cylinders from the same lot as the previously tested specimens. If either of the latter specimens fails to meet requirements, the entire lot represented must be rejected.

(2) *Guided bend test.* A bend test specimen must be removed from the cylinder used for the mechanical test specified in paragraph (j) of this section. The specimen must be taken across the circumferential seam, must be a minimum of 1½ inches wide, edges must be parallel and rounded with a file, and back-up strip, if used, must be removed by machining. The specimen must be tested as follows:

(i) *Standard guided bend test.* The specimen must be bent to refusal in the guided bend test jig as illustrated in CGA C–3 (IBR, see § 171.7 of this subchapter). The root of the weld (inside surface of the cylinder) must be located away from the ram of the jig. The specimen must not show a crack or other open defect exceeding ⅛ inch in any direction upon completion of the test. Should this specimen fail to meet the requirements, one additional specimen must be taken from two additional cylinders from the same lot and tested. If either of the latter specimens fails to meet requirements, the entire lot represented must be rejected.

(ii) *Alternate guided bend test.* This test may be used as an alternate to the guided bend test. The test specimen must be in conformance with The Aluminum Association's ''Welding Aluminum: Theory and Practice, Fourth Edition, 2002'' (IBR, see § 171.7 of this subchapter). If the specimen fails to meet the requirements, one additional specimen must be taken from two additional cylinders or welded test plates from the same lot and tested. If any of these latter two specimens fails to meet the requirements, the entire lot must be rejected.

(m) *Rejected cylinders.* Repair of welded seams is authorized. Acceptable cylinders must pass all prescribed tests.

(n) *Markings.* (1) Markings must be as required in § 178.35 and in addition must be stamped plainly and permanently in one of the following locations on the cylinder:

(i) On the neck, neckring, valve boss, valve protection sleeve, or similar part permanently attached to the top of the cylinder.

(ii) On the footring permanently attached to the cylinder, provided the water capacity of the cylinder does not exceed 30 pounds.

(2) Embossing the cylinder head or side wall is not permitted.

* * * * *

■ 41. In § 178.70, revise paragraph (d) to read as follows:

§ 178.70 Approval of UN pressure receptacles.

* * * * *

(d) *Modification of approved pressure receptacle design type.* Modification of an approved UN (ISO) pressure receptacle design type is not authorized without the approval of the Associate Administrator. However, modification of an approved UN (ISO) pressure receptacle design type is authorized without an additional approval of the Associate Administrator provided the design modification is covered under the UN (ISO) standard for the design type. A manufacturer seeking modification of an approved UN (ISO) pressure receptacle design type may be required to submit design qualification test data to the Associate Administrator before production. An audit may be required as part of the process to modify an approval.

* * * * *

■ 42. In § 178.75, revise paragraphs (e)(3)(i) and (ii) and (f)(1) to read as follows:

§ 178.75 Specifications for MEGCs.

* * * * *

(e) * * *

(3) * * *

(i) Two valves in series must be placed in an accessible position on each discharge and filling pipe. One of the valves may be a backflow prevention valve.

(ii) The filling and discharge devices may be equipped to a manifold.

* * * * *

(f) * * *

(1) The size of the pressure relief devices: CGA S–1.1, excluding paragraph 9.1.1, (IBR, see § 171.7 of this subchapter) must be used to determine the relief capacity of individual pressure receptacles.

* * * * *

PART 180—CONTINUING QUALIFICATION AND MAINTENANCE OF PACKAGINGS

■ 43. The authority citation for part 180 continues to read as follows:

Authority: 49 U.S.C. 5101–5128; 49 CFR 1.81 and 1.97.

■ 44. In § 180.203:

■ a. Revise the definition for ''Commercially free of corrosive components;''

■ b. Remove the definitions ''Defect'' and ''Elastic expansion;''

■ c. Add definitions for ''Mobile unit'' and ''Over-pressurized'' in alphabetical order;

■ d. Remove the definition of ''Permanent expansion;''

■ e. Revise the definition for ''Proof pressure test;'' and

■ f. Remove the definitions of ''Rejected cylinder,'' ''Test pressure,'' ''Total expansion,'' ''Visual inspection,'' and ''Volumetric expansion test.''

The additions and revisions read as follows:

§ 180.203 Definitions.

* * * * *

Commercially free of corrosive components means a hazardous material having a moisture content less than 55 ppm and free of components that will adversely react with the cylinder (*e.g.,* chemical stress corrosion).

* * * * *

Mobile unit means a vehicle specifically authorized under a RIN to carry out requalification operations

identified under the RIN within specified geographic areas away from the principle place of business. Mobile units must comply with the requirements outlined in the approval issuance letter from the Associate Administrator for Hazardous Materials Safety (see § 107.805 of subchapter A of this chapter).

* * * * *

Over-pressurized means a condition in which the internal pressure applied to a cylinder has reached or exceeded the yield point of the cylinder.

* * * * *

Proof pressure test means a liquid-based pressure test by interior pressurization without the determination of a cylinder's expansion.

* * * * *

■ 45. In § 180.205:
■ a. Revise paragraphs (c) introductory text and (d);
■ b. Add paragraphs (f)(5) and (6);
■ c. Revise paragraphs (g), (h)(3), and (i)(1)(viii);
■ d. Add paragraphs (i)(1)(ix) through (xi);
■ e. Revise paragraphs (i)(2) and (3); and
■ f. Add paragraph (j).

The revisions and additions read as follows:

§ 180.205 General requirements for requalification of specification cylinders.

* * * * *

(c) *Periodic requalification of cylinders.* Each cylinder bearing a DOT, CRC, BTC, or CTC specification marking must be requalified and marked as specified in the requalification table in § 180.209(a) or requalified and marked by a facility registered by Transport Canada in accordance with the Transport Canada TDG Regulations (IBR, see § 171.7 of this subchapter). Each cylinder bearing both a TC specification marking and also marked with a corresponding DOT specification marking must be requalified and marked as specified in the requalification table in § 180.209(a) or requalified and marked by a facility registered by Transport Canada in accordance with the Transport Canada TDG Regulations. Each cylinder bearing a DOT special permit (or exemption) number must be requalified and marked in conformance with this section and the terms of the applicable special permit (or exemption). Each cylinder bearing only a TC mark must be requalified and marked as specified in the Transport Canada TDG Regulations, except that registration with Transport Canada is not required and cylinders must be marked with the requalifier's DOT issued requalifier identification number. No cylinder may be filled with a hazardous material and offered for transportation in commerce unless that cylinder has been successfully requalified and marked in accordance with this subpart. A cylinder may be requalified at any time during or before the month and year that the requalification is due. However, a cylinder filled before the requalification becomes due may remain in service until it is emptied. A cylinder with a specified service life may not be refilled and offered for transportation after its authorized service life has expired.

* * * * *

(d) *Conditions requiring test and inspection of cylinders.* Without regard to any other periodic requalification requirements, a cylinder must be tested and inspected in accordance with this section prior to further use if—

(1) The cylinder shows evidence of dents, corrosion, cracked or abraded areas, leakage, or any other condition that might render it unsafe for use in transportation;

(2) The cylinder has been in an accident and has been damaged to an extent that may adversely affect its lading retention capability;

(3) The cylinder shows evidence of or is known to have thermal damage, or have been over-heated;

(4) Except in association with an authorized repair, evidence of removal of wall thickness via grinding, sanding or other means; or

(5) The Associate Administrator determines that the cylinder may be in an unsafe condition.

* * * * *

(f) * * *

(5) Except in association with an authorized repair, removal of wall thickness via grinding, sanding or other means is not permitted. Removal of paint or loose material to prepare the cylinder for inspection is permitted (*e.g.,* shot blasting).

(6) Chasing of cylinder threads to clean them is permitted, but removal of metal must not occur. Re-tapping of cylinder threads is not permitted, except by the original manufacturer, as provided in § 180.212.

* * * * *

(g) *Pressure test.* (1) Unless otherwise provided, each cylinder required to be retested under this subpart must be retested by means suitable for measuring the expansion of the cylinder under pressure. Testing must be performed in accordance with CGA C–1 (except for paragraph 5.3.2.2, if the required accuracy of the pressure indicating device can be demonstrated by other recognized means such as calibration certificates) (IBR, see § 171.7 of this subchapter).

(2) The pressure indicating device and expansion indicating device must meet the resolution requirements of CGA C–1. Midpoint visual interpolation is allowed.

(3) Each day before retesting, the retester shall confirm, by using a calibrated cylinder or other method authorized in writing by the Associate Administrator, that:

(i) The pressure-indicating device, as part of the retest apparatus, is accurate within ±1.0% of the prescribed test pressure of any cylinder tested that day. The pressure indicating device, itself, must be certified as having an accuracy of ±0.5%, or better, of its full range, and must permit readings of pressure from 90%–110% of the minimum prescribed test pressure of the cylinder to be tested. The accuracy of the pressure indicating device within the test system can be demonstrated at any point within 500 psig of the actual test pressure for test pressures at or above 3000 psig, or 10% of the actual test pressure for test pressures below 3000 psig.

(ii) The expansion-indicating device, as part of the retest apparatus, meets the accuracy requirements of CGA C–1.

(4) Test equipment must be verified each day before retesting as required in CGA C–1.

(i) The retester must demonstrate calibration in conformance with this paragraph (g) to an authorized inspector on any day that it retests cylinders.

(ii) A retester must maintain calibrated cylinder certificates in conformance with § 180.215(b)(4).

(5) A system check may be performed at or below 90% of test pressure prior to the retest. In the case of a malfunction of the test equipment or operator error, the test may be repeated in accordance with CGA C–1, section 5.7.1. This paragraph (g) does not authorize retest of a cylinder otherwise required to be condemned under paragraph (i) of this section.

(h) * * *

(3) Unless the cylinder is repaired or rebuilt in conformance with requirements in § 180.211, it may not be filled with a hazardous material and offered for transportation where use of a specification packaging is required.

* * * * *

(i) * * *

(1) * * *

(viii) For an aluminum or an aluminum-lined composite special permit cylinder, the cylinder is known to have been or shows evidence of having been overheated. Arc burns must be considered evidence of overheating.

(ix) The cylinder is known to have been or shows evidence of having been over-pressurized.

(x) For a cylinder with a specified service life, its authorized service life has expired.

(xi) The cylinder has been stamped on the sidewall, except as provided in part 178 of this subchapter.

(2) When a cylinder must be condemned, the requalifier must—

(i) Communicate condemnation of the cylinder as follows:

(A) Stamp a series of Xs over the DOT-specification number and the marked pressure or stamp ''CONDEMNED'' on the shoulder, top head, or neck using a steel stamp;

(B) For composite cylinders, securely affix to the cylinder a label with the word ''CONDEMNED'' overcoated with epoxy near, but not obscuring, the original cylinder manufacturer's label; or

(C) As an alternative to the stamping or labeling as described in this paragraph (i)(2), at the direction of the owner, the requalifier may render the cylinder incapable of holding pressure; and

(ii) Notify the cylinder owner, in writing, that the cylinder is condemned and may not be filled with hazardous material and offered for transportation in commerce where use of a specification packaging is required.

(3) No person may remove, obliterate, or alter the required condemnation communication of paragraph (i)(2) of this section.

(j) *Training materials.* Training materials may be used for training persons who requalify cylinders using the volumetric expansion test method.

■ 46. In § 180.207, revise paragraphs (a)(3), (b)(2), (c) introductory text, (d) introductory text, and (d)(1) to read as follows:

§ 180.207 Requirements for requalification of UN pressure receptacles.

(a) * * *

(3) A pressure receptacle with a specified service life may not be requalified after its authorized service life has expired. A pressure receptacle with a specified service life may not be refilled and offered for transportation after its authorized service life has expired unless approval has been obtained in writing from the Associate Administrator.

(b) * * *

(2) Each pressure receptacle that fails requalification must be rejected or condemned in accordance with the applicable ISO requalification standard.

* * * * *

(c) *Requalification interval.* Each UN pressure receptacle that becomes due for periodic requalification must be requalified at the interval specified in the following table before it is filled:

* * * * *

(d) *Requalification procedures.* Each UN pressure receptacle must be requalified in conformance with the procedures contained in the following standards, as applicable. Furthermore, when a pressure test is performed on a UN pressure receptacle, the test must be a water jacket volumetric expansion test suitable for the determination of the cylinder expansion or a hydraulic proof pressure test. The test equipment must conform to the accuracy requirements in § 180.205(g). Alternative methods (*e.g.,* acoustic emission) or requalification procedures may be performed if prior approval has been obtained in writing from the Associate Administrator.

(1) *Seamless steel:* Each seamless steel UN pressure receptacle, including pressure receptacles exceeding 150 L capacity installed in MEGCs or in other service, must be requalified in accordance with ISO 6406:2005(E) (IBR, see § 171.7 of this subchapter). However, UN cylinders with a tensile strength greater than or equal to 950 MPa must be requalified by ultrasonic examination in accordance with ISO 6406:2005(E). For seamless steel cylinders and tubes, the internal inspection and hydraulic pressure test may be replaced by a procedure conforming to ISO 16148:2016(E) (IBR, see § 171.1).

* * * * *

■ 47. In § 180.209:

■ a. Remove and reserve paragraph (b)(1)(iii); and

■ b. Revise paragraphs (c), (e), (g), (j), and (l)(1).

The revisions read as follows:

§ 180.209 Requirements for requalification of specification cylinders.

* * * * *

(c) *DOT 4-series cylinders.* A DOT 4-series cylinder, except a 4L cylinder, that at any time shows evidence of a leak, internal or external corrosion, denting, bulging or rough usage to the extent that it is likely to be weakened appreciably, or that has lost 5 percent or more of its official tare weight must be requalified before being refilled and offered for transportation. (Refer to CGA C–6 or C–6.3 (IBR, see § 171.7 of this subchapter), as applicable, regarding cylinder weakening.) After testing, the actual tare weight must be recorded as the new tare weight on the test report and marked on the cylinder. The previous tare weight must be strike-lined through, but not obliterated.

* * * * *

(e) *Cylinders in non-corrosive gas service.* A cylinder made in conformance with DOT Specifications 4B, 4BA, 4BW, or 4E protected externally by a suitable corrosion-resistant coating and used exclusively for non-corrosive gas that is commercially free from corroding components may be requalified by volumetric expansion testing every 12 years instead of every 5 years. As an alternative, the cylinder may be subjected to a proof pressure test at least two times the marked service pressure, but this latter type of test must be repeated every 10 years after expiration of the initial 12-year period. When subjected to a proof pressure test, as prescribed in CGA C–1 (IBR, see § 171.7 of this subchapter), the cylinder must be carefully examined under test pressure and removed from service if a leak or defect is found.

* * * * *

(g) *Visual inspections.* A cylinder conforming to a specification listed in the table in this paragraph (g) and used exclusively in the service indicated may, instead of a periodic hydrostatic test, be given a complete external visual inspection at the time periodic requalification becomes due. External visual inspection must be in conformance with CGA C–6 or C–6.3, as applicable. When this inspection is used instead of hydrostatic testing, subsequent inspections are required at five-year intervals after the first inspection. Inspections must be made only by persons holding a current RIN and the results recorded and maintained in conformance with § 180.215. Records must include: Date of inspection (month and year); DOT-specification number; cylinder identification (registered symbol and serial number, date of manufacture, and owner); type of cylinder protective coating (including statement as to need of refinishing or recoating); conditions checked (*e.g.,* leakage, corrosion, gouges, dents or digs in shell or heads, broken or damaged footring or protective ring or fire damage); and disposition of cylinder (returned to service, returned to cylinder manufacturer for repairs or condemned). A cylinder passing requalification by the external visual inspection must be marked in conformance with § 180.213. Specification cylinders must be in exclusive service as shown in table 2 to this paragraph (g):

TABLE 2 TO PARAGRAPH (g)

Cylinders conforming to—	Used exclusively for—
DOT 3A, DOT 3AA, DOT 3A480X, DOT 4AA480	Anhydrous ammonia of at least 99.95% purity.
DOT 3A, DOT 3AA, DOT 3A480X, DOT 3B, DOT 4B, DOT 4BA, DOT 4BW.	Butadiene, inhibited, that is commercially free from corroding components.
DOT 3A, DOT 3AA, DOT 3A480X, DOT 3B. DOT 4AA480, DOT 4B, DOT 4BA, DOT 4BW.	Cyclopropane that is commercially free from corroding components.
DOT 3A, DOT 3AA, DOT 3A480X, DOT 4B, DOT 4BA, DOT 4BW, DOT 4E.	Chlorinated hydrocarbons and mixtures thereof that are commercially free from corroding components.
DOT 3A, DOT 3AA, DOT 3A480X, DOT 4B, DOT 4BA, DOT 4BW, DOT 4E.	Fluorinated hydrocarbons and mixtures thereof that are commercially free from corroding components.
DOT 3A, DOT 3AA, DOT 3A480X, DOT 3B, DOT 4B, DOT 4BA, DOT 4BW, DOT 4E.	Liquefied hydrocarbon gas that is commercially free of corroding components.
DOT 3A, DOT 3AA, DOT 3A480X, DOT 3B, DOT 4B, DOT 4BA, DOT 4BW, DOT 4E.	Liquefied petroleum gas that meets the detail requirements limits in Table 1 of ASTM 1835, Standard Specification for Liquefied Petroleum (LP) Gases (incorporated by reference; see § 171.7 of this subchapter) or an equivalent standard containing the same limits.
DOT 3A, DOT 3AA, DOT 3B, DOT 4B, DOT 4BA, DOT 4BW, DOT 4E	Methylacetylene-propadiene, stabilized, that is commercially free from corroding components.
DOT 3A, DOT 3AA, DOT 3B, DOT 4B, DOT 4BA, DOT 4BW, DOT 4E	Propylene that is commercially free from corroding components.
DOT 3A, DOT 3AA, DOT 3B, DOT 4B, DOT 4BA, DOT 4BW	Anhydrous mono, di, trimethylamines that are commercially free from corroding components.
DOT 4B240, DOT 4BW240	Ethyleneimine, stabilized.
DOT 4BW	Alkali metal alloys, liquid, n.o.s., Alkali metal dispersions or Alkaline earth metal dispersions, Potassium, Potassium Sodium alloys and Sodium that are commercially free of corroding components.

* * * * *

(j) *Cylinder used as a fire extinguisher.* Only a DOT-specification cylinder used as a fire extinguisher in conformance with § 173.309(a) of this subchapter may be requalified in conformance with this paragraph (j). The testing procedures, calibration of the testing equipment, accuracy of the pressure indicating device, accuracy of the testing equipment must be as prescribed in CGA C–1.

(1) A DOT 4B, 4BA, 4B240ET or 4BW cylinder used as a fire extinguisher may be tested as follows:

(i) For a cylinder with a water capacity of 5.44 kg (12 pounds) or less, by the water-jacket, direct expansion or proof pressure test methods as prescribed in CGA C–1. A requalification must be performed by the end of 12 years after the original test date and at 12-year intervals thereafter.

(A) Each cylinder must be tested to a minimum of two (2) times service pressure.

(B) When testing using the water-jacket or direct expansion test method, the permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(C) When testing using the proof pressure test method, the cylinder must be carefully examined under test pressure and removed from service if a leak or defect is found.

(ii) For a cylinder having a water capacity over 5.44 kg (12 pounds), by the water-jacket, direct expansion or proof pressure test methods as prescribed in CGA C–1. For the water-jacket or direct expansion test, the requalification must be performed by the end of 12 years after the original test date and at 12-year intervals theafter. For the proof-pressure test, a requalification must be performed by the end of 12 years after the original test date and at seven (7) year intervals.

(A) Each cylinder must be tested to a minimum of two (2) times service pressure.

(B) When testing using the water-jacket or direct expansion test method, the permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

(C) When testing using the proof pressure test method, the cylinder must be carefully examined under test pressure and removed from service if a leak or defect is found.

(2) A DOT 3A, 3AA, or 3AL cylinder must be requalified by:

(i) The water-jacket or direct expansion method. A requalification must be performed 12 years after the original test date and at 12-year intervals thereafter.

(ii) Each cylinder must be tested to a minimum of 5/3 times service pressure.

(iii) When testing using the water-jacket or direct expansion test method, the permanent volumetric expansion may not exceed 10 percent of total volumetric expansion at test pressure.

* * * * *

(l) * * *

(1) It has been inspected, tested and marked in conformance with the procedures and requirements of this subpart or the Associate Administrator has authorized the filling company to fill foreign cylinders under an alternative method of qualification; and

* * * * *

■ 48. In § 180.212, add paragraph (a)(3) to read as follows:

§ 180.212 Repair of seamless DOT 3-series specification cylinders and seamless UN pressure receptacles.

(a) * * *

(3) If grinding is performed on a DOT 3-series cylinder or a seamless UN pressure receptacle, the following conditions apply after grinding has been completed. Grinding must not be used to remove arc burns from a cylinder, as such a cylinder must be condemned:

(i) Ultrasonic examination must be conducted to ensure that the wall thickness is not less than the minimum design requirement. The wall thickness must be measured in at least 3 different areas for every 10 square inches of grinding area.

(ii) The cylinder must be requalified in conformance with § 180.205.

(iii) The cylinder must be marked in accordance with § 180.213(f)(10) to indicate compliance with this paragraph (a)(3).

* * * * *

■ 49. In § 180.213, revise paragraphs (c) and (d)(2) and add paragraphs (f)(10) and (11) and (g) to read as follows:

§ 180.213 Requalification markings.

* * * * *

(c) *Requalification marking method.* The depth of requalification markings may not be greater than specified in the

applicable specification. The markings must be made by stamping, engraving, scribing or applying a label embedded in epoxy that will remain legible and durable throughout the life of the cylinder, or by other methods that produce a legible, durable mark.

(1) A cylinder used as a fire extinguisher (see § 180.209(j)) may be marked by using a pressure sensitive label.

(2) For a DOT 3HT cylinder, when stamped, the test date and RIN must be applied by low-stress steel stamps to a depth no greater than that prescribed at the time of manufacture. Stamping on the sidewall is not authorized.

(3) For a composite cylinder, the requalification markings must be applied on a pressure sensitive label, securely affixed and overcoated with epoxy in a manner prescribed by the cylinder manufacturer, near the original manufacturer's label. Stamping of the composite surface is not authorized.

(d) * * *

(2) A cylinder subject to the requirements of § 171.23(a)(5) of this subchapter must be marked with the date and RIN in accordance with this paragraph (d) and paragraph (f)(11) of this section, or marked in accordance with the requalification authorized by the Associate Administrator in accordance with § 171.23(a)(5)(i) of this subchapter.

* * * * *

(f) * * *

(10) For designation of grinding with ultrasonic wall thickness examination, the marking is as illustrated in paragraph (d) of this section, except the ''X'' is replaced with the letter ''R''.

(11) For designation of requalification of a foreign cylinder requalified in conformance with §§ 171.23(a)(5) of this subchapter and 180.209(l), the marking is as illustrated in paragraph (d) of this section, except that the ''X'' is replaced with the letters ''EX'' to indicate that the cylinder is for export only.

(g) *Visual inspection requalification markings.* (1) Alternative to the marking requirements of paragraphs (d) and (f)(5) of this section, each cylinder successfully passing a visual inspection only, in accordance with § 180.209(g), may be marked with the visual inspection number (*e.g.,* V123456) issued to a person performing visual inspections. Examples of the way the markings may be applied are as follows:

Figure 2 to Paragraph (g)(1)

V123 03 14 E 654	V123456 0314 E
0314 E V123456	V123456 0314E
0314 E V123456	

(2) Where:

(i) ''03'' is the month of requalification (the additional numeral ''0'' is optional'');

(ii) ''V123456'' is the RIN;

(iii) ''14'' is the year of requalification; and

(iv) ''E'' to indicate visual inspection.

■ 50. In § 180.215, revise paragraphs (a)(6), (b), and (c)(2)(vii) and add paragraph (c)(3) to read as follows:

§ 180.215 Reporting and record retention requirements.

(a) * * *

(6) The information contained in each applicable CGA or ASTM standard incorporated by reference in § 171.7 of this subchapter applicable to the requalifier's activities.

(b) *Requalification records.* Daily records of visual inspection, pressure test, eddy current examination if required, and ultrasonic examination if permitted under a special permit, as applicable, must be maintained by the person who performs the requalification until either the expiration of the requalification period or until the cylinder is again requalified, whichever occurs first. A single date may be used for each test sheet, provided each test on the sheet was conducted on that date. Ditto marks or a solid vertical line may be used to indicate repetition of the preceding entry for the following entries only: Date; actual dimensions; manufacturer's name or symbol, if present; owner's name or symbol, if present; and test operator. Blank spaces may not be used to indicate repetition of a prior entry. A symbol may be used for the actual dimensions if there is a reference chart available at the facility that lists the actual dimensions of every symbol used. The records must include the following information:

(1) *Calibration test records.* For each test to demonstrate calibration, the date; serial number of the calibrated cylinder; calibration test pressure; total, elastic and permanent expansions; and legible identification of test operator. The test operator must be able to demonstrate that the results of the daily calibration verification correspond to the hydrostatic tests performed on that day. The daily verification of calibration(s) may be recorded on the same sheets as, and with, test records for that date, or may be recorded on a separate sheet.

(2) *Pressure test and visual inspection records.* The date of requalification; serial number; DOT-specification or special permit number; marked pressure; actual dimensions; manufacturer's name or symbol, if present; year of manufacture; owner's name or symbol, if present; gas service; result of visual inspection; actual test pressure; total, elastic and permanent expansions; percent permanent expansion; disposition, with reason for any repeated test, rejection or condemnation; and legible identification of test operator. For each cylinder marked pursuant to § 173.302a(b)(5) of this subchapter, the test sheet must indicate the method by which any average or maximum wall stress was computed. Records must be kept for all completed, as well as unsuccessful tests. The entry for a repeated test must indicate the date of the earlier test, if conducted on a different day.

(3) *Wall stress.* Calculations of average and maximum wall stress pursuant to § 173.302a(b)(3) of this subchapter, if performed.

(4) *Calibration certificates.* The most recent certificate of calibration must be maintained for each calibrated cylinder, pressure indicating device, and expansion indicating device.

(c) * * *

(2) * * *

(vii) Results of a test on a cylinder, including test method, test pressure, total expansion, permanent expansion, elastic expansion, percent permanent expansion (permanent expansion may not exceed ten percent (10 percent) of total expansion), and volumetric capacity (volumetric capacity of a rebuilt cylinder must be within ±3 percent of the calculated capacity);

* * * * *

(3) A record of grinding and ultrasonic examination in conformance with § 180.212(a)(3) must be completed for each cylinder on which grinding is performed. The record must be clear, legible, and contain the following information:

(i) Name and address of the test facility, date of test report, and name or original manufacturer;

(ii) Marks stamped on cylinder to include specification number, service pressure, serial number, symbol of manufacturer, and date of manufacture;

(iii) Cylinder outside diameter and length in inches;

(iv) Detailed map of where the grinding was performed on the cylinder; and

(v) Wall thickness measurements in grind area in conformance with § 180.212(a)(3)(i).

Issued in Washington, DC, on November 23, 2020, under authority delegated in 49 CFR part 1.97.

Drue Pearce,

Deputy Administrator, Pipeline and Hazardous Materials Safety Administration.

[FR Doc. 2020–26264 Filed 12–23–20; 8:45 am]

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Part IV

Securities and Exchange Commission

Privacy Act of 1974; System of Records; Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. PA–55; File No. S7–20–20]

Privacy Act of 1974; System of Records

AGENCY: Securities and Exchange Commission.

ACTION: Notice of revised system of records.

SUMMARY: In accordance with the Privacy Act of 1974 and the Office of Management and Budget (OMB) Circular No. A–108, the Securities and Exchange Commission (Commission or SEC) proposes to revise 28 Privacy Act systems of records. The revisions are the result of a comprehensive review of SEC SORNs and conform to new requirements prescribed in OMB Circular No. A–108. This notice also includes a Table of Contents of the agency's full inventory of Privacy Act Notices, which re-designates and renumbers the systems of records to provide a better guide to the system notices.

DATES: The changes will become effective January 27, 2021 to permit public comment on the new and revised routine uses. The Commission will publish a new notice if the effective date is delayed to review comments or if changes are made based on comments received. To assure consideration, comments should be received on or before January 27, 2021.

ADDRESSES: Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/other.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number S7–20–20 on the subject line.

Paper Comments

Send paper comments in triplicate to Vanessa A. Countryman, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090. All submissions should refer to S7–20–20. This file number should be included on the subject line if email is used. To help process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/other.shtml*). Comments are also available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. All comments received will be posted without change; we do not edit personal identifying information from submissions. You should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: For general and privacy related questions please contact: Ronnette McDaniel, Privacy and Information Assurance Branch Chief, 202–551–7200 or *privacyhelp@sec.gov.*

SUPPLEMENTARY INFORMATION: When an agency wishes to establish or significantly modify a system of records, it must notify in advance Congress and the Office of Management and Budget (''OMB'') in order to permit an evaluation of the probable or potential effects of the proposal on the privacy or other rights of individuals. Currently, the SEC has 37 Privacy Act SORNs in its inventory. As directed by OMB,[1] and as part of the SEC's continuous privacy monitoring program, the SEC periodically reviews these SORNs to confirm the accuracy of the information. The Office of Information Technology (''OIT''), Privacy and Information Assurance Branch (''Privacy Office''), in collaboration with the system of records system managers or their designee(s), reviewed SORNs managed by each division or office for needed updates. As a result of the review, revisions were made to SEC systems of records, as necessitated by changes in information handling practices within the SEC and in compliance with OMB Circular No. A–108, *Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act.*[2] Routine uses were also evaluated to ensure that they were necessary and compatible with the purposes for which the information is collected.

Accordingly, the Commission is proposing the following Table of Contents to provide a better guide to its inventory of systems of records, and the modified systems of records to read as follows:

TABLE OF CONTENTS

[SEC Privacy Act Systems Notices]

Old No.	New No.	System name
SEC–68	SEC–01	SEC's Division of Corporation Finance Records.
SEC–69	SEC–02	SEC's Division of Investment Management Records.
SEC–70	SEC–03	SEC's Division of Trading and Markets Records.
SEC–31	SEC–04	Office of General Counsel Working Files.
SEC–62	SEC–05	Office of Municipal Advisor Records.
SEC–14	SEC–06	Financial and Acquisition Management System.
SEC–15	SEC–07	Payroll, Attendance, Retirement and Leave Records.
SEC–16	SEC–08	Administrative Law Judge Case Tracking Records.
SEC–17	SEC–09	Minutes Regarding Action Taken by the Commission.
SEC–39	SEC–10	Personnel Management Employment and Staffing/Training Files.
SEC–24	SEC–11	Freedom of Information and Privacy Act Requests.
SEC–28	SEC–12	Office of the Chief Accountant Working Files.
SEC–33	SEC–13	Administrative and Litigation Release System.
SEC–36	SEC–14	Administrative Proceeding Files.
SEC–38	SEC–15	Disciplinary and Adverse Actions, Employee Conduct, and Labor Relations Files.
SEC–41	SEC–16	Child Care Subsidy Program.
SEC–42	SEC–17	Enforcement Files.
SEC–43	SEC–18	Office of Inspector General Working Files.
SEC–45	SEC–19	Mass Transportation Subsidy Program.
SEC–46	SEC–20	Facilities Access Badge System.

[1] *See* OMB Circular A–108, ''Federal Agency Responsibilities for Review, Reporting, and Publication under the Privacy Act,'' December 23, 2016 (81 FR 94424).

[2] 81 FR 94424 (December 23, 2016).

TABLE OF CONTENTS—Continued

[SEC Privacy Act Systems Notices]

Old No.	New No.	System name
SEC–48	SEC–21	Fitness Center Membership Payment and Fitness Records; SEC Employees Health and Fitness Program Records.
SEC–51	SEC–22	Continuity Support Center.
SEC–52	SEC–23	Visitor Badge and Employee Day Pass System.
SEC–54	SEC–24	Photographic Files.
SEC–55	SEC–25	Information Pertaining or Relevant to SEC Regulated Entities and Their Activities.
SEC–56	SEC–26	Mailing, Contact and Other Lists.
SEC–57	SEC–27	Office of International Affairs Records.
SEC–60	SEC–28	Ethics Conduct Rules Files.
SEC–63	SEC–29	Tips, Complaints, and Referrals Records.
SEC–64	SEC–30	SEC Security in the Workplace Incident Records.
SEC–65	SEC–31	Correspondence Response Systems.
SEC–66	SEC–32	Backup Care Employee and Family Records.
SEC–67	SEC–33	General Information Technology Records.

SYSTEM NAME AND NUMBER:

SEC–14:

SEC Financial and Acquisition Management System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

1. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Files may also be maintained in the Commission's Regional Offices.

2. Federal Aviation Administration, Mike Monroney Aeronautical Center, AMZ–740, 6500 S MacArthur Blvd., Headquarters Bldg. 1, Oklahoma City, OK 73169.

SYSTEM MANAGER(S):

Chief Financial Officer, Office of Financial Management, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–6041.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

31 U.S.C. 3501, *et seq.* and 31 U.S.C. 7701(c). Where the employee identification number is the social security number, collection of this information is authorized by Executive Order 9397.

PURPOSE(S) OF THE SYSTEM:

Serves as the core financial system and integrates program, financial and budgetary information. Records are collected to ensure that all obligations and expenditures other than those in the pay and leave system addressed in SEC–15 are in conformance with laws, existing rules and regulations, and good business practice, and to maintain subsidiary records at the proper account and/or organizational level where responsibility for control of costs exists.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

SEC employees, contractors, vendors, interns, customers and members of the public.

CATEGORIES OF RECORDS IN THE SYSTEM:

Employee personnel information: Limited to SEC employees, and includes name, address, Social Security number (SSN). Business-related information: Limited to contractors/vendors and customers, and includes name of the company/agency, point of contact, telephone number, mailing address, email address, contract number, CAGE code, vendor number (system unique identifier), DUNS number, and TIN, which could be a SSN in the case of individuals set up as sole proprietors. Financial information includes: Financial institution name, lockbox number, routing transit number, deposit account number, account type, debts (*e.g.,* unpaid bills/invoices, overpayments, etc.), and remittance address.

RECORD SOURCE CATEGORIES:

The information maintained in Department of Transportation, (DOT)/ Enterprise Service Center (ESC): Purchase orders, vouchers, invoices, contracts, and electronic records; Department of Interior (DOI)/Federal Personnel Payroll System (FPPS): Travel applications, disgorgement information, or other paper records submitted by employees, vendors, and other sources, including claims filed by witnesses in SEC actions; Delphi-Prism: Fed Traveler, Department of the Interior (DOI) Payroll System, Bureau of Public Debt, and EDGAR Momentum.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records; (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

4. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

5. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel

management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

6. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

7. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

8. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

9. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

10. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs.

11. To the OMB in connection with the review of private relief legislation as set forth in OMB Circular A–19 at any stage of the legislative coordination and clearance process as set forth in that circular.

12. To the Treasury, Government Accountability Office, or other appropriate agencies to provide appropriate audit documentation.

13. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by a name of employee, social security number (SSN) for employees, SSN/Tax Identification Number (TIN) for vendors doing business with the SEC, Name for both employees and vendors, Vendor Number (system unique) for both employees and vendors, DUNS/DUNS + 4.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41550 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—59 FR 27626 (May 27, 1994)
—62 FR 47884 and 47885 (September 11, 1997)
—63 FR 11938 (March 11, 1998)77 FR 16569 (March 21, 2012)

SYSTEM NAME AND NUMBER:

SEC–15:

Payroll, Attendance, Retirement and Leave Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

1. Payroll files, retirement case files, time and attendance reports, and service history files: SEC, 100 F Street NE, Washington, DC 20549.

2. Notices of personnel action and other pay-related records: Department of the Interior, National Business Center, Payroll Operations Division, Mail Stop D–2662, 7301 West Mansfield Avenue, Lakewood, CO 80235–2230; and

3. Retired personnel files: National Archives and Records Administration,

National Personnel Records Center (Civilian Personnel Records Center), 111 Winnebago Street, St. Louis, MO 63118.

SYSTEM MANAGER(S):

Associate Executive Director, Office of Human Resources, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 302; 31 U.S.C. 3512.

PURPOSE(S) OF THE SYSTEM:

The primary uses of the records are for the Commission's fiscal operations for payroll, time and attendance, leave, insurance, tax, retirement, qualifications, and benefits; to prepare related reports to other Federal agencies including the Department of Treasury and the Office of Personnel Management; and to locate SEC employees and determine such matters as their period of service, type of leave, qualifications, benefits, and pay.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Past and present employees, interns, fellows, volunteers and persons who work at the SEC under the Intergovernmental Personnel Act (employees).

CATEGORIES OF RECORDS IN THE SYSTEM:

These records include, but are not limited to: Employee name, address, phone number, Social Security number, organization code, pay rate, salary, grade, length of service, pay and leave records, source documents for posting time and leave attendance, and deductions for Medicare, Old Age, Survivors, and Disability Insurance (OASDI, also known as Social Security), bonds, Federal Employee Group Life Insurance (FEGLI), union dues, taxes, allotments, quarters, retirement, charities, Federal and commercial health benefits, Flexible Spending Account, Long Term Care Insurance, Thrift Savings Plan contributions, award, shift schedules, and pay differential, tax lien data, wage garnishments.

The payroll, retirement and leave records described in this notice form a part of the information contained in the Department of the Interior's integrated Federal Personnel and Payroll System (FPPS). Personnel records contained in the FPPS are covered under the government-wide system of records notice published by the Office of Personnel Management (OPM/GOVT–1) and Commission's system of records notice, SEC–39, Personnel Management Employment and Staffing Files.

RECORD SOURCE CATEGORIES:

Records source is from individuals on whom the records are maintained, official personnel records of individuals on whom the records are maintained, time and attendance records, withholding certificates, third-party benefit providers, and other pay-related records prepared by the individual or the Office of Human Resources.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To the National Business Center of the U.S. Department of the Interior.

3. To any Federal, state, or local government compiling tax withholding, retirement contributions, or allotments to charities, labor unions, wage garnishments, and other authorized recipients.

4. To any Federal governmental authority or its agents investigating (a) a violation or potential violation of a statute, rule, regulation, or order, or (b) an employee's grievance or complaint.

5. To any member of the public for employment verification at an employee's written request.

6. To any judgment creditor for the purpose of wage garnishment.

7. To any arbitrator under a negotiated labor agreement.

8. To the General Accountability Office, the Office of Management and Budget, and other Federal agencies to support payments of salaries and benefits to SEC employees.

9. To the Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services, the Federal Parent Locator System and the Federal Tax Offset System to (a) locate individuals, (b) identify income sources, (c) establish paternity, (d) verify social security numbers or employment, (e) issue, modify, or enforce orders of support, or (f) administer the Federal Earned Income Tax Credit Program.

10. To a Congressional office in response to an inquiry from that Congressional office made at the request of the individual to whom the record pertains.

11. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be utilized to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

12. To interns, grantees, experts, contractors and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical or stenographic functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C.552a.

13. When (a) it is suspected or confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the Commission has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Commission or another agency or entity) that rely upon the compromised information; and (c) the disclosure is made to such agencies, entities, and persons who are reasonably necessary to assist in connection with the Commission's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

14. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs.

15. To another Federal agency or Federal entity, when the SEC

determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape, and/or digital media. Paper records are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records may be retrieved by identifiers including, but not limited to, individual's name, an employee's name or social security number, birthday, and organizational code.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know;'' using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records should contact the FOIA/Privacy Act Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual should be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41594 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—58 FR 64416 (December 7, 1993)
—62 FR 47884 and 47885 (September 11, 1997)
—63 FR 11936 (March 11, 1998)
—64 FR 69051 (December 9, 1999)
—75 FR 17978 (April 8, 2010)

SYSTEM NAME AND NUMBER:

SEC–16:

Administrative Law Judge Case Tracking Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Chief Administrative Law Judge, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 556; 15 U.S.C. 78d, 78d–1; Pub. L. No. 87–592, 76 Stat. 394 (1962); 17 CFR 200.30–9, .200.30–10, .201.111.

PURPOSE(S) OF THE SYSTEM:

1. To track the status of each administrative proceeding pending in the Office of Administrative Law Judges (OALJ).

2. To enable the Chief Administrative Law Judge in determining appropriate assignments.

3. To aid in projecting budget requirements for OALJ.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

SEC administrative law judges, individual respondents, and counsel of record.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records are maintained on every case pending in OALJ. The system also stores records on cases while they are pending appeal and even after they have been resolved by decision or settlement. The records identify each administrative proceeding, the respondent(s) against whom the case was brought, and the administrative law judge to whom the case was assigned. Record categories include case summary, Office of the Secretary's service list, contact sheet, hearings, dispositions, events and mailings, and respondent's answer. Records may include the names, addresses, email addresses, telephone numbers, and fax numbers of respondents and counsel. They also contain information on party filings and submissions, such as the date of the filing or submission and the subject matter (but not copies of the actual filings or submissions), statistical data relating to number of assignments, and the time involved in disposition of assignments.

RECORD SOURCE CATEGORIES:

Information is obtained from: Orders and decisions issued by the SEC, Chief Administrative Law Judge, or individual Administrative Law Judges; transcripts of prehearings, hearings, and oral arguments; party filings, submissions, and correspondence and communications received in connection with a proceeding.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the

Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records; (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

23. To any governmental agency, governmental or private collection agent, consumer reporting agency or commercial reporting agency, governmental or private employer of a debtor, or any other person, for collection, including collection by administrative offset, Federal salary offset, tax refund offset, or administrative wage garnishment, of amounts owed as a result of Commission civil or administrative proceedings.

24. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information in the ALJ Case Tracking Records is retrieved by case name, case number, Administrative Proceeding Tracking System (APTS) status, ALJ status, ALJ case status type, date filed with ALJ, date filed with the Office of the Secretary, respondent's name, assigned ALJ, hearing date, ALJ statutory authority, or whether a case was initiated by an order instituting proceedings.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/Privacy Act Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/Privacy Act Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41563 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—43 FR 36536 (August 17, 1978)
—46 FR 63439 (December 31, 1981)
—59 FR 27626 (May 27, 1994)
—62 FR 47884 (September 11, 1997)

By the Commission.

SYSTEM NAME AND NUMBER:

SEC–17:

Minutes Regarding Action Taken by the Commission.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Secretary, Office of the Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 78a *et seq.*

PURPOSE(S) OF THE SYSTEM:

To record actions taken by the Commission and to distribute to senior supervisory personnel on the Commission's staff for informational purposes.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals who are the subject of official action taken by the SEC, including individuals who are named defendants or respondents in civil actions or administrative proceedings brought by the Commission.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records contain defendants' or respondents' names, and addresses and names of other related entities or individuals; present and voting SEC Commissioners' and staff names; and dates. The records describe the matter presented, and any recommendations of the staff.

RECORD SOURCE CATEGORIES:

Records are compiled from meetings of the Commission and from seriatims circulated to the Commission.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the

Commission or conducting records management inspections.

23. To any governmental agency, governmental or private collection agent, consumer reporting agency or commercial reporting agency, governmental or private employer of a debtor, or any other person, for collection, including collection by administrative offset, Federal salary offset, tax refund offset, or administrative wage garnishment, of amounts owed as a result of Commission civil or administrative proceedings.

24. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in Word on an Office of the Secretary restricted drive, in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records are indexed by date and can be retrieved by name from the Word file or from the paper copy. Older records can be retrieved from Records Management or from the National Archives and Records Administration.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained in-house as space permits, at which time they will be archived by Records Management and then retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration. Minutes are accessioned to NARA after 15 years.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize secure, password-protected electronic system that will utilize commensurate safeguards t commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/Privacy Act Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/Privacy Act Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41564 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—59 FR 27626 (May 27, 1994)
—62 FR 47884 (September 11, 1997)

SYSTEM NAME AND NUMBER:

SEC–24:

Freedom of Information and Privacy Act Requests.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, Office of Freedom of Information Act (FOIA) Services, 100 F Street NE, Washington, DC 20549. Other offices involved in the processing of requests may also maintain copies of the requests and related internal administrative records.

SYSTEM MANAGER(S):

FOIA/PA Officer, Office of FOIA Services, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 552, and 552a; Executive Order 9397.

PURPOSE(S) OF THE SYSTEM:

The records are used by Commission staff to process FOIA and Privacy Act requests and appeals, and to prepare reports to the Department of Justice, the Office of Management and Budget, and other oversight entities on the Commission's FOIA and PA activities.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records are maintained on persons requesting information from the Commission pursuant to provisions of the Freedom of Information Act; persons who are the subject of Freedom of Information Act requests; individuals who have submitted requests for information about themselves or on behalf of an individual under the provisions of the Privacy Act of 1974; and individuals filing an administrative appeal of a denial, in whole or part, of any such request.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records received, created or compiled in processing FOIA and PA requests or appeals, including internal memoranda, correspondence to or from other Federal agencies, correspondence and response letters, appeal of denials under the FOIA, request for amendment of records under the Privacy Act, appeal for denials under the Privacy Act, appeal determinations, and electronic tracking data.

These records may contain personal information retrieved in response to a request including requesters' and their

attorneys' or representatives' names, addresses, email, telephone numbers, and FOIA and PA case numbers; office telephone numbers of SEC employees and contractors; Names, telephone numbers, and addresses of the submitter of the information requested; Unique case identifier; Social Security Number; or other identifier assigned to the request or appeal.

RECORD SOURCE CATEGORIES:

Persons requesting information from the Commission pursuant to the Freedom of Information Act and the Privacy Act; agency employees assigned to handle processing the requests; agency records searched and identified as responsive in the process of responding to such requests; other agencies or entities that have referred to SEC requests concerning SEC records, or that have consulted with SEC regarding handling of particular requests; and submitters or subjects of records or information that have provided assistance to SEC in making access or amendment determinations.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

5. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

6. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

7. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

8. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

9. To respond to subpoenas in any litigation or other proceeding.

10. To a third party authorized in writing to receive such information by the individual about whom the information pertains.

11. To another Federal agency to (a) permit a decision as to access, amendment or correction of records to be made in consultation with or by that agency, (b) verify the identity of an individual or the accuracy of information submitted by an individual who requested access to, amendment of, or correction of records, or (c) to process payment of fees associated with FOIA/PA requests.

12. To the Department of Justice (DOJ) in order to obtain that department's advice on FOIA matters or regarding the agency's FOIA disclosure obligations.

13. To the Office of Management and Budget for the purpose of obtaining its advice on Privacy Act matters.

14. To the public pursuant to the provisions of the FOIA, 5 U.S.C. 552.

15. To the National Archives and Records Administration, Office of Government Information Services (OGIS), to the extent necessary to fulfill its responsibilities in 5 U.S.C. 552(h), to review administrative agency policies, procedures and compliance with the Freedom of Information Act (FOIA), and to facilitate OGIS' offering of mediation services to resolve disputes between persons making FOIA requests and administrative agencies.

16. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

17. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

18. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

19. To a Congressional office from the record of an individual in response to

an inquiry from the Congressional office made at the request of that individual.

20. In connection with any litigation challenging or seeking to enjoin actions by the Commission under the Freedom of Information Act, as amended.

21. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, and/or on computer disc. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Electronic files and paper format records are indexed and retrieved by a unique case number assigned to the request. Records may also be retrieved by the requestor name and/or the subject of the request.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records are maintained in accordance with general records schedules of the National Archives and Records Administration, General Records Schedule 4.2

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41550 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—62 FR 47884 (September 11, 1997)
—77 FR 65913 (October 31, 2012)
—78 FR 41962 (July 12, 2013)

SYSTEM NAME AND NUMBER:

SEC–28:

Office of the Chief Accountant Working Files.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Chief Accountant, Office of the Chief Accountant, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 77a *et seq.,* 78a *et seq.,* 7201 *et seq.,* and 17 CFR 200.22.

PURPOSE(S) OF THE SYSTEM:

1. To assist the Office of the Chief Accountant in performing the functions assigned to it by the Commission including the formulation and application of accounting or auditing policies in the case of documents required to be filed with the Commission and the determination of appropriate recommendations to the Commission relating to the disqualification of accountants to appear and practice before the Commission.

2. To respond to inquiries from Members of Congress, the press, and the public concerning accounting and auditing matters.

3. To assist investigations of possible violations of the Federal securities laws.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Accountants and persons associated with accountants and accounting firms and persons associated with SEC registrants, including individuals that submit requests for consultation with the Office of the Chief Accountant and individuals involved with or subjects of SEC investigations; and SEC personnel assigned to work on relevant matters.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records contain names, mailing addresses, telephone numbers, email addresses, and/or information pertaining to accounting and auditing practices, problems, issues, and opinions and information concerning the activities of individuals in connection with Commission enforcement actions or in proceedings pursuant to the Commission's rules of practice.

RECORD SOURCE CATEGORIES:

The information contained in the system is derived from official SEC records, letters and inquiries from the public, SEC staff memoranda, which may include information derived from investigations, litigation, and other submissions, and professional auditing and accounting literature and information received from individuals including where practicable those to whom the records relate.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C.

552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records; (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections. 23. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Paper records are searchable by name, subject, firm, date, and/or internal file number. Electronic records are searchable through routine word searches to include searches by name, subject, firm and/or keyword.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange

Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a(k)(2), this system of records is exempted from the following provisions of the Privacy Act, 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) and 17 CFR 200.303, 200.304, and 200.306, insofar as it contains investigatory materials compiled for law enforcement purposes. This exemption is contained in 17 CFR 200.312(a)(3).

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41550 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—59 FR 27626 (May 27, 1994)
—62 FR 47884 (September 11, 1997)
—79 FR 30661 (May 28, 2014)

SYSTEM NAME AND NUMBER:

SEC–33:

Administrative and Litigation Release System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Records in this system also may be maintained at the SEC Regional Offices.

SYSTEM MANAGER(S):

Secretary, Office of the Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 78a *et seq.*

PURPOSE(S) OF THE SYSTEM:

To allow SEC staff to maintain information regarding administrative, civil or criminal proceedings involving allegations of violations of the Federal securities laws or related statutes.

CATEGORIES OF INDIVIDUALS AND ENTITIES COVERED BY THE SYSTEM:

Records are maintained on persons who have been named as respondents or defendants in administrative, civil or criminal proceedings involving findings or allegations of violations of the Federal securities laws or related statutes.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records contain respondents' or defendants' names, and addresses. Releases pertaining to administrative proceedings are limited essentially to an identification of the respondents, a brief reference to the general nature of the underlying charges, and when appropriate, an identification of the particular securities involved. Litigation releases pertain to litigation matters and court enforcement actions brought under the Federal securities laws.

RECORD SOURCE CATEGORIES:

Records are obtained from administrative and court pleadings, transcripts, documents, and orders; SEC personnel; other SEC files; communications to the SEC; evidence gathered in connection with any matter within the jurisdiction of the SEC and from individuals, including where practicable, those to whom the records relate.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C.

552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, or who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

23. To any governmental agency, governmental or private collection agent, consumer reporting agency or commercial reporting agency, governmental or private employer of a debtor, or any other person, for collection, including collection by administrative offset, Federal salary offset, tax refund offset, or administrative wage garnishment, of amounts owed as a result of Commission civil or administrative proceedings.

24. In giving public notice of the institution and disposition of an administrative, civil, or criminal proceeding brought under the Federal securities laws or related statutes.

25. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored on a restricted Office of the Secretary drive and in a computerized database. Paper records are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be accessed by relevant name and file number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41550 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—59 FR 27626 (May 27, 1994)
—62 FR 47884 (September 11, 1997)

SYSTEM NAME AND NUMBER:

SEC—36:

Administrative Proceeding Files.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Secretary, Office of the Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 77h(e), 77u, 78v, 78o(b), 80a–40, and 80b–12; the Commission's Rules of Practice, 17 CFR 201.100 through 900 and the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106.

PURPOSE(S) OF THE SYSTEM:

The records in this system may be utilized in any proceeding where the Federal securities laws are in issue or in which the Commission or past or present members of its staff is a party or otherwise involved in an official capacity.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records are maintained on all individuals that are involved in administrative proceedings before the SEC, including, participants, witnesses, attorneys, SEC employees, contractors, interns, affiliates, and others working on behalf of the SEC.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include the names and addresses of parties; participants; witnesses, attorneys, SEC employees and others working on behalf of the SEC. Additionally, records may include orders for proceedings, answers, motions, responses, orders, offers of settlement and other pleadings; transcripts of all hearings and documents introduced as evidence therein; other relevant documents and correspondence relating to proceedings.

RECORD SOURCE CATEGORIES:

These records are obtained from counsel involved in the administrative proceeding, internal Commission files, and from individuals including, where practicable, the individual as to whom the record pertains.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects

or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction. In matters involving public proceedings, records maybe made publicly available. 19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the

Commission or conducting records management inspections.

23. To any governmental agency, governmental or private collection agent, consumer reporting agency or commercial reporting agency, governmental or private employer of a debtor, or any other person, for collection, including collection by administrative offset, Federal salary offset, tax refund offset, or administrative wage garnishment, of amounts owed as a result of Commission civil or administrative proceedings.

24. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach; or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are indexed by names of both parties cross-indexing to individual's name is available through searchable databases. Additionally, records can be retrieved by matter number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24 hour security guard service. Records are required to be safeguarded in accordance with applicable SEC rules and policies. Computerized records are safeguarded in secured, encrypted environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption, and Security Assessment & Authorization (SA&A). Records will be maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41550 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—43 FR 36536 (August 17, 1978)
—46 FR 63439 (December 31, 1981)
—54 FR 24454 (June 7, 1989)
—59 FR 27626 (May 27, 1994)
—62 FR 47884 (September 11, 1997)
—79 FR 69894 (November 24, 2014)

SYSTEM NAME AND NUMBER:

SEC–38:

Disciplinary and Adverse Actions, Employee Conduct, and Labor Relations Files.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, Office of Human Resources100 F Street NE, Washington, DC 20549–3990.

SYSTEM MANAGER(S):

Associate Executive Director, Office of Human Resources, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–3990.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 1302 and 2951 and 17 CFR 200.735–13

PURPOSE(S) OF THE SYSTEM:

Assigned staff uses records to verify employee and agency compliance with law, regulation, case decisions, agency policies, and the Collective Bargaining Agreement.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Present and former SEC employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system of records includes information in the following categories of records: (a) Disciplinary and adverse action cases, regulatory appeal files, grievances and complaints relating to an employee, union issues (including collective bargaining documents and dues withholding forms), leave bank/transfer date, and third party complaints; (b) Investigatory materials gathered in connection with the individual's initial appointment to the agency as well as materials gathered in connection with investigations into allegations of employee misconduct.

RECORD SOURCE CATEGORIES:

Employees, managers, union officials.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of

the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. In any proceeding where the human resources law or regulations are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

4. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

5. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

6. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

7. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

8. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

9. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

10. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs.

11. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are indexed and retrieved by employee name or assigned ID.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41550 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—62 FR 47884 (September 11, 1997)
—76 FR 30213 (May 24, 2011)

SYSTEM NAME AND NUMBER:

SEC–41:

Child Care Subsidy Program

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Childcare Subsidy Program Applications: FEEA–SEC Child Care Subsidy, 8441- W. Bowles Ave, suite 200, Littleton, CO 80123–9501. Utilization reports and other related records: Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

General Counsel, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 15, United States Code, section 77s, 77sss, 78d (b), 78w, 80a–37, and 80b–11.

PURPOSE(S) OF THE SYSTEM:

To determine eligibility for, and the amount of, the child care tuition subsidy for lower income SEC employees.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Present and former SEC employees and their children and child care providers.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records contain (1) employee's name, social security number, telephone numbers, address, grade, gross annual salary, gross family income that was reported on the latest Federal income tax return, and number of dependent children; (2) employee's child's name, date of birth, social security number, weekly tuition cost, amount of child care tuition subsidy from state or local government; and (3) employee's child care provider's name, address, telephone number, tax identification number, and license number.

RECORD SOURCE CATEGORIES:

Applications for child care subsidy and supporting records, which are voluntarily submitted by employees.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

4. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

5. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

6. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

7. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

8. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

9. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

10. To any Federal, state, or local government authority implementing child care subsidy programs or investigating a violation or potential violation of a statute, rule, regulation, or order.

11. To the Office of Personnel Management to be used for evaluating the child care subsidy program.

12. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs.

13. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records are retrievable by the employee's name or social security number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: fIrewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/Privacy Act Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a(k)(2), this system of records is exempted from the following provisions of the Privacy Act, 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) and 17 CFR 200.303, 200.304, and 200.306, insofar as it contains investigatory materials compiled for law enforcement purposes. This exemption is contained in 17 CFR 200.312(a)(5).

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41550 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—57 FR 14592 (April 21, 1992)
—59 FR 27626 (May 27, 1994)
—62 FR 47884 (September 11, 1997)
—65 FR 49037 (August 10, 2000)
—77 FR 65913 (October 31, 2012)

SYSTEM NAME AND NUMBER:

SEC–42:

Enforcement Files.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Files may also be maintained in the Commission's Regional Offices that conducted an investigation or litigation, or at a records management company under contract with the Commission. Closed investigatory files are stored at a Federal records center.

SYSTEM MANAGER(S):

Director, Division of Enforcement, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–0801; Records Officer, Office of Records Management Services, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549; New York Regional Office, Regional Director, 3 World Financial Center, Suite 400, New York, NY 10281–1022; Boston Regional Office, Regional Director, 33 Arch Street, 23rd Floor, Boston, MA 02110–1424; Philadelphia Regional Office, Regional Director, The Mellon Independence Center, 701 Market Street, Philadelphia, PA 19106–1532; Miami Regional Office, Regional Director, 801 Brickell Ave., Suite 1800, Miami, FL 33131, Atlanta Regional Office, Regional Director, 3475 Lenox Road NE, Suite 1000, Atlanta, GA 30326–1232; Chicago Regional Office, Regional Director, 175 W. Jackson Boulevard, Suite 900, Chicago, IL 60604; Denver Regional Office, Regional Director, 1801 California Street, Suite 1500, Denver, CO 80202–2656; Fort Worth Regional Office, Regional Director, Burnett Plaza, Suite 1900, 801 Cherry Street, Unit 18, Fort Worth, TX 76102; Salt Lake Regional Office, Regional Director, 15 W. South Temple Street, Suite 1800, Salt Lake City, UT 84101; Los Angeles Regional Office, Regional Director, 5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036–3648; San Francisco Regional Office, Regional Director, 44 Montgomery Street, Suite 2600, San Francisco, CA 94104.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 77s, 77t, 78u, 77uuu, 80a–41, and 80b–9.17 CFR 202.5.

PURPOSE(S) OF THE SYSTEM:

The records are maintained for purposes of the Commission's investigations and actions to enforce the Federal securities laws. Additionally, the information in the system is used in conjunction with the collection of amounts ordered to be paid in enforcement actions, a function that is a necessary component of litigation.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records are maintained on persons who have been involved in Commission investigations or litigation, or in activities which violated or may have violated Federal, state or foreign laws relating to transactions in securities, the conduct of securities business or investment advisory activities, and banking or other financial activities.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records contain names and addresses of persons involved in Commission investigations or litigation. Also, correspondence relevant to the matter, internal staff memoranda, Commission minutes and Commission orders, copies of subpoenas issued in the course of the matter, affidavits, transcripts of testimony and exhibits thereto, copies of pleadings and exhibits in related private or governmental actions, documents and other evidence obtained in the course of the matter, computerized records, working papers of the staff and other documents and records relating to the matter, opening reports, progress reports and closing reports, and miscellaneous records relating to investigations or litigation.

RECORD SOURCE CATEGORIES:

Information in these records is supplied by: Individuals including, where practicable, those to whom the information relates; witnesses, banks, corporations, or other entities; self-regulatory organizations; the Postal Inspection Service, the Department of Justice, state securities commissions, other Federal, state, or local bodies and

law enforcement agencies or foreign governmental authorities; public sources, *i.e.,* libraries, newspapers, television, radio, court records, filings with Federal, state, and local bodies; filings made with the SEC pursuant to law; electronic information sources; other offices within the Commission; documents, litigation, transcripts of testimony, evidence introduced into court, orders entered by a court and correspondence relating to litigation; pleadings in administrative proceedings, transcripts of testimony, documents, including evidence entered in such proceedings, and miscellaneous other sources.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities

Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To any governmental agency, governmental or private collection agent, consumer reporting agency or commercial reporting agency, governmental or private employer of a debtor, or any other person, for collection, including collection by administrative offset, Federal salary offset, tax refund offset, or administrative wage garnishment, of amounts owed as a result of Commission civil or administrative proceedings.

23. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

When the Commission seeks to collect a debt arising from a civil action or administrative proceeding, it may disclose the following information to a consumer reporting agency: (i) Information necessary to establish the identity of the debtor, including name, address and taxpayer identification number or social security number; (ii) the amount, status, and history of the debt; and (iii) the fact that the debt arose from a Commission action or proceeding to enforce the Federal securities laws.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS

The records are retrieved by the name under which the investigation is conducted or administrative or judicial litigation is filed. Access to information about an individual may be obtained through the Commission's Name-Relationship Search Index system by the name of the individual. Information concerning an individual may also be obtained by reference to computer-based indices maintained by the Division of Enforcement.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a(k)(2), this system of records is exempted from the following provisions of the Privacy Act, 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) and 17 CFR 200.303, 200.304, and 200.306, insofar as it contains investigatory materials compiled for law enforcement purposes. This exemption is contained in 17 CFR 200.312(a)(1).

HISTORY:

This SORN was last published in full in the **Federal Register** at 40 FR 39253 (August 27, 1975). Subsequent notices of revision can be found at the following citations:

—41 FR 5318 (February 5, 1976)
—41 FR 11631 (March 19, 1976)
—41 FR 41550 (September 22, 1976)
—42 FR 36333 (July 14, 1977)
—46 FR 63439 (December 31, 1981)
—59 FR 27626 (May 27, 1994)
—62 FR 47884 (September 11, 1997)
—67 FR 48497 (July 24, 2002)
—76 FR 30213 (May 24, 2011)

SYSTEM NAME AND NUMBER:

SEC–43: OFFICE OF INSPECTOR GENERAL WORKING FILES.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of the Inspector General, Securities and Exchange Commission (SEC), 100 F Street NE, Washington, DC 20549. Closed files may be stored at a Federal records center in accordance with the SEC's records retention schedule.

SYSTEM MANAGER(S):

Inspector General, Office of Inspector General, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Inspector General Act of 1978, as amended, Pub. L. 95–452, 5 U.S.C. App. 6; Dodd-Frank Wall Street Reform and Consumer Protection Act, Pub. L. 111–203, 15 U.S.C. 78d–4.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system of records is to enable the OIG to effectively and efficiently conduct investigations, audits, and inquiries relating to the programs and operations of the SEC; to allow OIG staff to provide legal advice and assistance to the Inspector General with respect to OIG investigations, audits, inquiries, actions, and agency operations; to represent the OIG in judicial and administrative proceedings in which the OIG or its personnel are involved as a party or a witness; to manage, track and report on matters and caseloads handled by OIG staff; to respond to communications and correspondence, as authorized by the Inspector General Act of 1978, as amended and the Dodd-Frank Wall Street Reform and Consumer Protection Act.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records contains records on individuals, including subjects, complainants, and witnesses, in connection with the SEC Office of Inspector General's (OIG) investigations, audits, or inquiries relating to programs and operations of the SEC. This system of records also includes records on individuals who are involved in litigation or administrative proceedings with the OIG, OIG employees whose conduct or performance raises concern, and individuals who correspond with the OIG such as members of Congress and their staff, members of the public and SEC employees who make suggestions through the OIG Employee Suggestion Hotline.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include: Case management systems that contain unique control numbers, descriptive information, and supporting documents for OIG matters; incoming complaints and complaint logs; preliminary inquiry files and indexes; correspondence; internal staff memoranda and legal analysis; copies of all subpoenas issued during investigations; subpoena logs; affidavits, declarations and statements from witnesses; transcripts of interviews conducted or testimony taken and accompanying exhibits; documents and records obtained during investigations, audits and administrative litigation; working papers of the staff; investigative plans, operation plans, status reports, reports of investigation, and closing memoranda; information and documents relating to grand jury proceedings; arrest and search warrant affidavits; information and documents relating to criminal, civil, and administrative actions; information and documents received from other law enforcement entities; personnel information for witnesses, subjects, and OIG staff; investigative peer review files; Congressional correspondence; SEC employee suggestions; and other internal and external communications.

RECORD SOURCE CATEGORIES:

Information in these records is supplied by: Individuals including, where practicable, those to whom the information relates; witnesses, corporations and other entities; records of individuals and of the SEC; records of other entities; Federal, foreign, state or local bodies and law enforcement agencies; documents and correspondence relating to litigation and administrative proceedings; public sources; and miscellaneous other sources.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (a) it is suspected or confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the OIG has determined that, as a result of the suspected or confirmed compromise, there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the SEC or OIG or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC or OIG's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

2. To another Federal agency or Federal entity, when the OIG determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach; or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal government, or national security resulting from a suspected or confirmed breach.

3. Where there is an indication of a violation or a potential violation of law, whether civil, criminal or regulatory in nature, to the appropriate agency, whether Federal, foreign, state, or local, or to a securities self-regulatory organization, charged with enforcing or implementing the statute, or rule, regulation or order.

4. To Federal, foreign, state, or local authorities in order to obtain information or records relevant to an OIG investigation or inquiry.

5. To non-governmental parties where those parties may have information the OIG seeks to obtain in connection with an investigation or inquiry.

6. To respond to subpoenas in any litigation or other proceeding.

7. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

8. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

9. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

10. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

11. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

12. To inform complainants, victims, and witnesses of the results of an investigation or inquiry.

13. To any persons during the course of any inquiry, audit, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

14. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

15. To qualified individuals or organizations in connection with the performance of a peer review or other study of the OIG's audit or investigative functions.

16. To a Federal agency responsible for considering debarment or suspension action if the record would be relevant to such action.

17. To the Department of Justice for the purpose of obtaining its advice on Freedom of Information Act matters.

18. To a Congressional office in response to an inquiry from the Congressional office.

19. To the Office of Government Ethics (OGE) to comply with agency reporting requirements established by OGE in 5 CFR 2638, subpart F.

20. To a Federal, state, local, foreign or administrative body, or before an arbitrator, when the SEC is a party to or has an interest in litigation or other legal proceedings, including to legal counsel representing the SEC or SEC employees, or other actual or potential parties, in connection with litigation, discovery or settlement discussions.

21. To an authorized investigator, administrative judge, or complaints examiner appointed by the Equal Employment Opportunity Commission when requested in connection with the investigation of a complaint of discrimination filed against the SEC under 29 CFR part 1614.

22. To the Merit Systems Protection Board or Office of the Special Counsel for the purpose of litigation, including administrative proceedings, appeals, special studies, investigations of alleged or possible prohibited personnel practices, and such other functions as may be authorized by law.

23. To the news media and the public when there exists a legitimate public interest (*e.g.,* to provide information on events in the criminal process, such as an indictment).

24. To the Council of the Inspectors General on Integrity and Efficiency, another Federal Office of Inspector General, or other Federal law enforcement office in connection with an allegation of wrongdoing by the Inspector General or OIG staff members.

25. To a contractor when there has been an SEC or OIG investigation or inquiry into the conduct or performance of the contractor's employees.

26. In reports published by the OIG pursuant to its authority granted in the Inspector General Act of 1978, as amended, Public Law 95–452, 5 U.S.C. App. 6, and Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111–203, 15 U.S.C § 78d-4.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets or are maintained in secure off-site storage.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The records may be retrieved by the name of the SEC employee, complainant, subject, witness, victim or member of the public; the OIG staff name for the audit, investigation or inquiry; or other indexed information.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A). Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

CONTESTING RECORD PROCEDURES:

See record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

Pursuant to 5 U.S.C. 552a(j)(2) and 17 CFR 200.313(a), this system of records is exempt from the provisions of the Privacy Act of 1974, 5 U.S.C. 552a, except subsections (b), (c)(1) and (2), (e)(4)(A) through (F), (e)(6), (7), (9), (10), and (11), and (i), and 17 CFR 200.303, 200.403, 200.306, 200.307, 200.308,

200.309, and 200.310, insofar as the system contains information pertaining to criminal law enforcement investigations.

Pursuant to 5 U.S.C. 552a(k)(2) and 17 CFR 200.313(b), this system of records is exempt from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f), and 17 CFR 200.303, 200.304, and 200.306, insofar as the system contains investigatory materials compiled for law enforcement purposes.

HISTORY:

This SORN was last published in full in the **Federal Register** at 79 FR 30661 (May 28, 2014).

SYSTEM NAME AND NUMBER:

SEC–45:

Mass Transportation Subsidy Program.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission (SEC), Operations Center, Office of Human Resources, 100 F Street NE, Washington, DC 20549. Records are also maintained at SEC Regional Offices. U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SYSTEM MANAGER(S):

Assistant Director, Office of Human Resources, 100 F Street NE, Washington, DC 20549–2465.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Executive Order: 12191; Pub. L. 101–509, Section 629; Pub. L. 103–172; 26 CFR 1.132–6; and 42 U.S.C. 13201 *et seq.*

PURPOSE(S) OF THE SYSTEM:

To encourage employees to use public transportation as a means to conserve petroleum, reduce traffic congestion, and improve air quality.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

SEC employees who participate in the Mass Transportation Subsidy Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include the employee's name, address, office telephone number, mode of transportation, transportation costs, date of entry into transit program, last four digits of social security number, organization, SmartTrip number, and date of annual certification.

RECORD SOURCE CATEGORIES:

Records include SEC Form 2445, Application to Transit Subsidy Program, SEC Form 2344, Return/Termination of Public Transportation Subsidy; Employee Certification for Public Transportation Subsidy; Receipt for Public Transportation Subsidy; SEC Form 2318, Disbursing Agents, Voucher; and SEC Form 2407, Authorization for Third-Party Receipt of Public Transportation Subsidy.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

4. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

5. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

6. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

7. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

8. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

9. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

10. To the appropriate personnel for periodic review of revalidation for subsidy.

11. To the Office of Inspector General for investigating allegations of abuse.

12. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs.

13. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained and stored in an electronic format.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name, last four digits of SSN or assigned division within the SEC.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 63 FR 37423 (July 10, 1998). Subsequent notices of revision can be found at the following citations:

SYSTEM NAME AND NUMBER:

SEC–46:

Facilities Access Badge System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

SYSTEM MANAGER(S):

Securities and Exchange Commission, Office of Security Services, Office of Support Operations, 100 F Street NE, Washington, DC 20549–1627.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and Executive Order 13231 of October 16, 2001, on Critical Infrastructure Protection ; the Federal Property and Administrative Services Act of 1949, 40 U.S.C. 101 *et seq.;* Homeland Security Presidential Directive 12 (HSPD–12), Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004.

PURPOSE(S) OF THE SYSTEM:

Records are for physical and operational security to identify authorized personnel permitted unescorted access to Commission facilities. It is also used to issue Special Credentials used as a physical and operational security measure to identify SEC employees in the performance of their duties. Records are for physical and operational security and can only be used for purposes compatible with the purpose for which it was collected as cited in the Privacy Act of 1974, 5 U.S.C. 552(a)7.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Commission employees, members of the press, contractors, volunteers, tenants, interns, consultants, and employees of other Federal agencies who require access to Commission facilities for extended periods of time.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records include the Government Personal Identity Verification (PIV) Card. The SEC system of records may contain the following: Name, date of birth, sex, social security number, citizenship, weight, height, color of hair and eyes, photograph, employee record number, card chip number, authorized access rights, date of issuance, date of return, date background investigation completed, Headquarters and Field Office Access Card (name, date of birth, weight, height, color of hair and eyes, photograph, employee record number, card chip number, authorized access rights, date of issuance, and date of expiration); Special Credential (signature of authorizing official, photograph, control number, date of issuance and date of expiration).

RECORD SOURCE CATEGORIES:

The issuing official or person issued the badge.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or tribal law enforcement agencies; to assist in or coordinate law enforcement activities with the SEC.

3. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

4. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of

assisting the Commission in the efficient administration of its programs, including by performing clerical, technical, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

5. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

6. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

7. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

8. To respond to subpoenas in any litigation or other proceeding.

9. To the Office of Inspector General or Office of Human Resources for investigative purposes.

10. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Electronic records may be retrieved by the employee's name and identification number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 63 FR 37423 (July 10, 1998). Subsequent notices of revision can be found at the following citations:

—72 FR 2036 (January 17, 2007)

SYSTEM NAME AND NUMBER:

SEC–48:

Fitness Center Membership, Payment, and Fitness Records SEC Employee's Health and Fitness Program Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

Aquila Fitness Consulting Systems, Ltd, 429 Lenox Avenue, Suite 4W21, Miami Beach, FL 33139–6532.

SYSTEM MANAGER(S):

Associate Executive Director, Office of Human Resources, Securities and Exchange Commission, Operations Center, 6432 General Green Way, Mail Stop 0–1, Alexandria, VA 22312–2413.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7901, *et seq.*

PURPOSE(S) OF THE SYSTEM:

The system enables SEC Fitness Center staff to track Fitness Center membership, fee payments, and the physical fitness of members. The primary use of these records is to allow the SEC to provide a variety of health and fitness resources to its employees.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

SEC employees who voluntarily sign up for membership benefits for SEC fitness programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may contain employee name, division, office address, email address, home address, home and cell telephone numbers, date of birth, health pre-screening questions, membership number, fee and payment information (including electronic debit information), and fitness progress charts.

RECORD SOURCE CATEGORIES:

All information is provided by Fitness Center members.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

3. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

4. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

5. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

6. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs.

7. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the individual's name or membership number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 64 FR 19840 (April 22, 1999). Subsequent notices of revision can be found at the following citations:

—77 FR 16569 (March 21, 2012)

SYSTEM NAME AND NUMBER:

SEC–51:

Continuity Support Center (CSC).

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Executive Director, Office of the Executive Director, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Executive Order 12656 (Nov. 18, 1988), Assignment of Emergency Preparedness Responsibilities; National Security Presidential Directive 51/Homeland Security Presidential Directive 20; *National Continuity Policy,* May 9, 2007.

PURPOSE(S) OF THE SYSTEM:

1. To maintain emergency contact information for current members and employees of the Commission for use in developing and maintaining emergency contingency operations plans, such as a formal continuity of operations (COOP) plan, for the Commission.

2. To provide alert and notification, determine team and task assignments, develop and maintain an emergency contact system for general emergency preparedness programs and specific situations (including threat alerts, weather related emergencies or other critical situations).

3. To activate COOP for Commission wide response to threat alerts issued by the Department of Homeland Security (DHS).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Members and employees of the Commission and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, job title, organizational code number, work and home addresses, work and personal electronic mail addresses, work, home, and cellular telephone numbers; pager numbers and Blackberry PIN numbers.

RECORD SOURCE CATEGORIES:

Records are obtained from the position control system and from the individual.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

4. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

5. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

6. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

7. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

8. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

9. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

10. To any Federal government authority for the purpose of coordinating and reviewing agency continuity of operations plans or emergency contingency plans developed for responding to Department of Homeland Security threat alerts.

11. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs.

12. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

These records are retrieved by individual's names, or by the categories listed above under ''Categories of Records in the System.''

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security

cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 68 FR 23168 (April 30, 2003).

SYSTEM NAME AND NUMBER:

SEC–52:

Visitor Badge and Employee Day Pass System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, Security Branch, Office of Administrative Services, 100 F Street NE, Washington, DC 20549–1627.

SYSTEM MANAGER(S):

Chief of Security Branch, Office of Administrative Services, Security Branch, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1627.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301 and Executive Order 13231 of October 16, 2001 on Critical Infrastructure Protection; Homeland Security Presidential Directive 12 (HSPD–12), Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004.

PURPOSE(S) OF THE SYSTEM:

This system is primarily designed as a physical and operational security system to control access to Commission facilities by visitors and representatives from other Federal agencies. It is also used to issue temporary badges for Commission staff or contractors who are not in possession of their badge and are authorized to enter SEC facilities. Records are for physical and operational security and can only be used for purposes compatible with the purpose for which it was collected as cited in the Privacy Act of 1974, 5 U.S.C. 552(a)7.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Authorized visitors and Commission employees who access Commission facilities are covered by this system.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include the name, photograph, country represented the number of the printed barcode issued for each badge, visitor category, the location, date, and time of entry to the secure Commission facility. Records may include the following information from scanned driver's licenses and passports: First and last name. Further information contained within the system will be the name of the person being visited and the reason for the visit. The system may maintain check in and check out times, current status of visitor, and a barcode assigned by the system software for each visitor record.

RECORD SOURCE CATEGORIES:

Information is provided by the visitor seeking access to Commission facilities to meet with Commission employees or contractors, by Commission employees who pre-register visitors, and by Commission employees or contractors with badges, who on that occasion do not have their access badge and seek access to SEC facilities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or tribal law enforcement agencies; to assist in or coordinate law enforcement activities with the SEC.

3. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

4. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

5. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, technical, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

6. To members of advisory committees that are created by the

Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

7. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

8. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

9. To respond to subpoenas in any litigation or other proceeding.

10. To the Office of Inspector General or the Office of Human Resources for investigative purposes.

11. Records may be used by staff of the Commission's Security Branch, the Office of Human Resources, and the Office of the Inspector General in routine reports or investigations to review access to SEC facilities and to assess compliance with established security procedures and policies.

12. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by the Individual's name, person visited, date of visit and/or barcode number (as printed in the form of a barcode on the badge).

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 71 FR 3907 (January 24, 2006).

SYSTEM NAME AND NUMBER:

SEC–54:

Photographic Files.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Branch Chief, Library Services, Securities and Exchange Commission, Library, 100 F Street NE, Room 1550, Washington, DC 20549–2465.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301, Departmental Regulations.

PURPOSE(S) OF THE SYSTEM:

1. To digitize SEC photographic files in support of the preservation of these materials.

2. To be used for reproduction by Commission staff organizing such events as awards ceremonies, farewell ceremonies and receptions, Commission anniversary ceremonies and receptions, and Commission training and educational programs.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Commission staff, visitors from other Federal agencies and members of the public.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records in the system include photographic prints, negatives, and slides. Records may also include digital photographs, as well as digitized images of photographic prints, negatives, and slides. Indexing data, including such data elements as date, event, and personal name and title, will be created for these materials.

RECORD SOURCE CATEGORIES:

Photographic files are provided to the Library for inclusion in the Library's collection on an ongoing basis. Donors include Commission employees who have photographed an event or individuals donating their photographic collections to the Library for the purposes of preservation and access. Indexing information is derived from information recorded on photographs, or from Commission staff or other

individuals who have knowledge of the event and individuals photographed.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

5. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

6. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

7. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

8. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

9. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

10. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

11. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

12. To respond to subpoenas in any litigation or other proceeding.

13. For distribution and presentation for news, public relations and community affairs purposes.

14. In support of research activities conducted by staff of the Commission and other Federal agencies, as well as members of the public.

15. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by such information as date of event, name of event, and/or name(s) of individual(s), where such information is available.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National

Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 71 FR 63810 (October 31, 2006).

SYSTEM NAME AND NUMBER:

SEC–55:

Information Pertaining or Relevant to SEC Registrants and Their Activities

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Records also are maintained in the SEC Regional Offices.

SYSTEM MANAGER(S):

Chief Information Officer, Office of Information Technology, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 78a *et seq.,* 80a–1 *et seq.,* and 80b–1 *et seq.*

PURPOSE(S) OF THE SYSTEM:

1. For use by authorized SEC personnel in connection with their official functions including, but not limited to, conducting examinations for compliance with Federal securities laws, investigations into possible violations of the Federal securities laws, and other matters relating to the SEC's regulatory and law enforcement functions.

2. To maintain continuity within the SEC as to each Regulated Entity and to provide SEC staff with the background and results of earlier examinations of Regulated Entities, as well as an insight into current industry practices or possible regulatory compliance issues.

3. To conduct lawful relational searches or analysis or filtering of data in matters relating to the SEC's examination, regulatory or law enforcement functions.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records concern individuals associated with entities or persons that are regulated by the SEC to include broker-dealers, investment advisers, investment companies, self-regulatory organizations, clearing agencies, nationally recognized statistical rating organizations, transfer agents, municipal securities dealers, municipal advisors, security-based swap dealers, security-based swap data repositories, major security-based swap participants, security-based swap execution facilities, and funding portals (individually, a ''Regulated Entity;'' collectively, ''Regulated Entities''). Records may also concern persons, directly or indirectly, with whom Regulated Entities or their affiliates have client relations or business arrangements.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may contain Regulated Entities' and their associated persons' names, addresses, telephone numbers and email addresses. Additionally, there may be information relating to the business activities and transactions of Regulated Entities and their associated persons, as well as their compliance with provisions of the Federal securities laws and with other applicable rules.

RECORD SOURCE CATEGORIES:

Record sources include filings made by Regulated Entities; information obtained through examinations or investigations of Regulated Entities and their activities; information contained in SEC correspondence with Regulated Entities; information received from other Federal, state, local, foreign or other regulatory organizations or law enforcement agencies; complaint information received by the SEC via letters, telephone calls, emails or any other form of communication; and data obtained from third-party sources.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records; (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct.

5. In any proceeding where the Federal securities laws are in issue or in

which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To any governmental agency, governmental or private collection agent, consumer reporting agency or commercial reporting agency, governmental or private employer of a debtor, or any other person, for collection, including collection by administrative offset, Federal salary offset, tax refund offset, or administrative wage garnishment, of amounts owed as a result of Commission civil or administrative proceedings.

23. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

24. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape, and/or digital media. Paper records and records on digital media are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information is indexed by name of the Regulated Entity or by certain SEC identification numbers. Information regarding individuals may be obtained through the use of cross-reference methodology or some form of personal identifier. Access for inquiry purposes is via a computer terminal.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. Records are required to be safeguarded in accordance with applicable SEC rules and policies. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A). Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

Notification Procedures

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 74 FR 36281 (July 22, 2009). Subsequent notices of revision can be found at the following citations:

—75 FR 35853 (June 23, 2010)

—79 FR 69894 (November 24, 2014)

SYSTEM NAME AND NUMBER:

SEC–56:

Mailing, Contact and Other Lists.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Records are also maintained in the SEC Regional Offices.

SYSTEM MANAGER(S):

U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Components: Office of the Chairman and Commissioners, Division of Corporation Finance, Division of Trading and Markets, Division of Investment Management, Division of Enforcement, Office of the General Counsel, Office of the Chief Accountant, Office of Economic Analysis, Office of Compliance Inspections and Examinations, Office of International Affairs, Office of Investor Education and Advocacy, Office of Information Technology, Office of the Executive Director, Office of Human Resources, Office of Financial Management, Office of Administrative Services, Office of Risk Assessment, Office of the Inspector General, Office of Legislative and Intergovernmental Affairs, Office of Public Affairs, Office of the Secretary, Office of Equal Employment Opportunity, and Office of Administrative Law Judges.

FOR REGIONAL OFFICES

New York Regional Office, Regional Director, 3 World Financial Center, Suite 400, New York, NY 10281–1022; Boston Regional Office, Regional Director, 33 Arch Street, 23rd Floor, Boston, MA 02110–1424; Philadelphia Regional Office, Regional Director, The Mellon Independence Center, 701 Market Street, Suite 2000, Philadelphia, PA 19106–1532; Miami Regional Office, Regional Director, 801 Brickell Avenue, Suite 1800, Miami, FL 33131–4901, Atlanta Regional Office, Regional Director, 3475 Lenox Road NE, Suite 1000, Atlanta, GA 30326–1232; Chicago Regional Office, Regional Director, 175 West Jackson Boulevard, Suite 900, Chicago, IL 60604–2908; Denver Regional Office, Regional Director, 1801 California Street, Suite 1500, Denver, CO 80202–2656; Fort Worth Regional Office, Regional Director, Burnett Plaza, Suite 1900, 801 Cherry Street, Unit #18, Fort Worth, TX 76102–6882; Salt Lake Regional Office, Regional Director, 15 West South Temple Street, Suite 1800, Salt Lake City, UT 84101–1573; Los Angeles Regional Office, Regional Director, 5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036–3648; San Francisco Regional Office, Regional Director, 44 Montgomery Street, Suite 2600, San Francisco, CA 94104–4716.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 77a *et seq.,* 78a *et seq.,* 80a–1 *et seq.,* and 80b–1 *et seq.*

PURPOSE(S) OF THE SYSTEM:

1. To track and process complaints/inquiries/requests/comments and communications from members of the public, including industry representatives, counsel, and others.

2. To handle subscription requests for informational literature, reports, and other SEC materials, via individual, mass, and targeted mailing in the furtherance of SEC activities.

3. To process registration, conduct surveys, and issue supplemental information for SEC-related activities and events.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records contain information related to individuals and employees who submit requests for information, subscriptions, inquiries, guidance, informal advice and other assistance to the SEC in any format, including but not limited to paper, telephone, and electronic submissions; SEC personnel assigned to handle such correspondence; individuals who have registered for SEC events and responded to questionnaires, request forms and feedback forms; and individuals who elect to participate in SEC surveys and studies.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may contain information relating to but not limited to name, title, affiliation, mailing address, telephone number, cell phone number, fax number, email address, business affiliation, other contact and related supporting information provided to the Commission by individuals or derived from other sources covered by this system of records and not currently covered under an existing SORN.

RECORD SOURCE CATEGORIES:

The information is supplied by the individual and/or company making the request. Data may also be added pertaining to the fulfillment of the request. Information may also be obtained from other SEC records systems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

5. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

6. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

7. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

8. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

9. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

10. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

11. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

12. To respond to subpoenas in any litigation or other proceeding.

13. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by any of the following: Email address, name, or an assigned file number for the purpose of responding to the requestor. Information may additionally be retrieved by other personal identifiers.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 74 FR 36281 (July 22, 2009). Subsequent notices of revision can be found at the following citations:

—75 FR 9968 (April 13, 2010)

SYSTEM NAME AND NUMBER:

SEC–57: OFFICE OF INTERNATIONAL AFFAIRS RECORDS.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Office of International Affairs, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Deputy Director, Office of International Affairs, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1004.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 77s, 77t, 78u, 77uuu, 80a–41, 80b–9, and 17 CFR 202.5.

PURPOSE(S) OF THE SYSTEM:

Tracks data gathered by the Office of International Affairs with respect to processing (1) requests for enforcement cooperation with foreign regulators and law enforcement agencies; (2) international regulatory policy matters designed to protect investors, improve market efficiency, and eliminate opportunities for ''regulatory arbitrage''; (3) technical assistance and international training programs for emerging securities markets; (4) directory of contacts for foreign regulators and stock exchanges; (5) SEC staff foreign travel; and (6) USAID Reimbursement.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Foreign and domestic contacts for Enforcement workload/Commission and foreign requests; foreign and domestic contacts for policy requests; Foreign officials trained in SEC Headquarters; Chairmen, CEOs, and Presidents of foreign regulators and stock exchanges; SEC staff traveling overseas; and information on vendors providing support for SEC's technical assistance program and individuals entitled to USAID reimbursements.

CATEGORIES OF RECORDS IN THE SYSTEM:

Contact information of individuals related to Enforcement cases and policy requests. Contact information of international institute foreign officials trained in SEC Headquarters; Contact information for Chairmen, CEOs, and Presidents of foreign regulators and stock exchanges; SEC staff traveling overseas; and information on vendors providing support for SEC's technical assistance program and individuals entitled to USAID reimbursements. Correspondence relevant to the matter, internal staff memoranda, Commission Minutes and Commission Orders, working papers of the staff and other documents and records relating to the matter, opening reports, progress reports and closing reports, miscellaneous records relating to cross-border investigations or litigation and other international enforcement and regulatory matters.

RECORD SOURCE CATEGORIES:

Information contained in this system is obtained from enforcement requests related to an SEC investigation; international institute training programs; foreign regulators and stock exchanges; SEC travel records; and USAID reimbursable programs.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or

regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

23. To any governmental agency, governmental or private collection agent, consumer reporting agency or commercial reporting agency, governmental or private employer of a debtor, or any other person, for collection, including collection by administrative offset, Federal salary offset, tax refund offset, or administrative wage garnishment, of amounts owed as a result of Commission civil or administrative proceedings.

24. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Data are retrievable by the individual's name or other identifier, such as case number, name, as well as non-identifying information.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 74 FR 36281 (July 22, 2009).

SYSTEM NAME AND NUMBER:

SEC–60:

Ethics Conduct Rules Files.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

The Ethics Counsel and the Designated Agency Ethics Official, Office of the General Counsel, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1050.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

The Federal securities laws (15 U.S.C. 77s, 78w, 77sss, 80a–37 and 80b–11) and the regulations promulgated thereunder, including the Ethics Conduct Rules currently located at 17 CFR part 200 Subpart M.

PURPOSE(S) OF THE SYSTEM:

For use by authorized SEC Ethics Office personnel, designated by the Ethics Counsel, and from time to time certain other SEC personnel, designated by the Ethics Counsel in his or her discretion, in connection with their official functions related to administering and supervising compliance with the Commission's Ethics Conduct Rules.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

SEC Members and employees, past and present.

CATEGORIES OF RECORDS IN THE SYSTEM:

Information relating to the SEC's ''Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission'' (''Ethics Conduct Rules''), currently located at 17 CFR part 200 Subpart M, including outside employment and activities, and covered securities transactions, securities holdings and securities accounts.

RECORD SOURCE CATEGORIES:

Information is provided by current Members and employees of the Commission or their designees in accordance with the requirements of the SEC Ethics Conduct Rules.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records, (2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To a Federal, State, or local law enforcement agency if the disclosing agency becomes aware of a violation or potential violation of law or regulation.

3. To a court or party in a court or Federal administrative proceeding if the Government is a party or in order to comply with a judge-issued subpoena.

4. To a source when necessary to obtain information relevant to a conflict of interest or securities law investigation or decision.

5. To the National Archives and Records Administration or the General Services Administration in records management inspections.

6. To the Office of Management and Budget during legislative coordination on private relief legislation.

7. To the Department of Justice or in certain legal proceedings when the disclosing agency, and employee of the disclosing agency, or the United States is a party to litigation or has an interest in the litigation and the use of such records is deemed relevant and necessary to the litigation.

8. To reviewing officials in a new office, department or agency when an employee transfers from one position to another subject to the Ethics Conduct Rules.

9. To a Member of Congress or a congressional office in response to an inquiry made on behalf of an individual who is the subject of the record.

10. To interns, grantees, experts and contractors who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a; and

11. As a data source for management information for production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained; may also be utilized to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

12. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by the individual's name or other personal identifiers, as well as non-identifying information. Information regarding individuals may be obtained through the use of cross-reference methodology.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained for six years or otherwise in accordance with records schedules of the Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/Privacy Act Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/Privacy Act Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 74 FR 46254 (September 8, 2009).

SYSTEM NAME AND NUMBER:

SEC–62:

Office of Municipal Advisor Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission (''Commission'' or ''SEC'') 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Assistant Director, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–7561.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Dodd-Frank Wall Street Reform and Consumer Protection Act, Section 975(a), Pub. L. 111–203 (2010); 15 U.S.C. 78a *et seq.;* 80b–1 *et. seq.;* and 17 CFR 202.1 through 202.10.

PURPOSE(S) OF THE SYSTEM:

The records are used by SEC staff to track, process, respond to, and maintain documentation of correspondence, inquiries/requests/comments, communications, and related information from or regarding members of the public, including industry representatives, counsel, and others, relating to Municipal Advisors; to document Commission or SEC staff responses on a formal or informal basis.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Persons applying for registration or exemption from registration as a Municipal Advisor, persons currently or formerly registered with the Commission as a Municipal Advisor, and their partners, officers, directors, associated persons, control persons, control affiliates, employees, owners, principal shareholders, other related persons, and their representatives or counsel; and representatives of regulated entities and their counsel, members of the public, representatives of other governmental agencies or Congress, and others who submit correspondence, inquiries, information, comments, or other forms of communication to the Commission or SEC staff relating to Municipal Advisors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Both electronic and paper records in this system may include information concerning an individual's activities and transactions as or pertaining to, or relationships with, a Municipal Advisor; the name of the correspondent or inquirer/requester/commenter/communicant or their representative; the name of the entity; the subject of the correspondence, inquiry/request/comment or communication; the date of the correspondence, inquiry/request/comment or communication; and the Commission or SEC staff response provided, or other disposition, on a

formal or informal basis. Paper records may include, but are not limited to, letters, facsimiles, imaged documents, other written forms of communication, and related documentation.

RECORD SOURCE CATEGORIES:

Information collected is received from individuals primarily through correspondence or other written or verbal forms of communication, including without limitation telephone calls, emails and other forms of electronic communication, letters, or facsimiles to the Commission and SEC staff.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or

conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

23. To any governmental agency, governmental or private collection agent, consumer reporting agency or commercial reporting agency, governmental or private employer of a debtor, or any other person, for collection, including collection by administrative offset, Federal salary offset, tax refund offset, or administrative wage garnishment, of amounts owed as a result of Commission civil or administrative proceedings.

24. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by any of the following: Name, receipt date, entity name, registration number, telephone/cellular/facsimile number, email or internet address, subject matter, or other indexed information.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 75 FR 51854 (August 23, 2010).

SYSTEM NAME AND NUMBER:

SEC–63:

Tips, Complaints, and Referrals (TCR) Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Files may also be maintained in the Commission's Regional Offices that conducted an investigation or litigation.

SYSTEM MANAGER(S):

Deputy Director, Division of Risk, Strategy, and Financial Innovation, U.S. Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 77a *et seq.,* 78a *et seq.,* 80a–1 *et seq.,* 80b–1 *et seq.,* and 5 U.S.C. 302.

PURPOSE(S) OF THE SYSTEM:

For use by authorized SEC personnel in receiving, recording, assigning, tracking, and taking action on tips, complaints, and referrals received from individuals and entities related to actual or potential violations of the Federal securities laws; investor harm; or conduct of public companies, securities professionals, regulated entities and associated persons.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

(1) Individuals that submit tips, complaints, or related information about actual or potential violations of the Federal securities laws; investor harm; conduct of public companies, securities professionals, regulated entities, and associated persons; and internal and external referrals of misconduct; (2) Individuals that are the subjects of a tip or complaint related to an actual or potential securities law violation; (3) Attorneys or other related individuals; and (4) SEC personnel or contractors

assigned to handle such tips, complaints, and referrals.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include individual names, dates of birth, social security numbers, addresses, telephone numbers, tip, complaint, and referral information including allegation descriptions, dates, and supporting details; supporting documentation; web forms; emails; criminal history; working papers of the staff; and other documents and records relating to the matter.

RECORD SOURCE CATEGORIES:

Information in these records may be supplied by investors and the general public, Commission-regulated entities including broker-dealers, investment advisers, self-regulatory organizations, other government agencies, and foreign regulators.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1

through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

23. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records may be retrieved by an individual's or entity's name, receipt date, subject matter, keywords that may include personal information, and/or other personal identifier. The system will also enable authorized SEC personnel to search for and retrieve records using conventional methods including but not limited to the use of unique record identifiers, keyword searches, geographic data (*e.g.* ZIP code), date and time searches, and sorts and filters.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a(k)(2), this system of records is exempted from the following provisions of the Privacy Act, 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) and 17 CFR 200.303, 200.304, and 200.306, insofar as it contains investigatory materials compiled for law enforcement purposes. This exemption is contained in 17 CFR 200.312(a)(1).

HISTORY:

This SORN was last published in full in the **Federal Register** at 76 FR 30213 (May 24, 2011). Subsequent notices of revision can be found at the following citations:

—76 FR 57636 (September 16, 2011)

SYSTEM NAME AND NUMBER:

SEC–64:

SEC Security in the Workplace Incident Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Chief, SEC Security Branch, 100 F Street NE, Washington, DC 20549–2465.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 7902(d) and (e).

PURPOSE(S) OF THE SYSTEM:

The records are used by SEC personnel to take action on, or to respond to a complaint about a threat, harassment, intimidation, violence, or other inappropriate behavior involving one or more SEC employees, contractors, interns, or other individuals against an SEC employee; and to make assessments of violent or potentially violent situations and then make recommendations regarding interventions for those persons involved with the situations.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Past and present employees, interns, and volunteers of the Securities and Exchange Commission (employees), contractors, visitors, and others who have access to SEC facilities who report

potential or actual workplace violence; persons accused of threatening to commit, or committing workplace violence, and persons interviewed or investigated in connection with reports or allegations of potential or actual workplace violence.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records include, but are not limited to: Case number, victim's name, office telephone number, room number, office/division, duty station, position, supervisor, supervisor's telephone number, location of incident, activity at time of incident, circumstances surrounding the incident, perpetrator, name(s) and telephone number(s) of witness(es), injured party(s), medical treatment(s), medical report, property damages, report(s) to police, and related information needed to investigate violence, threats, harassment, intimidation, or other inappropriate behavior causing SEC employees, contractors, or other individuals to fear for their personal safety in the SEC workplace.

RECORD SOURCE CATEGORIES:

Records source is from individuals who report potential or actual workplace security incidents, and reports made on individuals interviewed or investigated in connection with allegations of potential or actual workplace security incidents.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. When a person or property is harmed, or when threats of harm to a person or property are reported, disclosure will be made, as appropriate, to law enforcement authorities, medical treatment authorities, and those persons being threatened or harmed.

3. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign securities authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

4. To a bar association, a state accountancy board, the Public Company Accounting Oversight Board, or any similar Federal, state, or local licensing authority for possible disciplinary action.

5. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

6. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

7. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

8. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

9. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

10. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

11. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

12. To a Congressional office in response to an inquiry from that Congressional office made at the request of the individual to whom the record pertains.

13. To respond to subpoenas in any litigation or other proceeding.

14. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

15. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach; or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by name or case designation (those who reported a violent or potentially violent event and those who were reported), event date, and event location

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a(k)(2), this system of records is exempted from the following provisions of the Privacy Act, 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) and 17 CFR 200.303, 200.304, and 200.306, insofar as it contains investigatory materials compiled for law enforcement purposes. This exemption is contained in 17 CFR 200.312(a)(1).

HISTORY:

This SORN was last published in full in the **Federal Register** at 76 FR 30213 (May 24, 2011). Subsequent notices of revision can be found at the following citations:

—76 FR 57636 (September 17, 2011)

SYSTEM NAME AND NUMBER:

SEC–65:

Correspondence Response Systems.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549. Also, records covered by Subsystem A are received by and maintained in the Commission's Regional Offices, whose addresses are listed below under System Manager(s) and Address.

SYSTEM MANAGER(S):

Subsystem A: Chief Counsel, Office of Investor Education and Advocacy, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549; New York Regional Office, Regional Director, 3 World Financial Center, Suite 400, New York, NY 10281–1022; Boston Regional Office, Regional Director, 33 Arch Street, 23rd Floor, Boston, MA 02110–1424; Philadelphia Regional Office, Regional Director, The Mellon Independence Center, 701 Market Street, Suite 2000, Philadelphia, PA 19106–1532; Miami Regional Office, Regional Director, 801 Brickell Avenue, Suite 1800, Miami, FL 33131–4901, Atlanta Regional Office, Regional Director, 3475 Lenox Road, NE, Suite 1000, Atlanta, GA 30326–1232; Chicago Regional Office, Regional Director, 175 West Jackson Boulevard, Suite 900, Chicago, IL 60604–2908; Denver Regional Office, Regional Director, 1801 California Street, Suite 1500, Denver, CO 80202–2656; Fort Worth Regional Office, Regional Director, Burnett Plaza, Suite 1900, 801 Cherry Street, Unit #18, Fort Worth, TX 76102–6882; Salt Lake Regional Office, Regional Director, 15 West South Temple Street, Suite 1800, Salt Lake City, UT 84101–1573; Los Angeles Regional Office, Regional Director, 5670 Wilshire Boulevard, 11th Floor, Los Angeles, CA 90036–3648; San Francisco Regional Office, Regional Director, 44 Montgomery Street, Suite 2600, San Francisco, CA 94104–4716.

Subsystem B: Office of the Chairman, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

15 U.S.C. 77s, 77sss, 78d, 78d–1, 78d–2, 78w, 78*ll*(d), 79t, 80a–37, and 80b–11.

PURPOSE OF THE SYSTEM:

The records will be used by the staff to track and process complaints/inquiries/requests from members of the public and others.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Subsystem A:

Records are maintained in the Investor Response Information System (IRIS) on members of the public and others who submit questions or complaints to the Commission generally, or to Divisions and Offices of the Commission, or who contact the Office of Investor Education and Advocacy or the Commission's Regional Offices.

Subsystem B:

Records are maintained in the Chairman's Correspondence System (CCS) on members of the public, members of Congress or their staff, and others who address their inquiries or complaints to the Commission's Chairman's Office or to the Office of Legislative and Intergovernmental Affairs.

CATEGORIES OF RECORDS IN THE SYSTEM:

Both electronic and paper records in this system/subsystems may contain the name of the complainant/inquirer/requester or their representative, the name of the entity and/or subject of the complaint/inquiry/request, the date relating to the receipt and disposition of the complaint/inquiry/request, Personally Identifiable Information (PII) and other sensitive information such as investment account information, and, where applicable, the type of complaint/inquiry/request and other information derived from or relating to the complaint/inquiry/request. Paper records may include, but are not limited to, letters of complaint/inquiry/request, responses, and related documentation.

RECORD SOURCE CATEGORIES:

Information collected in all subsystems is received from individuals primarily through web forms, email,

letters, telephone calls, or personal visits to the Commission's offices.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (a) it is suspected or confirmed that the security or confidentiality of information in the system of records has been compromised; (b) the SEC has determined that, as a result of the suspected or confirmed compromise, there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the SEC or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. To national securities exchanges and national securities associations that are registered with the SEC, the Municipal Securities Rulemaking Board; the Securities Investor Protection Corporation; the Public Company Accounting Oversight Board; the Federal banking authorities, including, but not limited to, the Board of Governors of the Federal Reserve System, the Comptroller of the Currency, and the Federal Deposit Insurance Corporation; state securities regulatory agencies or organizations; or regulatory authorities of a foreign government in connection with their regulatory or enforcement responsibilities.

4. By SEC personnel for purposes of investigating possible violations of, or to conduct investigations authorized by, the Federal securities laws.

5. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

6. In connection with proceedings by the Commission pursuant to Rule 102(e) of its Rules of Practice, 17 CFR 201.102(e).

7. To a bar association, state accountancy board, or other Federal, state, local, or foreign licensing or oversight authority; or professional association or self-regulatory authority to the extent that it performs similar functions (including the Public Company Accounting Oversight Board) for investigations or possible disciplinary action.

8. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

9. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

10. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

11. To any trustee, receiver, master, special counsel, or other individual or entity that is appointed by a court of competent jurisdiction, or as a result of an agreement between the parties in connection with litigation or administrative proceedings involving allegations of violations of the Federal securities laws (as defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)) or pursuant to the Commission's Rules of Practice, 17 CFR 201.100 through 900 or the Commission's Rules of Fair Fund and Disgorgement Plans, 17 CFR 201.1100 through 1106, or otherwise, where such trustee, receiver, master, special counsel, or other individual or entity is specifically designated to perform particular functions with respect to, or as a result of, the pending action or proceeding or in connection with the administration and enforcement by the Commission of the Federal securities laws or the Commission's Rules of Practice or the Rules of Fair Fund and Disgorgement Plans.

12. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

13. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

14. In reports published by the Commission pursuant to authority granted in the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), which authority shall include, but not be limited to, section 21(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78u(a)).

15. To members of advisory committees that are created by the Commission or by Congress to render advice and recommendations to the Commission or to Congress, to be used solely in connection with their official designated functions.

16. To any person who is or has agreed to be subject to the Commission's Rules of Conduct, 17 CFR 200.735–1 through 200.735–18, and who assists in the investigation by the Commission of possible violations of the Federal securities laws (as such term is defined in section 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. 78c(a)(47)), in the preparation or conduct of enforcement actions brought by the Commission for such violations, or otherwise in connection with the Commission's enforcement or regulatory functions under the Federal securities laws.

17. To a Congressional office from the record of an individual in response to

an inquiry from the Congressional office made at the request of that individual.

18. To members of Congress, the press, and the public in response to inquiries relating to particular Registrants and their activities, and other matters under the Commission's jurisdiction.

19. To prepare and publish information relating to violations of the Federal securities laws as provided in 15 U.S.C. 78c(a)(47)), as amended.

20. To respond to subpoenas in any litigation or other proceeding.

21. To a trustee in bankruptcy.

22. To members of Congress, the General Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

23. To respond to inquiries from individuals who have submitted complaints/inquiries/request, or from their representatives.

24. To entities against which complaints/inquiries/requests are directed when Commission staff requests them to research the issues raised and report back to the staff.

POLICIES AND PRACTICES STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases and/or on computer disc. Paper records and records on computer disc are stored in file rooms and/or file cabinets, as well as off-site locations including the Federal Records Center, pursuant to applicable record retention guidelines.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

The files (both paper and electronic) in Subsystems A and B are retrievable by the name, receipt date, name of the registered representative or associated person named in the complaint/inquiry/request, or the name of the entity/issuer that is the subject of the complaint/inquiry/request.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records are safeguarded in a secured environment. Buildings where records are stored have security cameras and 24 hour security guard service. The records are kept in limited access areas during duty hours and in file cabinets and/or offices or file rooms at all other times. Computerized records are safeguarded through use of access codes and information technology security. Contractors and other recipients providing services to the Commission are contractually obligated to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Under 5 U.S.C. 552a(k)(2), this system of records is exempted from the following provisions of the Privacy Act, 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), (I), and (f) and 17 CFR 200.303, 200.304, and 200.306, insofar as it contains investigatory materials compiled for law enforcement purposes. This exemption is contained in 17 CFR 200.312(a)(1).

HISTORY:

This SORN was last published in full in the **Federal Register** at 76 FR 30213 (May 24, 2011). Subsequent notices of revision can be found at the following citations:

—76 FR 57636 (September 18, 2011)

SYSTEM NAME AND NUMBER:

SEC–66:

Backup Care Employee and Family Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Bright Horizons Family Solutions, 200 Talcott Avenue, Watertown, MA 02472. Records may also be maintained at subcontracted childcare center locations. Electronic Reports of SEC Employees' registrations and uses are maintained at the Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

SYSTEM MANAGER(S):

Associate Executive Director, Office of Human Resources, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–3901.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

40 U.S.C 590.

PURPOSE(S) OF THE SYSTEM:

The records are used to determine an employee's eligibility to request backup care benefits for family members.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current SEC employees who voluntarily sign up for backup care benefits and their family members for whom care is needed.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may contain employee name, email address, home address, home and cell telephone numbers, and date of birth; family member's name, address, date of birth, physician medical form, and medical identification number; photos of child, and individuals authorized to pick up child; and provider's name.

RECORD SOURCE CATEGORIES:

All information is provided by SEC employees registering for the services.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower

studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

3. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

4. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

5. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

6. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

7. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach; or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic format. Electronic records are stored in computerized databases, magnetic disc, tape and/or on digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are retrieved by the individual's name.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with records schedules of the United States Securities and Exchange Commission and as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 77 FR 65913 (October 31, 2012). Subsequent notices of revision can be found at the following citations:

—78 FR 41962 (July 12, 2013)

SYSTEM NAME AND NUMBER:

SEC–67:

General Information Technology Records.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

Securities and Exchange Commission, Headquarters, 100 F Street NE, Washington, DC 20549 and the SEC's Regional Offices.

SYSTEM MANAGER(S):

Chief Information Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 302, Delegation of Authority; 44 U.S.C. 3534; Federal Information Security Act (Pub. L. 104–106, section 5113); Electronic Government Act (Pub. L. 104–347, section 203); and E.O. 9397 (SSN), as amended by E.O. 13487.

PURPOSE(S) OF THE SYSTEM:

The purpose of this system is to (1) provide authentication and authorization to individuals with access to SEC-controlled information and information system networks; (2) collect, review, and maintain any logs, audit trails, or other such security data regarding the use of SEC information or information systems; and (3) to enable the Commission to detect, report, and take appropriate action against improper or unauthorized access to SEC-controlled information and information systems networks. The records will also enable the SEC to provide individuals access to certain programs and meeting attendance and, where appropriate, allow for sharing of information between individuals in the same operational program to facilitate collaboration. SEC management personnel may use statistical data, with all personal identifiers removed or masked, for system efficiency, workload calculation, or reporting purposes.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Records are maintained on all individuals who are authorized to access SEC information or information systems; including: employees, contractors, students, interns, volunteers, affiliates, others working on behalf of the SEC, and individuals formerly in any of these positions. Records may also include individuals who voluntarily join an SEC-owned and operated web portal for collaboration purposes; individuals who request access but are denied, and/or who have had access revoked.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system of records may include: Users' names; social security numbers; business telephone numbers; cellular phone numbers; pager numbers; levels of access; physical and email addresses; titles; departments; division; contractor/employee status; computer logon addresses; password hashes; user identification codes; dates and times of access; IP addresses; logs of internet activity; types of access/permissions required; failed access data; archived transaction data; historical data; and justifications for access to SEC computers, networks, or systems. For individuals who telecommute from home or a telework center, the records may contain the internet Protocol (IP) address and telephone number at that location. For contractors, the system may contain the company name, contract number, and contract expiration date. The system may also contain details regarding: Programs; databases; functions; and sites accessed and/or used, dates and times of use, information products created, received, or altered during use, and access or functionality problems reported for technical support and resolution.

RECORD SOURCE CATEGORIES:

Information is supplied by the record subject, their supervisors, and the personnel security staff. Logs and details about access times and functions used are provided by the system.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Commission as a routine use pursuant to 5 U.S.C. 552 a(b)(3) as follows:

1. To appropriate agencies, entities, and persons when (1) the SEC suspects or has confirmed that there has been a breach of the system of records,·(2) the SEC has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, the SEC (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the SEC's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

2. To other Federal, state, local, or foreign law enforcement agencies; securities self-regulatory organizations; and foreign financial regulatory authorities to assist in or coordinate regulatory or law enforcement activities with the SEC.

3. In any proceeding where the Federal securities laws are in issue or in which the Commission, or past or present members of its staff, is a party or otherwise involved in an official capacity.

4. To a Federal, state, local, tribal, foreign, or international agency, if necessary to obtain information relevant to the SEC's decision concerning the hiring or retention of an employee; the issuance of a security clearance; the letting of a contract; or the issuance of a license, grant, or other benefit.

5. To a Federal, state, local, tribal, foreign, or international agency in response to its request for information concerning the hiring or retention of an employee; the issuance of a security clearance; the reporting of an investigation of an employee; the letting of a contract; or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

6. To produce summary descriptive statistics and analytical studies, as a data source for management information, in support of the function for which the records are collected and maintained or for related personnel management functions or manpower studies; may also be used to respond to general requests for statistical information (without personal identification of individuals) under the Freedom of Information Act.

7. To any persons during the course of any inquiry, examination, or investigation conducted by the SEC's staff, or in connection with civil litigation, if the staff has reason to believe that the person to whom the record is disclosed may have further information about the matters related therein, and those matters appeared to be relevant at the time to the subject matter of the inquiry.

8. To interns, grantees, experts, contractors, and others who have been engaged by the Commission to assist in the performance of a service related to this system of records and who need access to the records for the purpose of assisting the Commission in the efficient administration of its programs, including by performing clerical, stenographic, or data analysis functions, or by reproduction of records by electronic or other means. Recipients of these records shall be required to comply with the requirements of the Privacy Act of 1974, as amended, 5 U.S.C. 552a.

9. To respond to subpoenas in any litigation or other proceeding.

10. To a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

11. To members of Congress, the Government Accountability Office, or others charged with monitoring the work of the Commission or conducting records management inspections.

12. To a commercial contractor in connection with benefit programs administered by the contractor on the Commission's behalf, including, but not limited to, supplemental health, dental, disability, life and other benefit programs.

13. To another Federal agency or Federal entity, when the SEC determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach; or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are maintained in electronic and paper format. Electronic records are stored in computerized databases, magnetic disc, tape and/or digital media. Paper records and records on computer disc are stored in locked file rooms and/or file cabinets.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information may be retrieved, sorted, and/or searched by an identification number assigned by the computer, the last two digits of a social security number, email address, or by the name of the individual, or other employee

data fields previously identified in this SORN.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

These records will be maintained until they become inactive, at which time they will be retired or destroyed in accordance with the SEC's records retention schedule, as approved by the National Archives and Records Administration.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to SEC facilities, data centers, and information or information systems is limited to authorized personnel with official duties requiring access. SEC facilities are equipped with security cameras and 24-hour security guard service. The records are kept in limited access areas during duty hours and in locked file cabinets and/or locked offices or file rooms at all other times. Computerized records are safeguarded in a secured environment. Security protocols meet the promulgating guidance as established by the National Institute of Standards and Technology 4 (NIST) Security Standards from Access Control to Data Encryption and Security Assessment & Authorization (SA&A).

Records are maintained in a secure, password-protected electronic system that will utilize commensurate safeguards that may include: Firewalls, intrusion detection and prevention systems, and role-based access controls. Additional safeguards will vary by program. All records are protected from unauthorized access through appropriate administrative, operational, and technical safeguards. These safeguards include: Restricting access to authorized personnel who have a ''need to know''; using locks; and password protection identification features. Contractors and other recipients providing services to the Commission shall be required to maintain equivalent safeguards.

RECORD ACCESS PROCEDURES:

Persons wishing to obtain information on the procedures for gaining access to or contesting the contents of these records may contact the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

CONTESTING RECORD PROCEDURES:

See Record access procedures above.

NOTIFICATION PROCEDURES:

All requests to determine whether this system of records contains a record pertaining to the requesting individual may be directed to the FOIA/PA Officer, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–2465.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

This SORN was last published in full in the **Federal Register** at 79 FR 30661 (May 28, 2014).

By the Commission.

Dated: December 21, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–28601 Filed 12–23–20; 8:45 am]

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *https://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

H.R. 2246/P.L. 116–227

To designate the facility of the United States Postal Service located at 201 West Cherokee Street in Brookhaven, Mississippi, as the ''Deputy Donald William Durr, Corporal Zach Moak, and Patrolman James White Memorial Post Office Building''. (Dec. 21, 2020; 134 Stat. 1100)

H.R. 2454/P.L. 116–228

To designate the facility of the United States Postal Service located at 123 East Sharpfish Street in Rosebud, South Dakota, as the ''Ben Reifel Post Office Building''. (Dec. 21, 2020; 134 Stat. 1101)

H.R. 2969/P.L. 116–229

To designate the facility of the United States Postal Service located at 1401 1st Street North in Winter Haven, Florida, as the ''Althea Margaret Daily Mills Post Office Building''. (Dec. 21, 2020; 134 Stat. 1102)

H.R. 3005/P.L. 116–230

To designate the facility of the United States Postal Service located at 13308 Midland Road in Poway, California, as the ''Ray Chavez Post Office Building''. (Dec. 21, 2020; 134 Stat. 1103)

H.R. 3275/P.L. 116–231

To designate the facility of the United States Postal Service located at 340 Wetmore Avenue in Grand River, Ohio, as the ''Lance Corporal Andy 'Ace' Nowacki Post Office''. (Dec. 21, 2020; 134 Stat. 1104)

H.R. 3680/P.L. 116–232

To designate the facility of the United States Postal Service located at 415 North Main Street in Henning, Tennessee, as the ''Paula Croom Robinson and Judy Spray Memorial Post Office Building''. (Dec. 21, 2020; 134 Stat. 1105)

H.R. 3847/P.L. 116–233

To designate the facility of the United States Postal Service located at 117 West Poythress Street in Hopewell, Virginia, as the ''Reverend Curtis West Harris Post Office Building''. (Dec. 21, 2020; 134 Stat. 1106)

H.R. 3870/P.L. 116–234

To designate the facility of the United States Postal Service located at 511 West 165th Street in New York, New York, as the ''Normandia Maldonado Post Office Building''. (Dec. 21, 2020; 134 Stat. 1107)

H.R. 4034/P.L. 116–235

To designate the facility of the United States Postal Service located at 602 Pacific Avenue in Bremerton, Washington, as the ''John Henry Turpin Post Office Building''. (Dec. 21, 2020; 134 Stat. 1108)

H.R. 4200/P.L. 116–

36 To designate the facility of the United States Postal Service located at 321 South 1st Street in Montrose, Colorado, as the ''Sergeant David Kinterknecht Post Office''. (Dec. 21, 2020; 134 Stat. 1109)

H.R. 4279/P.L. 116–237

To designate the facility of the United States Postal Service located at 445 Main Street in Laceyville, Pennsylvania, as the ''Melinda Gene Piccotti Post Office''. (Dec. 21, 2020; 134 Stat. 1110)

H.R. 4672/P.L. 116–238

To designate the facility of the United States Postal Service located at 21701 Stevens Creek Boulevard in Cupertino, California, as the ''Petty Officer 2nd Class (SEAL) Matthew G. Axelson Post Office Building''. (Dec. 21, 2020; 134 Stat. 1111)

H.R. 4725/P.L. 116–239

To designate the facility of the United States Postal Service located at 8585 Criterion Drive in Colorado Springs, Colorado, as the ''Chaplain (Capt.) Dale Goetz Memorial Post Office Building''. (Dec. 21, 2020; 134 Stat. 1112)

H.R. 4785/P.L. 116–240

To designate the facility of the United States Postal Service located at 1305 U.S. Highway 90 West in Castroville, Texas, as the ''Lance Corporal Rhonald Dain Rairdan Post Office''. (Dec. 21, 2020; 134 Stat. 1113)

H.R. 4875/P.L. 116–241

To designate the facility of the United States Postal Service located at 2201 E. Maple Street in North Canton, Ohio, as the ''Lance Cpl. Stacy 'Annie' Dryden Post Office''. (Dec. 21, 2020; 134 Stat. 1114)

H.R. 4971/P.L. 116–242

To designate the facility of the United States Postal Service located at 15 East Market Street in Leesburg, Virginia, as the ''Norman Duncan Post Office Building''. (Dec. 21, 2020; 134 Stat. 1115)

H.R. 5317/P.L. 116–243

To designate the facility of the United States Postal Service located at 315 Addicks Howell Road in Houston, Texas, as the ''Deputy Sandeep Singh Dhaliwal Post Office Building''. (Dec. 21, 2020; 134 Stat. 1116)

H.R. 5954/P.L. 116–244

To designate the facility of the United States Postal Service located at 108 West Maple Street in Holly, Michigan, as the ''Holly Veterans Memorial Post Office''. (Dec. 21, 2020; 134 Stat. 1117)

S. 4902/P.L. 116–245

To designate the United States courthouse located at 351 South West Temple in Salt Lake City, Utah, as the ''Orrin G. Hatch United States Courthouse''. (Dec. 21, 2020; 134 Stat. 1118)

H.R. 1520/P.L. 116–246

Further Extension of Continuing Appropriations Act, 2021 (Dec. 22, 2020; 134 Stat. 1119)

H.R. 1830/P.L. 116–247

National Purple Heart Hall of Honor Commemorative Coin Act (Dec. 22, 2020; 134 Stat. 1120)

H.R. 3349/P.L. 116–248

Republic of Texas Legation Memorial Act (Dec. 22, 2020; 134 Stat. 1124)

S. 134/P.L. 116–249

Combat Online Predators Act (Dec. 22, 2020; 134 Stat. 1126)

S. 578/P.L. 116–250

ALS Disability Insurance Access Act of 2019 (Dec. 22, 2020; 134 Stat. 1128)

S. 1153/P.L. 116–251

Stop Student Debt Relief Scams Act of 2019 (Dec. 22, 2020; 134 Stat. 1129)

S. 3703/P.L. 116–252

Promoting Alzheimer's Awareness to Prevent Elder Abuse Act (Dec. 22, 2022; 134 Stat. 1133)

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